

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Advanced Health Limited | Guideline | 028 | 024 | "... including osmotic cervical dilators such as laminaria.." To clarify terminology and technical definitions, the definition of osmotic cervical dilators must be clearly defined. Laminaria and Dilapan-S are not the same, nor are they comparable for the purpose of induction of labour. Laminaria is a type of seaweed and not used within the UK. Dilapan-S is a synthetic osmotic dilator. The committee should separate the review of these products, as the outcomes associated with Dilapan-S are significantly different to that of laminaria. Dilapan-S should be referred to as a 'synthetic osmotic dilator'. Laminaria should be referred to as 'natural laminaria Tents'. | Thank you for your comment. The committee agreed that osmotic cervical dilators was the over-arching term that included all devices that worked by absorbing fluid and swelling in the cervix, and were also aware that there were both naturally-derived and synthetic products included in this category. Based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour. |
| Advanced Global Health Limited | General | | | Dilapan-S, a synthetic osmotic dilator, was released for use in induction of labour to the UK in 2018. The product is formed of patented hydrogel, aquacryl. Laminaria is a form of seaweed, now not used in the UK. Throughout the guidelines, osmotic dilators have been defined as 'laminaria and dilapan'. Although both mechanisms of the two devices operate by osmosis, they are not comparable products and the outcomes of clinical studies that used laminaria are substantially different to Dilapan-S. It is therefore not appropriate nor correct to combine the two in the form of an analysis for the purpose of IOL. As per clinical studies (DILAFOL; Saad et al, 2019), we suggest that Dilapan-S should be referred to as a synthetic osmotic dilator and laminaria as a natural osmotic dilator. Additionally, given the availability of upcoming new evidence (SOLVE, COMRED trials), post March-2020, we suggest that an analysis is re-run with studies which evaluate synthetic and natural osmotic dilators separately. | Thank you for your comment. The committee agreed that osmotic cervical dilators was the over-arching term that included all devices that worked by absorbing fluid and swelling in the cervix, and were also aware that there were both naturally-derived and synthetic products included in this category. However, the committee agreed these were sufficiently similar that they could be analysed under the grouping of osmotic cervical dilators. Based on stakeholder feedback, the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour. We have checked the references individually to ensure there is nothing we have missed that should have been included. Saad 2019 had already been included in the evidence report. Note that the reference in the evidence report has been corrected because it was for an abstract of the same trial and published on the same year, but data was extracted using the full text study. We are aware that the SOLVE and COMRED trials have been completed but have not been fully published yet. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date. |
| Advanced Global Health Limited | General | | | As of June 2021 Dilapan-S has now been compared with the foley balloon catheter, misoprostol and dinoprostone vaginal | Thank you for your comment. Based on stakeholder feedback, the committee has reconsidered the evidence |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>insert. All three of these randomised control trials (listed below) should be considered in this evaluation.</p> <p><u>DILAFOL Trial</u> In 2019, the DILAFOL trial (Saad et al. 2019) was published demonstrating that Dilapan-S is non-inferior to the single balloon catheter. Additionally, Dilapan-S was associated with an excellent safety profile and had significantly better patient satisfaction compared to the foley catheter as far as sleep, relaxing time and performing daily activities. Given this important non-inferiority study, we request a response explaining why Dilapan-S (synthetic osmotic dilators) is not included alongside the single balloon catheter.</p> <p>To our knowledge several important studies not included in the review are now at a point of evaluation. These studies supplement other important studies designed to demonstrate non-inferiority between methods of induction.</p> <p><u>COMRED Trial</u> In 2021, the COMRED trial (ClinicalTrials.gov Identifier: NCT03670836) drew to a conclusion. The non-inferiority randomised control trial compared misoprostol and Dilapan-S. The outcomes related to vaginal delivery within set periods, efficacy, maternal and fetal adverse events, length of hospital stay and maternal satisfaction. The results of this study were made available via a recent poster at the ACOG conference¹. The NICE committee should review the outcomes of this study.</p> <p>1. Gavara et al. (2021) An RCT Comparing Cervical Ripening Efficacy of DilapanS to Oral Misoprostol for Labor Induction at Term. ACOG ePoster. Gavara r. 04/03/21; 318840; 2520</p> <p><u>SOLVE Trial</u></p> | <p>for osmotic cervical dilators and included them as an option for the mechanical induction of labour. We have checked the references individually to ensure there is nothing we have missed that should have been included. Please see below our response to each reference: - Saad et al (2019) - DILAFOL trial - DOI: 10.1016/j.ajog.2019.01.008: this study was had already been included in the evidence review. Note that the reference in the evidence review has been corrected because it was for an abstract of the same trial and published on the same year, but data was extracted using the full text study - Gavara et al. (2021) An RCT Comparing Cervical Ripening Efficacy of DilapanS to Oral Misoprostol for Labor Induction at Term. ACOG ePoster. Gavara r. 04/03/21; 318840; 2520: this poster is not eligible for inclusion because it was published after the last search was conducted (May 2020) and only published peer-reviewed studies were eligible for inclusion in this evidence review For further details regarding inclusion and exclusion criteria of studies, please see the review protocol in appendix A of evidence report B. We are aware that the SOLVE and COMRED trials have been completed but have not been fully published yet. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------|-------------------|---------|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>In 2021, the SOLVE trial (ClinicalTrials.gov Identifier: NCT03001661) finished the recruitment phase. This is a pivotal study and a fundamental contribution to induction of labour research. This randomised control trial compared the synthetic osmotic dilator (Dilapan-S) and dinoprostone vaginal insert, led by the University of Birmingham. Outcomes orientate around the failure to achieve vaginal delivery within 24, 36 and 48 hours. The NICE Committee should review the outcomes of this study. Pending non-inferiority and other clinical outcomes for Dilapan-S, the committee should consider the full inclusion of Dilapan-S in the guidelines.</p> <p>We hope this evidence will instigate the re-evaluation of synthetic osmotic dilators. As committee members may note, there is a growing trend for the adoption of mechanical methods for induction of labour. There is also a growing preference of patients wishing to have mechanical methods of induction of labour.</p> | |
| Advanced Global Health Limited | General | | | <p>Maternal Satisfaction – Patient choice and maternal satisfaction continues to remain a fundamental part of the method chosen for induction of labour. The NICE committee should note that synthetic osmotic dilators have been proven to have a statistically greater maternal satisfaction when compared to Foley Balloon. This may also be the case following the publication of the SOLVE and COMRED trial.</p> <p>DILAFOL Trial¹ – “Patients with Dilapan-S were more satisfied than patients with the Foley balloon as far as sleep (p=0.01), relaxing time (P=0.001) and performance of desired daily activities (P=0001).</p> | <p>Thank you for your comment. Maternal satisfaction was considered an important outcome and the committee took it into account for decision making. The DILAFOL trial was included in the review and the evidence regarding maternal satisfaction was included and considered by the committee. We are aware that the SOLVE and COMRED trials have been completed but have not been fully published yet. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date.</p> |
| Advanced Global Health Limited | Evidence Review C | 008 | 019 Table 1 | <p>“Osmotic cervical dilators (also known as laminaria or dilapan)”. This requires correcting. Laminaria and Dilapan-S are not the same and therefore should be regarded as a separate item review. Dilapan-S is a synthetic osmotic dilator. Laminaria, often referred to as ‘natural laminaria tents’ is a type of seaweed. Dilapan-S is formed of patented</p> | <p>Thank you for your comment. The committee agreed that osmotic cervical dilators was the over-arching term that included all devices that worked by absorbing fluid and swelling in the cervix, and were also aware that there were both naturally-derived and synthetic products included in this category. However, the committee agreed these were</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | hydrogel. The products lead to different outcomes. Dilapan is technically named Dilapan-S. | sufficiently similar that they could be analysed under the grouping of osmotic cervical dilators. Based on stakeholder feedback, the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour. |
| Advanced Global Health Limited | Guideline | 009 | 013 | <p>Un-evaluated evidence exists demonstrating the efficacy of synthetic osmotic dilators in patients who have had a previous caesarean birth. Maier et al. (2020)¹ found that synthetic osmotic dilators provide women with a chance to experience vaginal birth and may be offered to women who have had a previous caesarean birth to allow cervical priming without uterine contractility.</p> <p>1. J Maier, S Klauke, K Brandt et al., Zervixreifung nach Kaiserschnitt: Prospektive Multicenter „in-label use“ Analyse eines osmotischen Dilators vs. „off-label use“ Prostaglandin PGE₂, Z Geburtshilfe Neonatol 2020; 224(06): 395-396 DOI: https://doi.org/10.1055/s-0040-1709322</p> | Thank you for your comment. It was not within the scope of this guideline update to update the recommendations on induction after previous caesarean birth so we have not examined the evidence for the most effective method of induction. However, the recommendations on methods of induction for this group of women advise the use of mechanical methods, and this would include cervical osmotic dilators |
| Advanced Global Health Limited | Guideline | 014 | 014 | <p>“For women with a Bishop score of 6 or less, offer induction of labour with dinoprostone as vaginal tablet, vaginal gel or controlled release vaginal delivery system.”</p> <p>The committee should note that the SOLVE trial (NCT03001661) has drawn to a conclusion. In the event that synthetic osmotic dilators show non-inferiority to dinoprostone, synthetic osmotic dilators should be considered for recommendation as a frontline method of induction of labour.</p> | Thank you for your comment. We are aware that the SOLVE trial has been completed but has not been fully published yet. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date. However, based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour. |
| Advanced Global Health Limited | Guideline | 014 | 024 | <p>“For women with a Bishop score of 6 or less, consider a mechanical method to induce labour (for example, a balloon catheter)...”</p> <p>The DILAFOL trial¹, published in 2019, should be re-examined. As a non-inferiority RCT, the study demonstrated that synthetic osmotic dilators, for example Dilapan-S, is non-inferior to Foley balloon. In alignment with the NICE</p> | Thank you for your comment. The DILAFOL study was included in the evidence review but did not provide data on the critical outcome of vaginal delivery at 24 hours. However, based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>critical and important outcomes, the DILAFOL study collected data enabling the analysis of vaginal delivery within 24 hours (ARM-to-delivery), maternal satisfaction and safety and pain relief outcomes.</p> <p>Given the outcomes of this important RCT, the wording should be updated to state "for example, a balloon catheter or synthetic osmotic dilator."</p> <p>Saad et al. (2019) A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL).</p> | |
| Advanced Global Health Limited | Guideline | 028 | 015 | <p>"Misoprostol was as effective as dinoprostone vaginal birth within 24 hours." It should be noted that in the COMRED¹ study, in the intent to treat analysis Dilapan-S was found to have a greater vaginal delivery within 36 hours compared with misoprostol (61.6% v 59.2%). Given that the COMRED trial has demonstrated non-inferiority to misoprostol. The NICE committee should include synthetic osmotic dilators (Dilapan-S) where misoprostol is included. The NICE committee should also contact the authors for further data analysis if required.</p> <p>Gavara et al. (2021) An RCT Comparing Cervical Ripening Efficacy of DilapanS to Oral Misoprostol for Labor Induction at Term. ACOG ePoster. Gavara r. 04/03/21; 318840; 2520</p> | <p>Thank you for your comment. Based on stakeholder feedback, the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour. We are aware that the trial has been completed but has not been fully published yet. The poster by Gavara et al. (2021) is not eligible for inclusion because it was published after the last search was conducted (May 2020) and only published peer-reviewed studies were eligible for inclusion in this evidence review. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date.</p> |
| Advanced Global Health Limited | Guideline | 028 | 025 | <p>"Balloon catheters were also effective at promoting vaginal birth within 24 hours and did not appear to markedly increase the risk of other adverse outcomes." In the DILAFOL trial¹ balloon catheters were compared with Dilapan-S. Although the vaginal delivery rate within 24 hours was not published, the study's primary outcome identified that vaginal delivery within the Dilapan-S group was 81.3% versus 76.1% in the single balloon catheter. Vaginal delivery within 24 and 36 hours would be available for an analysis, similar to the outcomes of the SOLVE trial. If the outcomes of the SOLVE trial are available for evaluation and with the</p> | <p>Thank you for your comment. Based on stakeholder feedback, the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour. The DILAFOL trial was included in the evidence review but there was no data on vaginal birth in 24 hours. We are also aware that the SOLVE trial has been completed but has not been fully published yet. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | DILAFOL trial considered, please could the NICE committee provide a comment regarding the available evidence of vaginal delivery within 24 hours for synthetic osmotic dilators (i.e. Dilapan-S). Saad et al. (2019) A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL). | |
| Advanced Global Health Limited | Guideline | 028 | 026 | <p>"There was no evidence for the effectiveness of osmotic cervical dilators at promoting vaginal birth within 24 hours...".</p> <p>This is incorrect for the following reasons:</p> <ol style="list-style-type: none"> 1. In 2018 Gupta et al.¹ published the results of a multi-center, multi-country observational study. The study reports a mean gain in Bishop's score of 3.6, mean overall vaginal delivery rate of 76.6%, mean vaginal delivery rate within 24 hours 45.7% and mean vaginal delivery rate within 36 hours of 66%. 2. Recruitment for the SOLVE trial (NCT03001661) has drawn to a conclusion. The committee should seek to review this evidence as the secondary outcomes relate to the 'Failure to achieve vaginal delivery within 24, 36 and 48 hours from randomisation'. <p>Given the outcomes of these studies, the guideline should be updated to confirm that synthetic osmotic dilators do have evidence for the effectiveness of osmotic cervical dilators at promoting vaginal birth within 24 hours.</p> <p>Furthermore, the committee should acknowledge the availability of three RCTs (DILAFOL, COMRED, SOLVE trials) in which synthetic osmotic dilators have been compared to Foley Balloon, low dose misoprostol and dinoprostone. Given the results of these RCTs,</p> | <p>Thank you for your comment. Based on stakeholder feedback, the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour, so they have been removed from this list.</p> <p>We have checked the references individually to ensure there is nothing we have missed that should have been included. Please see below our response to each reference:</p> <p>- Gupta et al (2018) - DOI: 10.1016/j.ejogrb.2018.08.004: this is an observational study and only randomised trials and systematic reviews of randomised trials were prioritised for inclusion in this evidence review</p> <p>- Saad et al (2019) DILAFOL trial - DOI: 10.1016/j.ajog.2019.01.008: this study had already been included in the evidence review. Note that the reference in the evidence report has been corrected because it was for an abstract of the same trial and published on the same year, but data was extracted using the full text study</p> <p>For further details regarding inclusion and exclusion criteria of studies, please see the review protocol in appendix A of evidence report B.</p> <p>We are also aware that the COMRED and SOLVE trials have been completed but has not been fully published yet. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date. However, based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>synthetic osmotic dilators should be included in the guidelines alongside the other ripening methods.</p> <p>Gupta et al. (2018) Synthetic osmotic dilators in the induction of labour – An international multicentre observational study. <i>EJOG</i>. 229(2018)70-75</p> | mechanical induction of labour, so they have been removed from this list. |
| Advanced Global Health Limited | Guideline | 028 | 027 | <p>"There was no evidence for the effectiveness of osmotic cervical dilators at promoting vaginal delivery within 24 hours." In a multi-centre, multi-country observational study Gupta et al. (2018)¹ reported the mean vaginal delivery rate within 24 and 36 hours with Dilapan-S from the starting point of cervical ripening. When Dilapan-S was inserted for 12 hours, the mean vaginal delivery rate was 45.7% within 24 hours and 66% within 36 hours. The overall vaginal delivery rate was 76.6%. The NICE committee should update the guidelines to reflect this information.</p> <p>Synthetic osmotic dilators are a safe, effective and cost-effective option for Inducing Labour.</p> <p>Gupta et al. (2018) Synthetic osmotic dilators in the induction of labour – An international multicentre observational study. <i>EJOG</i>. 229:70-75.</p> | Thank you for your comment. Based on stakeholder feedback, the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour, so they have been removed from this list. Gupta et al (2018) - DOI: 10.1016/j.ejogrb.2018.08.004 was not eligible for inclusion because this is an observational study and only randomised trials and systematic reviews of randomised trials were prioritised for inclusion in this evidence review |
| Advanced Global Health Limited | Guideline | 029 | 007 | <p>"Most hospitals use vaginal dinoprostone for induction of labour". In a recent publication¹ Harkness et al (2021) identified the following trends in a national survey "98% Trusts and Boards reported using pharmaceutical methods such as Propress (PGE2), for cervical ripening, and 70% mechanical methods, including Cooks balloon and Dilapan-S. Although the NICE statement, line 7, is correct that the NICE committee should consider the frontline method of choice for ripening. There is a growing demand for mechanical methods, such as synthetic osmotic dilators being used as the frontline method for cervical ripening.</p> <p>The same survey stated "We found that over half of NHS Trusts and Boards offered home cervical ripening prior to the</p> | Thank you for your comment. We have now amended the recommendations to include osmotic cervical dilators, based on a re-review of the data and stakeholder feedback, and so have amended this rationale section in-line with the changes in the recommendations. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------|-------------------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>COVID-19 pandemic, that 28% had changed their criteria for offering home cervical ripening in response to the pandemic, and that almost a third now report more women going home after having this procedure. This shift towards home cervical ripening was accompanied by an apparent move towards using mechanical methods, such as balloon catheter and Dilapan-S, which were often considered safer and more acceptable for use at home than more established pharmaceutical methods. "</p> <p>Additionally, the survey highlighted the following; "Switching to use of Dilapan-S as a method of cervical ripening was notable."</p> <p>This text was identified as confidential and has been removed</p> <p>Harkness et al. (2021) Induction of labour during COVID-19 pandemic: a national survey of impact on practice in the UK. <i>BMC Pregnancy and Childbirth</i>. 21:310.</p> | |
| Advanced Global Health Limited | Evidence Review C | 078 | 029 | <p>Laminaria and Dilapan-S should not be compared. Dilapan-S is a synthetic device leading to different outcomes when compared to laminaria. Laminaria is associated with less favourable outcomes, whereas Dilapan-S is associated with excellent outcomes and an excellent safety profile. This is and is likely to be demonstrated in the following studies:</p> <ul style="list-style-type: none"> • Gupta et al (2018) - DOI: 10.1016/j.ejogrb.2018.08.004 • Saad et al (2020) - DOI: 10.1016/j.ajog.2019.01.008 | <p>Thank you for your comment. The committee agreed that osmotic cervical dilators was the over-arching term that included all devices that worked by absorbing fluid and swelling in the cervix, and were also aware that there were both naturally-derived and synthetic products included in this category. However, the committee agreed these were sufficiently similar that they could be analysed under the grouping of osmotic cervical dilators. Based on stakeholder feedback, the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour. We have checked the references individually to ensure there is nothing we have missed that should have been included. Please see below our response to each reference:</p> <p>- Gupta et al (2018) - DOI: 10.1016/j.ejogrb.2018.08.004:</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <ul style="list-style-type: none"> Baev et al (2019) - DOI: 10.1080/14767058.2019.1671340 Crosby et al (2018) - DOI: 10.1007/s11845-017-1731-8 Gupta et al. – SOLVE trial – recruitment finished – (NCT03001661) <p>Gavara et al. – COMRED trial – Poster Published (NCT03670836) - https://acog.multilearning.com/acog/2021/2021-acog-meeting/318840?evna</p> | <p>this is an observational study and only randomised trials and systematic reviews of randomised trials were prioritised for inclusion in this evidence review</p> <p>- Saad et al (2020) - DOI: 10.1016/j.ajog.2019.01.008: this study was published in 2019 and had already been included in the evidence review (see Saad 2019). Note that the reference in the evidence report has been corrected because it was for an abstract of the same trial and published on the same year, but data was extracted using the full text study</p> <p>- Baev et al (2019) - DOI: 10.1080/14767058.2019.1671340: this is an observational study and only randomised trials and systematic reviews of randomised trials were prioritised for inclusion in this evidence review</p> <p>- Crosby et al (2018) - DOI: 10.1007/s11845-017-1731-8: this is an observational study and only randomised trials and systematic reviews of randomised trials were prioritised for inclusion in this evidence review</p> <p>- Gupta et al – SOLVE Trial (ClinicalTrials.gov Identifier: NCT03001661): the results of this trial have not been published yet, and only published peer-reviewed studies were eligible for inclusion in this evidence review</p> <p>- Gavara et al – COMRED Trial (ClinicalTrials.gov Identifier: NCT03670836): the results of this trial have not been published yet, and only published peer-reviewed studies were eligible for inclusion in this evidence review</p> <p>- Gavara et al. (2021) An RCT Comparing Cervical Ripening Efficacy of DilapanS to Oral Misoprostol for Labor Induction at Term. ACOG ePoster. Gavara r. 04/03/21; 318840; 2520: this poster is not eligible for inclusion because it was published after the last search was conducted (May 2020) and only published peer-reviewed studies were eligible for inclusion in this evidence review</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------|-------------------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | We will pass the information on the ongoing trials to the NICE surveillance team who monitor guidelines to make sure they are up to date. For further details regarding inclusion and exclusion criteria of studies, please see the review protocol in appendix A of evidence report B. |
| Advanced Global Health Limited | Evidence Review C | 078 | 030 | Correct "ther" to there | Thank you for your comment. We were unable to find this error on page 78 of Evidence review C. |
| Advanced Global Health Limited | Evidence C | 079 | 045 | <p>Suitable evidence is available confirming the efficacy and safety profile of synthetic osmotic dilators, for example Dilapan-S:</p> <ul style="list-style-type: none"> Gupta et al (2018) - DOI: 10.1016/j.ejogrb.2018.08.004 Saad et al (2020) - DOI: 10.1016/j.ajog.2019.01.008 Baev et al (2019) - DOI: 10.1080/14767058.2019.1671340 Crosby et al (2018) - DOI: 10.1007/s11845-017-1731-8 <p>It should be noted that two relevant RCTs have also completed recruitment; the SOLVE trial and COMRED trial.</p> <p>The committee should re-review the evidence supporting synthetic osmotic dilators for example Dilapan-S. The following should be noted:</p> <p>Saad et al. 2020 – DILAFOL Trial – a published RCT demonstrating that Dilapan-S is non-inferior to the foley balloon catheter. Dilapan-S was shown to have an excellent</p> | <p>Thank you for your comment. We have checked the references individually to ensure there is nothing we have missed that should have been included. Please see below our response to each reference:</p> <ul style="list-style-type: none"> Gupta et al (2018) - DOI: 10.1016/j.ejogrb.2018.08.004: this is an observational study and only randomised trials and systematic reviews of randomised trials were prioritised for inclusion in this evidence review Saad et al (2020) - DOI: 10.1016/j.ajog.2019.01.008: this study was published in 2019 and had already been included in the evidence review (see Saad 2019). Note that the reference in the evidence report has been corrected because it was for an abstract of the same trial and published on the same year, but data was extracted using the full text study Baev et al (2019) - DOI: 10.1080/14767058.2019.1671340: this is an observational study and only randomised trials and systematic reviews of randomised trials were prioritised for inclusion in this evidence review Crosby et al (2018) - DOI: 10.1007/s11845-017-1731-8: this is an observational study and only randomised trials and systematic reviews of randomised trials were prioritised for inclusion in this evidence review <p>For further details regarding inclusion and exclusion criteria of studies, please see the review protocol in appendix A of evidence report B.</p> <p>We are aware that the SOLVE and COMRED trials have been completed but have not been fully published yet. We will pass this information on the NICE surveillance team</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------|-------------------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>safety profile, efficacy and patient satisfaction. Given the outcomes, the balloon catheter should not be included in the guidelines without Dilapan-S.</p> <p>Gupta et al – SOLVE Trial (ClinicalTrials.gov Identifier: NCT03001661) – the recruitment of the SOLVE trial has concluded. The NICE committee should consider reviewing the outcomes of this important UK RCT. In the event of non-inferiority of Dilapan-S to dinoprostone, Dilapan-S should be favourably included in the NICE guidelines.</p> <p>Gavara et al – COMRED Trial (ClinicalTrials.gov Identifier: NCT03670836) – the recruitment of COMRED trial has concluded. The NICE committee should consider reviewing the outcomes of this important RCT. In the event of non-inferiority of Dilapan-S to misoprostol, Dilapan-S should be included in the NICE guidelines alongside misoprostol.</p> <p>Gavara et al. (2021) An RCT Comparing Cervical Ripening Efficacy of DilapanS to Oral Misoprostol for Labor Induction at Term. ACOG ePoster. Gavara r. 04/03/21; 318840; 2520</p> | <p>who monitor guidelines to make sure they are up to date. However, based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour.</p> |
| Advanced Global Health Limited | Evidence Review C | 149 | | <p>"Osmotic cervical dilators (also known as laminaria or dilapan)". This requires correcting. Laminaria and Dilapan-S are not the same and therefore should be regarded as a separate item review. Dilapan-S is a synthetic osmotic dilator. Laminaria, often referred to as 'natural laminaria tents' is a type of seaweed. Dilapan-S is formed of patented hydrogel. The products lead to different outcomes. Dilapan is technically named Dilapan-S.</p> | <p>Thank you for your comment. The committee agreed that osmotic cervical dilators was the over-arching term that included all devices that worked by absorbing fluid and swelling in the cervix, and were also aware that there were both naturally-derived and synthetic products included in this category. However, the committee agreed these were sufficiently similar that they could be analysed under the grouping of osmotic cervical dilators. Based on stakeholder feedback, the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour.</p> |
| Association for Improvements in the Maternity Services | algorithm | | | <p>suggest change "obtain consent" to, "request/check consent"</p> | <p>Thank you for your comment. We have changed the algorithm to read 'Ask for consent'.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------|-----------|---------|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Association for Improvements in the Maternity Services | Algorithm | | All stages | Rather than 'before making decisions' this should say 'before they make their decisions' to clarify that it is women who are the decision-makers. | Thank you for your comment. We have made this change to the algorithm. |
| Association for Improvements in the Maternity Services | algorithm | | cord prolapse | as above re continuous CTG - offer or consider - logically, no way ctg can have any predictive role here - not going to prolapse with intact membranes, and ctg is always offered following rupture of membranes in IOL for this reason ('To reduce the likelihood of cord prolapse:' - CTG doesn't reduce risk...) | Thank you for your comment. We have amended the wording here in line with the revised wording in the guideline, to avoid the suggestion that CTG can prevent cord prolapse. |
| Association for Improvements in the Maternity Services | Guideline | General | | We feel that in any discussion of 'risks' women should be told what the actual risk is in different circumstances rather simply that something 'increases' the risk. Without this information they cannot make an informed decision. Baseline risks should be given for comparison, and risks should be stated in a consistent format as the actual rather than the relative risk. | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| Association for Improvements in the Maternity Services | Guideline | General | | Discussions should include information about the quality of the evidence underlying each recommendation. | Thank you for your comment. The quality of evidence for each outcome is included in the evidence statements in each evidence review, and in the GRADE tables in Appendix F of each evidence review. |
| Association for Improvements in the Maternity Services | Guideline | General | | We are pleased to see that the Guideline Development Group has taken some care in their language to make it clear that it is the woman who is the decision-maker, but unfortunately this has not been done throughout. We would ask that all wording is reviewed to recognise the principle of autonomy, and make clear that the carer's role is to provide the information to support the individual's informed decision-making, NOT to make the decision for them. Especially in cases where 'consider' has been used it ought to read 'consider offering'. | Thank you for your comment. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline. 'Offer' is the wording used by NICE to reflect a recommendation based on strong evidence, and 'consider' is where there is more uncertainty, so using the terminology 'consider offering' would be confusing for users of the guideline. |
| Association for Improvements in the Maternity Services | Guideline | General | | We feel it would be helpful to clarify that for all indications where induction is offered women should also be offered the option of a planned caesarean as well as expectant management | Thank you for your comment. We have added a link the NICE guideline on caesarean birth at the beginning of the guideline, and have added the option of caesarean birth to some recommendations where it was applicable, and not already mentioned as an option (for example, for |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------|----------------------------|---------|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | suspected fetal macrosomia and in the case of cord prolapse). |
| Association for Improvements in the Maternity Services | Guideline | General | | We would ask that the term 'prolonged pregnancy' be changed to read 'longer pregnancy' or other similar term which does not imply the presence of pathology. | Thank you for your comment. We have changed the title of this section to 'Pregnancy lasting longer than 41 weeks'. |
| Association for Improvements in the Maternity Services | Guideline | general | | We are deeply concerned that in many places "the committee were aware that.." is used without reference to any research that would inform whether it would be appropriate to offer induction. We feel that the guideline should in all cases make clear what evidence, if any, there is to support the recommendation and the quality of that evidence. We are particularly concerned about recommendations based on race without any evidence to support the benefit of offering induction early on this basis. | Thank you for your comment. The recommendations relating to timing, macrosomia and methods of induction were all based on systematic reviews of the literature and the studies included in these reviews, the quality of the evidence and the findings of the systematic review are included in the evidence reviews which are referenced from the guideline and are available on the NICE website alongside the guideline for consultation. However, where there is a lack of evidence the committee do use informal consensus to make recommendations. Based on stakeholder feedback we have amended the recommendations for earlier induction based on a person's ethnic background and instead included information on increased risks from a national audit (MBRRACE). |
| Association for Improvements in the Maternity Services | Equality impact assessment | | 3.4 | IOL does make things more difficult for women with complex social factors/ unsupported. Longer stays, transport costs for birth supporters, childcare concerns etc | Thank you for your comment. We have added this consideration to section 4 of the EIA form to reflect your comments. |
| Association for Improvements in the Maternity Services | Algorithm | | Bishop score 6 or less | Replace 'Consider' with 'Offer the option of' for both oral misoprostol and mechanical methods | Thank you for your comment. The wording in this box on the algorithm has been amended to ensure it reflects all the changes made to the guideline based on stakeholder feedback. |
| Association for Improvements in the Maternity Services | Algorithm | | Bishop score more than 6 | As above - why ARM and IV oxytocin together rather than waiting a while after ARM? | Thank you for your comment. The wording in this box on the algorithm has been amended to ensure it reflects all the changes made to the guideline based on stakeholder feedback. |
| Association for Improvements in the Maternity Services | Guideline | 001 | Box | "We suggest checking whether the wording "and this should be taken to include people who do not identify as women but who have given birth" is acceptable to the a range of individuals and organisations in the LGBTQ+ community" | Thank you for your comment. To ensure consistency between NICE guidelines the NICE editorial team have developed a more inclusive description and rationale for the use of the terminology relating to the intended population for maternity and obstetric guidelines, |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | guidelines, and this is included in the introductory information at the beginning of the guideline. |
| Association for Improvements in the Maternity Services | Guideline | 004 | 001 | The statement "People have the right to be involved in discussions and make informed decisions about their care" should more accurately say "People have the right to be given the information that they need to make informed decisions about their care, and to have those decisions respected" to reflect the legal principle of autonomy (see www.birthrights.org.uk/factsheets/consenting-to-treatment/) | Thank you for your comment. This is standard wording that is provided at the start of all NICE guidelines so we have not amended it here, but have ensured that the specific recommendations about induction of labour make clear that the woman's decision should be respected. |
| Association for Improvements in the Maternity Services | Guideline | 004 | 006 | It is not clear when the explanation should be taking place and we would suggest that this should be provided in early pregnancy, including information in a written or other accessible format. | Thank you for your comment. We have not provided a specific time in pregnancy at which discussions about mode of birth should start as this may vary between women, but we have clarified that in most cases (if the woman wishes) this will be an ongoing conversation during pregnancy and not a one-off discussion. We have added to the later recommendation about the provision of information that this should include written information. The link to the NICE guideline on patient experiences provides more details on the accessibility of information. |
| Association for Improvements in the Maternity Services | Guideline | 004 | 010 | Suggest adding "discuss with the woman their preferences and priorities for their birth experience. Where induction of labour is chosen, consider how these wishes can be best facilitated in an obstetric setting, taking into account any staffing and equipment limitations". | Thank you for your comment. We have clarified the recommendations to state that the decision whether or not to have an induction of labour rests with the woman, and that this decision should be respected. It is not the woman's responsibility to be involved in discussions about staffing and equipment. |
| Association for Improvements in the Maternity Services | Guideline | 004 | 011 | "their choice of place of birth may be limited, as they may need interventions" should say " ...may be recommended to have further interventions". | Thank you for your comment. We have changed the wording to 'recommended'. |
| Association for Improvements in the Maternity Services | Guideline | 004 | 019 | We would like to see the wording "concerns about fetal wellbeing" strengthened to make it clear that hyperstimulation can cause actual fetal compromise and in some cases the need for an unplanned caesarean. | Thank you for your comment. We have amended the wording of this recommendation to state that hyperstimulation can lead to changes in fetal heart rate and result in fetal compromise. |
| Association for Improvements in the Maternity Services | Guideline | 004 | 019 | It is not clear whether 'some methods' includes the use of an oxytocin drip and we feel that the methods which have this potential effect should be stated. | Thank you for your comment. We have amended this sentence to make it clear that this just refers to pharmacological methods of induction (which would include oxytocin). |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Association for Improvements in the Maternity Services | Guideline | 004 | 019 | Other information which should be given to women in early pregnancy includes the greater pain which they may experience from induction and the use of oxytocin compared with spontaneous labour, especially in the event of hyperstimulation, and the fact that they are more likely to require an epidural for pain relief. | Thank you for your comment. The information about the pain associated with induced labour is already included in a subsequent recommendation, and in the section on pain relief later in the guideline, which also includes the option of an epidural for pain relief. |
| Association for Improvements in the Maternity Services | Guideline | 005 | 003 | Section 1.1.3. Add that women should be informed about the number of vaginal examinations likely to be recommended, and the discomfort this may involve. | Thank you for your comment. The committee agreed that the need for vaginal examinations should be added to the list of factors to be discussed with women and have made that change. |
| Association for Improvements in the Maternity Services | Guideline | 005 | 003 | Also add that they have the right to stop the induction process at any time. | Thank you for your comment. The committee have added details to the recommendations stating that women can decide that they no longer wish to proceed with the induction process. |
| Association for Improvements in the Maternity Services | Guideline | 005 | 003 | 1.1.3 We suggest including that women should be advised that low Bishop's score is linked to a higher chance of failed induction/unplanned caesarean, and that a baseline examination for cervical assessment be offered for those whose decision might be affected by the findings. | Thank you for your comment. The evidence review carried out for the methods of induction found that women with a low Bishop score can be induced successfully, so we have not added this to the recommendations. However, the methods section does include recommendations on the use of a cervical assessment to determine Bishop score and then informing the women how this score will impact on their method of induction. |
| Association for Improvements in the Maternity Services | Guideline | 005 | 022 | We suggest adding the wording "Advise women that they are entitled to decline the offer of treatment such as induction of labour or caesarean birth, even when it would benefit their or their baby's health and..." ahead of "support the woman in whatever decision she makes". We also suggest adding the words "Do not attempt to coerce a woman into changing her decision, even if you disagree with it." | Thank you for your comment. We have added a new section to this recommendation which states: recognise that women can decide to proceed with, delay, decline or halt an induction. Respect a woman's decision, even if you disagree with it, and do not allow your views to influence the care they are given |
| Association for Improvements in the Maternity Services | Guideline | 006 | 003 | We would ask that women be told the percentage or proportion of labours which will have started by 42 weeks, or even better to quantify by 40, 41, 42 and 43 weeks. | Thank you for your comment. We have added information into the guideline about the percentages of labour which start spontaneously at each week of gestation. |
| Association for Improvements in the Maternity Services | Guideline | 006 | 005 | We are please to see this amended wording recognising the need to take account of individual circumstances, but it would be even better to say "Discuss her individual circumstances and preferences and provide any information | Thank you for your comment. The recommendation already states that a woman's individual circumstances and preferences should be taken into consideration, and the following recommendations provide more advice on |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | she requires to help her decide about options for birth, including:" | providing information to help the woman make her decision. |
| Association for Improvements in the Maternity Services | Guideline | 006 | 012 | In order to make an informed decision women need to know what the actual increase in the risk of each adverse outcome would be, rather than just being told it 'increases' without knowing by how much. For example, they should be told the actual stillbirth rate per 1000 at 40, 41, 42 and 43 weeks of pregnancy. We would therefore like to see this wording amended to say "Offer women information about the increase in actual risks beyond 40+0 weeks of:" | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| Association for Improvements in the Maternity Services | Guideline | 006 | 020 | The wording should be "Consider offering induction..." We are concerned that the recommendation to consider induction from 39 weeks for women at a higher risk of complications is not evidence based, and could lead to large numbers of women having unwanted inductions purely because they fall into one of these 'higher risk' categories. We think that the recommendation ought at least to put greater emphasis on the need for an individualised assessment of risks, including socioeconomic factors and the woman's medical as well as obstetric history. We note that although there are no RCTs to inform this recommendation, there is a recent UK cohort study of induction in older mothers (Knight et al 2017 Perinatal mortality associated with induction of labour versus expectant management in nulliparous women aged 35 years or over: An English national cohort study (plos.org)). This found no difference in perinatal deaths with induction at 39 weeks, but a reduced rate with induction at 40 weeks compared to expectant management. Although such a study has limitations, given the lack of other evidence we suggest that the recommendation should read "Discuss with women... whether she wishes to bring forward the birth to between 39+0 and 40+0 weeks" | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. Thank you for the reference provided. We have checked it to ensure there is nothing we have missed that should have been included, but since it is an observational study, it would not be eligible for inclusion. |
| Association for Improvements in the Maternity Services | Guideline | 006 | 024 | The section "Take into account:" <ul style="list-style-type: none"> the risk of complications the woman's preferences | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <ul style="list-style-type: none"> the woman's previous obstetric history" should be replaced with wording which reflects the autonomy of the woman as the decision-maker and the need for tailored information e.g. "Support her decision-making by offering to discuss with her: <ul style="list-style-type: none"> the actual increase in the risk of complications in the light of her obstetric history, health status and socio-economic factors <p>her preferences and other factors of importance in her decision-making".</p> | with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Association for Improvements in the Maternity Services | Guideline | 007 | 016 | suggest "recognising the need to avoid pressuring the person towards intervention" etc | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again. |
| Association for Improvements in the Maternity Services | Guideline | 008 | 004 | This section needs to make clear that a woman could choose to continue expectant management beyond 37 weeks if she had not gone into labour by then. The GDG may wish to suggest a further discussion of the options at this point, either to accept induction or continue expectant management. Alternatively the wording could be amended to "the options of expectant management until at least 37+0 weeks..." | Thank you for your comment. The management of PPRM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not reviewed the data on the risks and benefits of induction of labour compared to expectant management in preterm prelabour rupture of the membranes, or the risks of managing expectantly beyond 37 weeks, and so have not been able to make the changes you suggest. However, the recommendations do already include advice to discuss this decision with the woman. |
| Association for Improvements in the Maternity Services | Guideline | 008 | 005 | Replace the words "When making a shared decision" with "Provide information about the following factors to enable her to make an informed decision." | Thank you for your comment. The NICE definition of shared decision-making is a collaborative process, making sure the person understands the risks and benefits through discussion and we think this applies to decisions about maternity choices, although the final decision is ultimately the woman's. We have reviewed the use of the terminology 'shared decision-making' throughout the guideline and have amended it in a number of places. However, there are some circumstances where there may be factors that relate to the decision that are within the remit of the healthcare professional too - such as their professional responsibility to act in the woman's best interests, and in this example to determine if suitable |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------|-------------------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | neonatal facilities are available. In this case we think the decision would therefore be shared, and so have not amended it in this recommendation. |
| Association for Improvements in the Maternity Services | Guideline | 008 | 007 | This should specify the need to offer information about actual risks e.g rates of sepsis per 1000 women/babies after preterm prelabour rupture of the membranes with immediate induction or expectant management till 37 weeks. | Thank you for your comment. Management of preterm PROM was not included in the scope of this update, so we have not been able to add more detailed information about the absolute risks to the woman and her baby. |
| Association for Improvements in the Maternity Services | Guideline | 008 | 021 | <p>Since women have the right to decline induction even if it is 24 hours since prelabour rupture of the membrane it is incorrect to recommend that the only choices to be offered are</p> <ul style="list-style-type: none"> • “induction of labour as soon as possible or • expectant management for up to 24 hours” <p>This section should therefore say:</p> <ul style="list-style-type: none"> • induction of labour as soon as possible or • induction after 24 hours or • expectant management <p>and “Discuss the risks and benefits of all three options...”</p> <p>We would also ask that the guideline makes it clear that women have the right to decline ‘expectant management’ and just to wait for spontaneous labour to start without any form of surveillance or monitoring, but also that there is very limited evidence about what is offered in the package of care referred to as ‘expectant management’.</p> | Thank you for your comment. The management of PROM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not reviewed the data on the risks and benefits of induction of labour compared to expectant management in prelabour rupture of the membranes, or the risks of managing expectantly beyond 24 hours, and so have not been able to make the changes you suggest. However, the action to be taken after 24 hours of expectant management is described in the following recommendation and the recommendations do already include advice to discuss this decision with the woman. As with all healthcare decisions it is the woman's choice whether or not to take up the offer of interventions. |
| Association for Improvements in the Maternity Services | Guideline | 009 | 010 - 012 | In order to make an informed decision women need to know what the actual increase is in the risk of these adverse outcomes with induction. | Thank you for your comment. Induction of labour after previous caesarean birth was not included in the scope of this update, so we have not been able to add more detailed information about the absolute risks to the woman and her baby. |
| Association for Improvements in the Maternity Services | Evidence review D | 009 | 004 | seems to imply women with IUD and unscarred uterus don't also need one-to-one care | Thank you for your comment. This recommendation has now been moved up to the intrauterine fetal death overarching section to indicate that all women should receive one-to-one care midwifery care during labour and birth. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------|-------------------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Association for Improvements in the Maternity Services | Guideline | 009 | 017 | Rather than "If delivery is indicated" suggest "if there are reasons for the baby to be born early..." | Thank you for your comment. We have changed this to 'if birth needs to be expedited...' |
| Association for Improvements in the Maternity Services | Guideline | 009 | 023 | "may benefit" rather than "would benefit" | Thank you for your comment. We have amended the wording of this recommendation to say '...when it may benefit their or their baby's health.' to reflect the uncertainty. |
| Association for Improvements in the Maternity Services | Guideline | 010 | 009 | We would request that delivery is change to birth in this sentence | Thank you for your comment. We have changed 'delivery' to 'birth'. |
| Association for Improvements in the Maternity Services | Guideline | 010 | 023 | This should recommend giving actual figures for how common shoulder dystocia is in cases of fetal macrosomia, and by how much induction may reduce the risk, as well as by how much it increases the risk of tears, to enable women to make an informed decision. | Thank you for your comment. We have added more details about absolute risks to these recommendations as you suggest. |
| Association for Improvements in the Maternity Services | Evidence review D | 010 | 029 | committee decided not to recommend mifepristone.... should this read "at the higher dose of 600mg"? | Thank you for your comment. No evidence for the safety or efficacy of mifepristone was identified in women with a previous caesarean birth, and the committee were concerned that it may lead to a very prolonged induction process, which may be distressing for women, therefore mifepristone was not recommended as a possible treatment option for women with intrauterine fetal death and a previous caesarean birth. |
| Association for Improvements in the Maternity Services | Guideline | 012 | 007 | We would like clarity around why the recommendation is to wait 36-48 hours after mifepristone as parents may not want to wait so long. | Thank you for your comment. The doses and timing of administration are as specified in the summary of product characteristics (SPC) for mifepristone. The detail has now been removed from the recommendation because the recommendation says to base the choice and dosage of dinoprostone or misoprostol on clinical circumstances and national protocols. |
| Association for Improvements in the Maternity Services | Guideline | 013 | 003 | Needs to include something about when a sweep might not be possible or advisable | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, including when it may be inadvisable. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Association for Improvements in the Maternity Services | Guideline | 013 | 005 | This should recommend that women are given actual figures for the likelihood of going into labour with or without a membrane sweep to enable them to judge the potential benefit of having this. | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, including the rate of labour starting. |
| Association for Improvements in the Maternity Services | Guideline | 013 | 010 | Replace "Obtain consent from the woman before carrying out membrane sweeping." with "Do not carry out a membrane sweep unless you have obtained the woman's informed consent." Some women might decline it! | Thank you for your comment. We have reworded this recommendation to ensure there is a discussion with women and that if they agree to membrane-sweeping, consent is obtained. |
| Association for Improvements in the Maternity Services | Guideline | 013 | 014 | What is the justification for offering a membrane sweep at 39 weeks? (This conflicts with membrane sweep discussion later in the document.) As far as we know there is no evidence to support membrane sweep <40 weeks and Avdiyocski (2019) suggests an increased risk of pre-labour rupture of membranes with early membrane sweep: this doesn't seem to have been considered. | Thank you for your comment. The recommendations have now been clarified to state that membrane sweeps should be discussed after 39 weeks (as opposed to 'from 39 weeks') so sweeps will happen from week 40 onwards. |
| Association for Improvements in the Maternity Services | Guideline | 013 | 016 | Should say 'consider offering' not 'consider, although we feel "discuss" would be better. What is meant by "additional membrane sweeping if labour does not start spontaneously"? What is the evidence for this? This probably needs to either specify a gestation or an elapsed time after the first sweep at which to discuss the timing of further sweeps (if the evidence supports this). | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, the likelihood of success, optimal timing or frequency. However, we have amended this recommendation to emphasise that additional membrane sweeping should only be considered after a discussion with the woman. |
| Association for Improvements in the Maternity Services | Guideline | 013 | 019 | A vaginal examination to assess the Bishop's score and any method of induction are also things to be offered. It would be better to say "Explain to women that a vaginal examination to assess the readiness of the cervix (recorded as the Bishop score) will be offered as this will help her to decide which method of induction to use first." | Thank you for your comment. This recommendation is about explaining to women the purpose of the vaginal examination and the Bishop score. We have amended the wording of this recommendation to explain to women that this will help guide the method of induction they will be offered first, and that consent should be obtained. |
| Association for Improvements in the Maternity Services | Guideline | 014 | 002 | Women should be told the actual risks of hyperstimulation with both dinoprostone and misoprostol | Thank you for your comment. There was evidence from the systematic review on the rates of hyperstimulation with dinoprostone and misoprostol so this has been added in a table. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------|-----------|---------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Association for Improvements in the Maternity Services | Guideline | 014 | 010 | The preceding section says that induction will be stopped should hyperstimulation occur but not what might happen then. This section therefore needs an additional comment about what women should be told about what their options would be in that situation. | Thank you for your comment. The management of uterine hyperstimulation is covered in a separate section of the guideline, and the options for the woman would need to be individualised depending on the clinical situation relating to her and the baby, so it was not possible to provide recommendations to cover this situation. |
| Association for Improvements in the Maternity Services | Guideline | 014 | 011 017 023 | Suggest recommendation 1.3.9, 1.3.10 and 1.3.11 are combined. This needs to include a recommendation to discuss the risks and benefits of both prostaglandins and mechanical methods, including the risk of hyperstimulation and the chances of success, and support the woman's decision about which to try. | Thank you for your comment. We have amended the recommendation on discussing methods of induction with women, to include the fact that hyperstimulation is less likely with mechanical methods, and included more details in a table about the risk of hyperstimulation with pharmacological methods. All the methods recommended were successful so we have not included more information on this. |
| Association for Improvements in the Maternity Services | Guideline | 015 | 001 | This implies that amniotomy and intravenous oxytocin infusion should be offered together, but women may prefer to try these sequentially. It would be better to say "offer induction of labour with amniotomy, followed by the offer of an intravenous oxytocin infusion if active labour does not start within an agreed individualised timeframe." | Thank you for your comment. This recommendation was based on evidence for the efficacy of amniotomy and oxytocin used together. However, the committee recognised that sequential use may be preferred by some women and so have added an additional recommendation to state this. |
| Association for Improvements in the Maternity Services | Guideline | 016 | 022 | Pleased to see this recommendation | Thank you for your comment and support of this recommendation. |
| Association for Improvements in the Maternity Services | Guideline | 017 | 003 | Offer to reassess... | Thank you for your comment. We have added 'offer' into this recommendation. |
| Association for Improvements in the Maternity Services | Guideline | 017 | 006 | Offer to carry out... | Thank you for your comment. The recommendation your comment relates to is a link to the NICE guideline on intrapartum care, so we have not made this change. |
| Association for Improvements in the Maternity Services | Guideline | 017 | 018 | Discuss the option of... in the light of the woman's medical and obstetric history | Thank you for your comment. The committee agreed that outpatient induction would only be suitable in low risk women (those who did not have any co-existing medical conditions or obstetric complications) and so did not amend the recommendation as you suggest. |
| Association for Improvements in the Maternity Services | Guideline | 018 | 014 | Pleased to see unsuccessful used here | Thank you for your comment and support for this terminology. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Association for Improvements in the Maternity Services | Guideline | 019 | 009 | <p>Multiple concerns with this paragraph; 1) CTG is listed in the "prevention" of complications section - this is not a preventative measure, but we presume is intended to expedite detection of fetal compromise in the event of significant cord compression. We suggest "take the following precautions to predict the likelihood of cord prolapse and expedite diagnosis of fetal compromise in such an event"</p> <p>2) The paragraph appears to imply that the woman should remain attached to CTG for the duration of her (potentially prolonged) antenatal stay - we suggest this is inappropriate and impractical. It would be better to recommend that CTG only be offered if there has been rupture of membranes in order to detect suspected fetal compromise at this point, leading to the offer of examination and diagnosis.</p> <p>3) We suggest that when a woman is considered to be at higher risk of cord prolapse, this should be specifically discussed, along with the potential implications including the possible need for an urgent caesarean.</p> | Thank you for your comment. We have amended the wording of this recommendation to clarify that cardiotocography cannot prevent cord prolapse but it can help avoid the adverse effects associated with cord prolapse. We have also amended the recommendation to state that continuous cardiotocography would only be required after the membranes had ruptured if the presenting part was not stable, so this is not likely to be the case for all women or for the whole duration of labour. The recommendations on monitoring suggest that unless there are clear indications for cardiotocography, intermittent auscultation may be used during induction. We have added that the option of caesarean birth should be considered as an option if there is a risk of cord prolapse. |
| Association for Improvements in the Maternity Services | Guideline | 020 | 022 | It is a very likely to be the case that labour will start naturally given time! Need to talk about within a timeframe acceptable to the woman. | Thank you for your comment. The duration of expectant management will depend on the circumstances of the individual situation so it is not possible to specify a timeframe in this general definition. |
| Association for Improvements in the Maternity Services | Guideline | 020 | 028 | Disappointing that membrane sweeping is seen as an adjunct rather than a method of IOL. It is implied further up the document that this is the beginning of the sequential IOL process. Given that there are recommendations to start at 39+0 to offer "additional" membrane sweeps (potentially over and over), it would be good to see this reconsidered. It is, after all, an intervention, and not a benign one. All references to the offer of membrane sweeps must be accompanied by an assessment of the evidence. | Thank you for your comment. The definition has been revised (and the recommendations your refer to), to recognise that membrane-sweeping is a method of induction, and to adjust the timings. |
| Association for Improvements in the Maternity Services | Guideline | 021 | 013 | We note with interest several reviews of the evidence quoted within this guideline and would suggest that there are limitations and ongoing areas of uncertainty which would justify further research, in particular with regard to recommendations on the timing of birth. Indeed, it seems to us to be the case that the changes to the recommendations | Thank you for your comment. As you have identified the evidence on timing of induction was limited, and hence we have made 2 research recommendations relating to timing, and have added to the research recommendation tables (in Evidence review C) that longer term outcomes such as maternal satisfaction should be measured in this research. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | included in this draft ARE NOT underpinned by clear evidence and have the potential, given what we know about the implementation context, to do significant harm. We would welcome further research into maternal satisfaction with IOL and more holistic effects over time on the family unit associated with different birth experiences. | |
| Association for Improvements in the Maternity Services | Guideline | 024 | 016 | We question why, given that you state “there was not enough evidence to identify the optimal timing of induction more precisely” between 41 and 42 weeks you decided to recommend “offer induction of labour at 41+0 weeks, to take place then or as soon as possible afterwards.” rather than “between 41+0 and 42+0 weeks” as in the previous version. We are concerned that this recommendation is based entirely on the SWEPIIS study which was stopped early and changed the primary outcome and is therefore not reliable evidence on which to base a recommendation with the potential to affect so many women and babies. We also note that the SWEPIIS study found a much higher incidence of perinatal deaths than any previous trial, or than the authors anticipated in designing the sample. This also casts doubt on whether these findings would have occurred had the trial continued as originally planned. | Thank you for your comment. The optimal timing referred to in this sentence relates to the use of individual patient data to determine if there is a gestational age at which the risks of continuing with the pregnancy outweigh the benefits. This is explained in more detail in the research rationale in appendix L of evidence review C. The methodological limitations of the SWEPIIS trial were reflected in the evidence review and taken into consideration by the committee when interpreting the evidence. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have now included tables with the estimated risks associated with a pregnancy continuing beyond 41+0 weeks by parity to aid understanding of the evidence reviewed. The supporting information explains how this data was derived, its limitations and how to interpret it. |
| Association for Improvements in the Maternity Services | Guideline | 025 | 004 | There can be little doubt that these recommendations ‘are likely to’ rather than ‘may’ increase the number of women who are offered induction. We note that there is no discussion of the impact this may have on mental wellbeing, or the long-term health impact of induced labour on both women and babies. | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. It may be that the new recommendations will encourage some women to have an earlier induction than they would previously, but a substantial change in the number of induced labours is not anticipated with the revised recommendations. |
| Association for Improvements in the Maternity Services | Guideline | 028 | 022 | Given the discussion here that there is evidence for mechanical methods such as balloon catheters being effective at promoting vaginal birth within 24 hours without an increased risk of hyperstimulation, we question why | Thank you for your comment. Balloon catheters were not as effective as pharmacological methods at promoting vaginal birth in 24 hours, so were suggested as options |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | pharmacological methods are presented as the first choice, and mechanical methods described only as an option to consider if 'pharmacological methods are not suitable' or the mother prefers it . | when pharmacological methods could not be used, or women preferred a mechanical method. |
| Association for Improvements in the Maternity Services | guideline | 029 | 012 | This should say "Induced labour may be recommended in circumstances where it appears that the benefits outweigh the risks for mother and baby of continuing a pregnancy..." | Thank you for your comment. We have amended the wording as you suggest. |
| Association of Radical Midwives | Guideline | 001 | | NICE has gone for trans inclusion by saying women includes pregnant trans men and non-binary folk. Medical staff and documents referring to pregnant trans men and non-binary people as women has been proved to cause iatrogenic harm. We suggest checking whether the wording is acceptable to a range of individuals and organisations in the LGBTQ+ community | Thank you for your comment. To ensure consistency between NICE guidelines the NICE editorial team have developed a more inclusive description and rationale for the use of the terminology relating to the intended population for maternity and obstetric guidelines guidelines, and this is included in the introductory information at the beginning of the guideline. |
| Association of Radical Midwives | Guideline | 004 | 008 | We recommend that counselling women should include a more balanced and comprehensive explanation of risks associated with induction, eg: <ul style="list-style-type: none"> an increased risk of PPH (Dahlen et al 2020) caesarean section, which (with first baby) increased chance of complication and stillbirth with a future pregnancy (4.6 in 1000 compared to 3.5 in 1000 after vaginal birth) (Leap and Hunter 2016). <p>increased risk of postnatal depression. Inducing more labours will have a knock-on effect on collective mental health. Women who have exposure to synthetic oxytocin have a higher relative risk of receiving a documented depressive or anxiety disorder diagnosis (Kroll-Desrosiers 2017). We recommend that NICE consider data relating to holistic maternity care and childbirth trauma; emotional and psychological outcomes are not, but should be, factored into risk management monitoring.</p> | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on these outcomes. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Association of Radical Midwives | Guideline | 006 | 020 - 025 | Recommending early induction is not the answer to tackling health inequalities or risk of increased morbidity and | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | mortality for women from Black, Asian and minority ethnic backgrounds. Professor Knight, who led the research into the underlying ethnic disparities in maternal mortality in the UK, stated that there was "no difference" in the causes from which women were dying across aggregated ethnic groups when looking at Black women, Asian women, white women or women from other groups. Research identified a number of themes that were considered potential explicit or structural biases impacting on care received a) "not like me", b) complexity and c) microaggression. NICE does not provided robust evidence that induction at 39 weeks for Black, Asian and ethnic minority women is medically indicated or desired by the community. | induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Association of Radical Midwives | Guideline | 006 | 002 - 003 | We are concerned that 'prolonged' hinges on consensus of a 40-week EDD although normal pregnancy length varies between individuals by up to 37 days (Jukic et al 2013). Many women report that their 'due date' was changed following dating scan. ARM suggests that a <i>range of dates</i> may be better used than a clinically assigned single EDD. One size does not fit all, yet an induction policy that hinges on this approach will result in unnecessary intervention. | Thank you for your comment. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the birth of preterm babies. |
| Association of Radical Midwives | Guideline | 006 | 002 | The proposed curtailment of normal pregnancy at 41 instead of 42 weeks has serious implications for pregnant individuals: birth choices suddenly become limited, midwifery led care becomes inaccessible. Interfering with the normal physiological process of labour and birth in the absence of medical necessity increases the risk of complications for mother and baby | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | an induction is a woman's choice and that choice should be respected. |
| Association of Radical Midwives | Guideline | 006 | 002 | We are concerned that the proposed curtailment of normal pregnancy at 41 instead of 42 weeks in the absence of medical necessity, has serious pathological implications for the fast-growing demographic of neurologically immature babies born too soon, for their mental health, for families, for the education system and potentially epigenetics. | Thank you for your comment. The committee did not identify any evidence to suggest that induction at 41 weeks will increase the number of babies born with neurological deficits which would usually be associated with preterm birth, |
| Association of Radical Midwives | Guideline | 006 | 010 | Do not advise and offer induction of labour solely for prolonged pregnancy. NICE advice should not be based on RCT evidence from tiny trials carried out in some cases decades ago and in countries with very different populations and healthcare systems not comparable with the UK. In the UK we are fortunate to have years of evidence from thousands of pregnancy outcomes detailed in the Confidential Enquiries (CESDI and its successors CEMACH, CMACE and MBRRACE), Hospital Episode Statistics and ONS. These should be used instead of flawed RCTs (participation in the ARRIVE trial was declined by 73% of women asked). All show the rate of stillbirth at 42 weeks is lower than the rate at 37-41+6 weeks. The RCOG programme Each Baby Counts provides evidence on morbidity at term, so should HSIB data, as yet not yet widely shared. NICE should use hard data from UK whole population statistics. We appreciate that the rationale is to lower the risk of antepartum stillbirth, but antepartum stillbirth comprises just over a third (35%) of recorded perinatal mortality and morbidity at term (after 37 weeks) while intrapartum stillbirth contributes 8%. Stillbirth is not the only bad outcome. Other risks are: neonatal death 10% and H.I.E. requiring cooling therapy 56% (source ONS 2019 figures, Each Baby Counts 2018 figures). ARM suspects that the raised risk at 41 weeks (0.899/1,000), coupled with the slight fall again at 42 weeks (0.7/1,000) betrays iatrogenic mortality and morbidity largely owed to induction of labour. The lower rate at 42+ weeks (which by definition includes all undelivered women) is | Thank you for your comment. RCT evidence provides the highest quality level of evidence when comparing the outcomes resulting from different interventions and will always be preferred (when it is available) as a basis for NICE guideline recommendations. Randomisation reduces bias and balances known and unknown participant characteristics, allowing the attribution of any differences in outcome to the interventions under study. However, we recognise that other sources of data can provide additional useful information and have now included Hospital Episode Statistics and MBRRACE data to provide supplementary information in this section of the guideline. In addition, based on stakeholder feedback, we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------|-----------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>evident in all confidential enquiry data from 2005 onwards. This lower figure implies that delivery at 42 weeks is safer than delivery at 41 weeks, even if labour is induced, as more than half are.</p> <p>Prof Philip Steer of Each Baby Counts reported to the Royal Society of Medicine that labour had been induced in 41% of the affected babies and that exogenous oxytocin was used in 60% of cases. Oxytocin is more likely to be used in induced labours. Direct pathological consequences</p> <p>Hospital Episode Statistics for 2019 show double the rate of caesarean section after induction (20%) as opposed to 10% after spontaneous onset of labour. There is a higher rate of instrumental delivery (with increased chance of severe perineal trauma) 17% rather than 14%.</p> <p>We suggest that NICE delay releasing the Inducing Labour guideline until there has been a critical analysis of the morbidity and mortality data gathered during 2020 when induction rates soared due to the pandemic.</p> | |
| Association of Radical Midwives | Guideline | 006 | 023 | <p>Every person needs individualised care, no one should be induced based on a population demographic. There is not robust evidence for inducing women at 39 weeks with BMI of 30.</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |
| Association of Radical Midwives | Guideline | 006 | 024 | <p>Recommending early induction for all 'assisted conception' brings almost all lesbians and other women in same sex relationships into the scope of the guidance. This is not evidence based.</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |
| Association of Radical Midwives | Guideline | 010 | 006 - 015 | <p>We suggest rephrasing to reflect ethos of informed consent:</p> <p>Advise women with a baby in the breech position, who have chosen to plan a vaginal breech birth, that:</p> | <p>Thank you for your comment. Induction of labour with breech presentation was not included in the scope of this guideline update and so we have not been able to add more detail about the risks and benefits of induction, compared to a spontaneous labour and so we have not</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <ul style="list-style-type: none"> induction of labour could lead to an increased risk of emergency caesarean birth, compared to spontaneous breech labour induction of labour could lead to an increased risk of neonatal intensive care unit admission for the baby, compared to spontaneous breech labour the methods used for induction of labour will be guided by the need to reduce these risks. See the recommendations on Methods for inducing labour. <p>1.2.20 If delivery is indicated, offer women who have a baby in the breech position a choice of:</p> <ul style="list-style-type: none"> an attempt at external cephalic version, immediately followed by induction of labour if successful caesarean birth or induction of labour in breech presentation <p>Take into account the woman's circumstances and preferences. Advise women that they are entitled to decline the offer of treatment such as external cephalic version, induction of labour or caesarean birth, even when it MAY benefit their or their baby's health.</p> | made the changes you suggest to these recommendations. |
| Association of Radical Midwives | Guideline | 010 | 005 | We suggest this section be re-written to reflect the ethos of informed choice and discussion, as is section 1.2.16 on 'Previous caesarean birth,' to make the service equitable. The guideline should reflect and respect that it is only | Thank you for your comment. Induction of labour with breech presentation was not included in the scope of this guideline update and so we have not been able to add more detail about the risks and benefits of induction, |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------|------------|---------|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | applicable to women who have chosen to plan a vaginal breech birth ie using neutral, non-judgemental language. | compared to a spontaneous labour and so we have not made the changes you suggest to these recommendations. |
| Association of Radical Midwives | Guideline | 010 | 020 | Ultrasound scanning is notoriously inaccurate in terms of assessing the size of the baby at term, so assessment should in addition be based on clinical findings, such as engagement of the fetal head, and health of individual women | Thank you for your comment. The committee recognise that diagnosis of fetal macrosomia can be difficult, but the recommendations on risk were based on randomised controlled trials where the methods of diagnosing suspected macrosomia would be the same in both arms, and so the identified risks will take into account any inaccuracy in diagnosis. The recommendations state that the options for birth should also take into account her individual circumstances and preferences. |
| Association of Radical Midwives | Guideline | 010 | 023 | Induction of labour implies mandatory EFM and immobility, thus dystocia and perineal trauma related to supine position will be more frequent. | Thank you for your comment. The recommendations on monitoring state that continuous cardiotocography is only required at the start of induction and after that intermittent auscultation can be used, unless there are concerns. |
| Association of Radical Midwives | Guideline | 012 | 014 | This undermines women's trust in their own bodies. It ignores the wide evidence base of benefits of going into spontaneous labour and of midwifery care. The recommendations should include discussion of the risk of inadvertent rupture of membranes, thus setting off a cascade of intervention and introducing ascending infection. As the evidence is inconclusive as to the benefits of artificial rupture of membranes, this should not be a routine offer. | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps. However, we have amended the recommendations to emphasise that the option of membrane-sweeping should be discussed with women, and their consent obtained. |
| Association of Radical Midwives | Guideline | 014 | 023 | ARM suggests that mechanical methods of induction need further research, they may reduce the need for pharmacological induction as there is higher chance the labour will progress physiologically unless risk of fetal and maternal compromise is detected. | Thank you for your comment. We have based the recommendations for mechanical methods on the network meta-analysis that was conducted for this question, and have amended the recommendations to include osmotic cervical dilators, based on a re-review of these data and stakeholder feedback. |
| Barking Havering & Redbridge University Trust | Appendix H | | 016, 017, 018 | No economic modelling was undertaken for this review because the clinical evidence, 17 especially with regard to perinatal deaths, was considered to make the cost-effectiveness of 18 recommendations on timing self-evident. The current induction of Labour rate within BHRUTH is 40% this is without the introduction of shorter gestation times ie 39 weeks instead of 40+10. | Thank you for your comment. As a result of stakeholder feedback the guideline no longer recommends that induction of labour be considered at 39+0 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications. The amended recommendations on timing of induction make the focus a discussion with the woman about the risks of earlier or |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | Queens hospital covers areas where there are predominantly of mixed / and ethnic minority, the implication of introducing a 39 week cut off for the ethnic minority groups will only further increase the intervention in all women. The guidance does not classify who these women are, do they have to be mixed or non-mixed, whose to determine how you classify them, first, second or third generation ethnic minority . How will units support this new development without actually indicating in real terms how much it will cost in terms of staffing obstetricians midwives ,space (estate ie more antenatal wards, labour-ward space) equipment. | later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| Barking Havering & Redbridge University Trust | Guideline | 014 | 017 | <p>"For women with a Bishop score of 6 or less, consider induction of labour low dose oral misoprostol (25 micrograms)". I refer the committee to the recently available data from COMRED trial¹, an RCT comparing low dose misoprostol and Dilapan-S. Dilapan-S was shown to be non-inferior to misoprostol, with improved patient satisfaction, higher mean vaginal delivery rate within 36 hours and better patient satisfaction.</p> <p>1. Gavara et al. (2021) An RCT Comparing Cervical Ripening Efficacy of DilapanS to Oral Misoprostol for Labor Induction at Term. ACOG ePoster. Gavara r. 04/03/21; 318840; 2520</p> | Thank you for your comment. We are aware that the COMRED trial has been completed but has not been fully published yet. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date. However, based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour. |
| Barking Havering & Redbridge University Trust | Guideline | 014 | 023 | <p>"For women with a Bishop score of 6 or less, consider a mechanical method to induce labour (for example, a balloon catheter)".</p> <p>Whilst the balloon catheter was an excellent mechanical dilator from a practical point of view, the insertion was painful during the inflation of the balloon, women felt uncomfortable having a catheter visible outside of the vagina. It could not be used for pregnancies with polyhydramnios or where the fetal head was not engaged.</p> | Thank you for your comment. The DILAFOL study was included in the evidence review but did not provide data on the critical outcome of vaginal birth at 24 hours. However, based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>This is not the case with Dilapan S which is a mechanical dilator without these concerns</p> <p>I refer the committee to the recently published DILAFOL study¹, which compared Foley Balloon and Dilapan-S. As found, Dilapan-S had a higher vaginal delivery rate, similar safety profile and statistically better patient satisfaction. In this study, Dilapan-S has shown non-inferiority to Foley balloon. This evidence should be considered.</p> <ol style="list-style-type: none"> 1. Saad AF, Villarreal J, Eid J, Spencer N, Ellis V, Hankins GD, Saade GR. A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial). Am J Obstet Gynecol. 2019 Mar;220(3):275.e1-275.e9. doi: 10.1016/j.ajog.2019.01.008. Epub 2019 Feb 18. PMID: 30790569. | |
| Barking Havering & Redbridge University Trust | Guideline | 015 | 023 | <p>"evidence does not support the following methods of induction of labour: osmotic cervical dilators."</p> <p>I recommend that the statement is reviewed on the following basis:</p> <ol style="list-style-type: none"> 1. The following studies demonstrate that synthetic osmotic dilators (Dilapan-S) are an effective agent of induction of labour: Gupta et al. (2018)¹, Saad et al. (2019)², Gavarna et al. (2021)³. 2. In addition, Queen's Hospital, Romford have been using Dilapan-S as a frontline induction agent for 17 months. We have undertaken two large audits; Jan-May 2020 (N=509) and Jan-May 2021 (N=546). The following results were identified: <p>This text was identified as confidential and has been removed</p> | <p>Thank you for your comment. Based on stakeholder feedback, the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour, so they have been removed from this list.</p> <p>We have checked the references individually to ensure there is nothing we have missed that should have been included. Please see below our response to each reference:</p> <ul style="list-style-type: none"> - Gupta et al (2018) - DOI: 10.1016/j.ejogrb.2018.08.004: this is an observational study and only randomised trials and systematic reviews of randomised trials were prioritised for inclusion in this evidence review - Saad et al (2019) - DOI: 10.1016/j.ajog.2019.01.008: this study had already been included in the evidence review. Note that the reference in the evidence report has been corrected because it was for an abstract of the same trial |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>We recommend the inclusion of synthetic osmotic dilators based on the aforementioned outcomes and supporting published clinical evidence.</p> <ol style="list-style-type: none"> Gupta J, Chodankar R, Baev O, Bahlmann F, Brega E, Gala A, Hellmeyer L, Hruban L, Maier J, Mehta P, Murthy A, Ritter M, Saad A, Shmakov R, Suneja A, Zahumensky J, Gdovinova D. Synthetic osmotic dilators in the induction of labour-An international multicentre observational study. Eur J Obstet Gynecol Reprod Biol. 2018 Oct;229:70-75. doi: 10.1016/j.ejogrb.2018.08.004. Epub 2018 Aug 3. PMID: 30107363. Saad AF, Villarreal J, Eid J, Spencer N, Ellis V, Hankins GD, Saade GR. A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial). Am J Obstet Gynecol. 2019 Mar;220(3):275.e1-275.e9. doi: 10.1016/j.ajog.2019.01.008. Epub 2019 Feb 18. PMID: 30790569. Gavara et al. (2021) An RCT Comparing Cervical Ripening Efficacy of DilapanS to Oral Misoprostol for Labor Induction at Term. ACOG ePoster. Gavara r. 04/03/21; 318840; 2520 | <p>and published on the same year, but data was extracted using the full text study</p> <p>- Gavara et al. (2021) An RCT Comparing Cervical Ripening Efficacy of DilapanS to Oral Misoprostol for Labor Induction at Term. ACOG ePoster. Gavara r. 04/03/21; 318840; 2520: this poster is not eligible for inclusion because it was published after the last search was conducted (May 2020) and only published peer-reviewed studies were eligible for inclusion in this evidence review. For further details regarding inclusion and exclusion criteria of studies, please see the review protocol in appendix A of evidence report B.</p> <p>The DILAFOL trial was included in the evidence review but there was no data on vaginal birth in 24 hours. We are also aware that the COMRED and SOLVE trials have been completed but has not been fully published yet. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date.</p> |
| Barking Havering & Redbridge University Trust | Guideline | 028 | 024 | <p>"including osmotic cervical dilators such as lamaniria". I believe the current wording will cause clinicians confusing. Laminaria is a form of seaweed, unused in the UK. Dilapan-S is a synthetic osmotic dilator. Although both operate via osmosis. The material and length of rods influence the outcomes and thus Dilapan-S should be referred to as synthetic osmotic dilators. Based on the available evidence, synthetic osmotic dilators should be included in the Inducing Labour guidelines, whereas laminaria should not.</p> | <p>Thank you for your comment. As included studies were not limited to those published in the UK only, the committee agreed that osmotic cervical dilators was the over-arching term that included all devices that worked by absorbing fluid and swelling in the cervix, and were also aware that there were both naturally-derived and synthetic products included in this category. Based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Barking Havering & Redbridge University Trust | Guideline | 028 | 027 | <p>“There was no evidence for the effectiveness of osmotic cervical dilators at promoting vaginal birth within 24 hours.” Please review this statement for the following reasons:</p> <ol style="list-style-type: none"> Gupta et al. (2018)¹ – In this 543 patient study led by Birmingham Women's Hospital, the overall vaginal delivery rate was 76.6%, with mean vaginal delivery rate within 24 hours of 45.7% and 66% within 36 hours. Furthermore, in our 546-patient audit we found the vaginal delivery rate within 24 hours was 55.9% and 92.7% within 48 hours of Dilapan-S being inserted. Many obstetricians also eagerly await the outcomes of the SOLVE trial. The primary outcome of this RCT comparing Propess and Dilapan-S is failure to deliver vaginally, with secondary outcomes associated with vaginal delivery within 24 and 36 hours. Finally, I have made the assumption that the authors of relevant studies can be contacted and the vaginal delivery within 24 hours can be extracted and analysed i.e. Saad et al. (2019) – DILAFOL trial. <p>Given the above information, I believe the original statement should be updated to state that evidence does exist regarding vaginal delivery within 24 hours.</p> <ol style="list-style-type: none"> Gupta J, Chodankar R, Baev O, Bahlmann F, Brega E, Gala A, Hellmeyer L, Hruban L, Maier J, Mehta P, Murthy A, Ritter M, Saad A, Shmakov R, Suneja A, Zahumensky J, Gdovinova D. Synthetic osmotic dilators in the induction of labour-An international multicentre observational study. Eur J Obstet Gynecol Reprod Biol. 2018 Oct;229:70-75. | <p>Thank you for your comment. Based on stakeholder feedback, the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour, so they have been removed from this list.</p> <p>We have checked the references individually to ensure there is nothing we have missed that should have been included. Please see below our response to each reference:</p> <ul style="list-style-type: none"> - Gupta et al (2018) - DOI: 10.1016/j.ejogrb.2018.08.004: this is an observational study and only randomised trials and systematic reviews of randomised trials were prioritised for inclusion in this evidence review - Saad et al (2019) - DOI: 10.1016/j.ajog.2019.01.008: this study had already been included in the evidence review. Note that the reference in the evidence report has been corrected because it was for an abstract of the same trial and published on the same year, but data was extracted using the full text study <p>For further details regarding inclusion and exclusion criteria of studies, please see the review protocol in appendix A of evidence report B.</p> <p>We are also aware that the SOLVE trial has been completed but has not been fully published yet. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date.</p> <p>However, based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour, so they have been removed from this list.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>doi: 10.1016/j.ejogrb.2018.08.004. Epub 2018 Aug 3. PMID: 30107363.</p> <p>2. Saad AF, Villarreal J, Eid J, Spencer N, Ellis V, Hankins GD, Saade GR. A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial). Am J Obstet Gynecol. 2019 Mar;220(3):275.e1-275.e9. doi: 10.1016/j.ajog.2019.01.008. Epub 2019 Feb 18. PMID: 30790569.</p> | |
| Belfast Health & Social Care Trust Maternity Service | Guideline | General | General | <p>1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.</p> <p>The recommendations that</p> <p>a) sweeps should be offered at 39 weeks (Rec 1.3.4)</p> <p>b) loL should be offered at 40 weeks (Rec 1.2.2) for healthy women having straightforward pregnancies, and</p> <p>c) the recommendation for loL at 39 weeks for specific women (Rec 1.2.4) are all problematic.</p> <p>These recommendations are not supported by robust, uncontested evidence and to implement will cause significant challenges in terms of service delivery.</p> <p>2. Would implementation of any of the draft recommendations have significant cost implications?</p> <p>Yes. Implementing the three recommendations above is likely to increase costs. We would anticipate a decrease in women on midwife-led pathways, a decrease in home births and MLU births, an increase in loL, CTG monitoring, epidurals, episiotomies, instrumental births, caesarean sections, increased length of stay, breastfeeding challenges, and postnatal morbidity e.g. SSIs.</p> | <p>Thank you for your comment. As a result of stakeholder feedback these 3 recommendations have all been revised.</p> <p>The guideline now recommends a discussion with the women at antenatal visits after 39+0 weeks as to whether they would like a vaginal examination for membrane sweeping.</p> <p>The amended recommendations on timing of induction make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) These three recommendations need to be removed. There is no 'good practice' associated with causing harm by introducing new interventions that are unsupported by clear, robust, uncontested evidence.</p> <p>4. The recommendations in this guideline were largely developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication.</p> | |
| Belfast Health & Social Care Trust Maternity Service | Guideline | General | General | <p>Belfast Trust are grateful that the NICE guidance regarding IOL is being renewed and modernised. We regret however that the recommendations and language in this draft guideline are not of the usual high standard we have learned to expect from NICE. In the Belfast Trust (5500 births per annum) we have modernised our IOL process since 2018. We have an ongoing a project utilising quality improvement methodology since that time, the results of which we anticipate will be published soon. Mechanical cervical ripening balloon (Foley catheter) inserted by a team of midwives has become our default method of IOL. This method has enabled safe outpatient IOL for 60% of our service users and has significantly reduced uterine hyperstimulation caused by prostaglandin use. The project has been very positively evaluated by service users and staff and was shortlisted for a national award by RCM and recognised by BICS. Our birth outcomes have improved with 80% vaginal birth rate following IOL. The content of this draft would be in conflict with the findings of work which we have shared widely and this causes significant concern to our team. NICE prides itself on providing guidance based on firm evidence, and states that its role is to improve long term</p> | <p>Thank you for your comments. We will address your main points in turn.</p> <p>1. Mechanical methods of induction were an option for induction of labour in the guideline, and still are, and this was based on evidence of their efficacy and reduced risk of hyperstimulation. We have amended the recommendations to include a discussion of these benefits with women.</p> <p>2. The scope of this update did not include a review of the risks and benefits of induction of labour compared to expectant management so we have not been able to include details of longer-term outcomes, but the section on information and decision-making has been revised to recommend consideration of these longer term factor.</p> <p>3. The membership of the committee and all their declarations of interest are available on the NICE website, from the beginning of the development process for the guideline.</p> <p>4. The recommendations on induction for prolonged pregnancy have been amended to make it clear this should be a discussion with the woman about the risks associated with a longer pregnancy, but that the decision</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>outcomes. We believe that the update as currently drafted is not evidence based, and is highly likely to result in poorer outcomes for women, babies, and families, as well as potentially harming the reputation of NICE and for guidelines based on evidence that genuinely improves outcomes. The guideline as drafted, focuses almost entirely on the intrapartum period, and does not consider longer-term outcomes. It also fails to take into account women's views and experiences of induction of labour, and matters that are important to them.</p> <p>It appears that the draft guidance has an emphasis on risk throughout and contains an unusually high number of recommendations which are solely based on the experience and opinions of the committee members. We believe that existing qualitative and observational studies should be given an increased emphasis as opposed to the experience or opinions of individuals. We would be supportive of openness and transparency in relation any conflicts of interest and professional connections, memberships and associations of all committee members and that these should be disclosed.</p> <p>It is our opinion that small increased risk of stillbirth after 41/42 weeks does not justify the proposed universal recommendations. We believe that the recommendations are likely to lead to increased harm for large groups of women, as well as their babies.</p> <p>There is inadequate evidence to support recommending sweeps at 39 weeks and induction of labour at 40 weeks. In our opinion we suspect that some trusts may decline to implement these recommendations in their current form, leaving practitioners vulnerable.</p> <p>We are concerned that NICE appear to be working in conflict against best evidence, and potentially leaving obstetricians and midwives with impossible choices and challenges. Already, there is significant variation in IoL rates, and evidence that many women are experiencing IoL for non-</p> | <p>is hers.</p> <p>5. The recommendation on sweeps has been amended to 'after 39 weeks' so sweeps would be offered in the 40th week onwards.</p> <p>6. Induction of labour was offered at 41 weeks, not 40 weeks, and as described above this recommendation is now a discussion with the women.</p> <p>7. The recommendations on information and decision-making have been revised to make it clear that having an induction of labour is a choice, and women are entitled to decline this choice.</p> <p>8. The follow-up in women who decline induction was intended to provide support and reassurance to women, so they do not feel they have been abandoned by the maternity services, but we have reworded these recommendations to clarify this intention.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>medical reasons. This will increase if the current draft recommendations remain.</p> <p>In Northern Ireland, we are aware of a comprehensive recent survey of women carried out by the charity BirthWise NI. The survey showed that, of women who described their birth as traumatic, 54% had undergone IoL, and 69% had experienced IoL that led to instrumental birth or unplanned caesarean births. Many of these women stated they would not agree to go through IoL again in a future pregnancy. Women currently frequently report they did not realise they had a choice as to whether to go ahead with IoL, and in view of the Montgomery ruling, we need to move away from pressure to undergo IoL, rather than increase this with weekly revisits of the discussion.</p> <p>We believe the current recommendations are not Montgomery-v-Lanarkshire-compliant, and are likely to increase perceived pressure on women, the possibility of coercion, and the subsequent increase in the risk of litigation.</p> | |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 004 | 006 | We believe that a statement should be included here regarding respecting and supporting women's decisions about their mode and place of birth. | Thank you for your comment. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 004 | 008 onwards | <p>Wording should be more explicit- Women should be made aware that IOL may impede /disqualify other options such as a home birth or birth in a midwifery led unit.</p> <p>Women must also be made aware that the level of pain perceived during induced labour is greater than that of spontaneous labour.</p> <p>More explicit wording regarding the incidence and implications of uterine hyperstimulation and specifically the methods of IOL that increase this risk.</p> <p>Information given to women must be individualised to the woman's condition and situation.</p> | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on these outcomes. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth, including clearer recommendation on the impact on place of birth. We have also passed on your suggestion to the NICE surveillance |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|-------------|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | RCM Blue Top Guideline on IOL should be referenced here. | team which monitors guidelines to ensure that they are up to date. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 005 | 016 - 025 | Women often report they 'have to' have IoL and frequently express surprise when it is highlighted that it is a choice. They also frequently report being told their baby might die if they do not agree to the induction. It would be helpful if the guideline addressed the issue of direct or indirect coercion, particularly in light of CG138 and the Montgomery ruling. | Thank you for your comment. We have added a new recommendation to this section to address this issue which states: 'Recognise that some women will decide to proceed with induction and some women will choose not to have an induction. Support women whatever their decision, even if you disagree with it and do not allow your views to influence the care they are given.' |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 005 | 011 | Add: 'and the risks and benefits of spontaneous onset of labour' In addition, the risks and benefits of induction of labour and the proposed methods should be discussed for everyone, not just in specific circumstances, and there should be individualised discussions for each woman | Thank you for your comment. The committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth with individual women. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 005 and 007 | 022 and 003 | Recommendations 1.1.4 and 1.2.5 on informed choice: These recommendations to support women whatever their choice are in direct contrast with Rec 1.2.7, which states that women should be given opportunities to revisit their decision at least weekly. Continued insistence that women might revisit their decision may be perceived as coercion and even lead health professionals to breach the Montgomery & Lanarkshire ruling. They are also in contrast with recommendations from RCM Blue Top Guideline on Induction of labour states clearly: <i>Midwives should ensure women and their families know that they have a choice about having an induction of labour Unless the clinical situation changes, midwives should not make frequent offers of this intervention.</i> | Thank you for your comment. We have reworded the first of these recommendations to emphasise that women can choose whether or not to discuss their decision again. However, the committee agreed that it is important that women are advised to contact their maternity unit if they have concerns about their baby, or that some women may decide that, as they have still not gone into spontaneous labour, they wish to re-discuss their options for birth, and so this recommendation has not been changed. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 006 | 012 - 019 | The committee has acknowledged the need for further research on longer term outcomes and studies of impact of IOL on infant wellbeing and development, however they repeatedly state that given the results of the SWEPSIS trial, it is unlikely that further trials of IOL versus expectant management will be conducted. Therefore, we believe it would be important to consider the evidence provided by observational studies. In general, | Thank you for your comment. The review carried out for this update compared earlier induction with later induction and it was not within the scope of this update to review the risks and benefits of induction compared to expectant management. However, the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>observational studies comparing women who received IOL versus those who didn't, can be prone to the risk of overestimating adverse outcomes in the IOL cohort if they failed to take the indication for IOL into account. However, a recent large study using linked data from Australia compared low-risk women at term who underwent IOL without medical reason with those with spontaneous labour onset, concluding that IOL for non-medical reasons (which excluded post-term) was associated with higher rates of obstetric interventions and more adverse maternal, fetal and child health outcomes, including admissions to hospital for infections up to 16 years of age.</p> <p>There is a need to provide balanced information here, including the risks associated with induction of labour and the potential for a cascade of intervention as well as the potential for a more challenging and traumatic birth.</p> <p>Research around stillbirth and neonatal death is conflicting – research has been under resourced, not of good quality, and many of the trials cohort all women in together so that the data is difficult to interpret. Trials, particularly ones such as the ARRIVE trial, should not be used as a basis for guidelines for a number of reasons: 73% of women declined to take part in the study so this cannot be considered a representative sample of the population, the type of care the women received was highly medicalised for low-risk pregnancies (which is not the usual mode of care in the UK) and most crucially there was no effect on stillbirth or neonatal death rates.</p> <p>Rydahl et al (2020) found that a change to earlier induction of labour had no effect on decreasing stillbirth rates, but did increase the number of women being induced, as well as increasing perineal trauma and uterine rupture. Women require the totality of this information, to enable them to make a fully informed decision.</p> <p>In line with CG138 women should also be informed of what the <i>absolute</i> risks of stillbirth are, not only informed that</p> | <p>have an induction. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based.</p> <p>The methodological limitations of the ARRIVE trial were reflected in the evidence report and taken into consideration by the committee when interpreting the evidence. The committee considered the proportion of women who declined to participate to be within normal parameters and considered this could be due to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal. The committee acknowledged that although all included studies were from high-income countries, these were conducted in a variety of settings (not just the United Kingdom) where healthcare is mainly accessible through private funding and where there are usually fewer midwives available to support women during birth, such as the US. However the committee agreed that the evidence was broadly applicable to the current UK context.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>there is an "increased risk" in order to properly inform their decisions.</p> <p>In addition, the SWEPSIS study has dubious applicability and the results continue to be debated amongst researchers and HCPs.</p> <p>"The truth is that research does not confirm with certainty whether induction is linked to any long-term adverse consequences for mothers and children". Dahlen (2021) Intrapartum interventions and outcomes for women and children following induction of labour at term in uncomplicated pregnancies: a 16-year population-based linked data study", BMJ Open</p> | |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 006 | 020 - 026 | <p>The service provision implications of such recommendation do not appear to have been considered. In some inner city hospitals, this recommendation will result in most women being offered an early IOL on ethnicity or age criteria alone. The consequences and impact of service provision of this recommendation need further consideration and these will have major impacts on safety and the delivery and experience of maternity care.</p> <p>We are very concerned about this recommendation and strongly believe that it will place unnecessary pressures on personnel and resources. For example, in 2019 25% of women giving birth in Northern Ireland were ≥35 years old so this would result in a quarter of women being offered IOL at 39 weeks</p> <p>We respectfully request the committee remove this recommendation.</p> | <p>Thank you for your comment. As a result of stakeholder feedback the guideline no longer recommends that induction of labour be considered at 39+0 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications. The amended recommendations on timing of induction make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications.</p> |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 006 | 014 - 019 | <p>We believe that it is crucial that statements like "increased risk" or, indeed, "increased benefit" should not be used, especially when this is about information to be given to women. Any statement relating to the information to be provided to women should make it crystal clear that this should be framed by absolute numbers (e.g. incidence per 1000). This is widely recognised as best practice.</p> | <p>Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | We would respectfully request that the committee rewrite this list to include absolute likelihood (risk/benefits) rather than just use the term 'increased likelihood'. | |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 006 | 020 - 025 | <p>This recommendation may increase the risk for these women, rather than decrease it. There is not enough evidence to support this recommendation, with the opinion of the committee apparently taking precedence. If this recommendation were to be brought in, it would have significant impacts on services, including:</p> <ul style="list-style-type: none"> a. A significant decrease in women experiencing SOL b. A decrease in women going into labour after sweep/mechanical induction c. Increased CTG monitoring d. Decrease in MLU and home births e. Increased use of epidurals f. An increase in caesarean birth (Dahlen et al 2021) g. Increased stillbirth in the next pregnancy, where the reason for caesarean is related to iol h. An increase in instrumental birth i. An increase in episiotomy linked to h) above j. An increased likelihood of breathing difficulties for the neonate, subsequent to f) above k. Longer length of postnatal stay l. Increased SSI and perineal infection m. Reduced bonding and breastfeeding n. Lower satisfaction levels for women o. Increased incidence of birth trauma p. Significant challenges to maternity services: increased resources directed towards iol, theatres, and postnatal wards q. Increase in adverse outcomes due to p) above, as resources are directed towards iol throughput, there is a greater chance of concerns being missed. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>1.2.4 IOL at 39 weeks for BMI, BAME and age 35+</p> <p>The use of the terms 'Consider induction of labour' for these women may lead to this practice becoming embedded as the management of choice.</p> <p>Vulnerable women are already at higher risk of adverse outcomes, and this may well be partly due to increased levels of intervention. This recommendation may reinforce existing vulnerabilities rather than reducing them.</p> <p>The recommendation to induce all women falling within the 'higher risk' of complication bracket early is based on the 'knowledge and expertise' of the committee (Evidence Review C page 19 lines 46). The committee did not have sufficient evidence to recommend a particular gestational age at which to consider early induction, but agreed that it should be considered earlier than the 41+0 week (although no earlier than term, in other words 37+0 weeks). The committee decided that considering induction at 39+0 weeks for women in these groups would likely reduce risks of prolonged pregnancy without over-burdening NHS resources, or increasing risks to babies due to earlier birth.</p> <p>There is no evidence to suggest outcomes will improve if these groups are offered earlier induction.</p> <p>The draft also cites MMBRACE and audit data showing that women in these groups have poorer birth outcomes. However, it is likely that the poorer outcomes for BAME women compared with white women, are due to institutional racism and co-existing risk factors such as poverty and poor diet, rather than biological differences making these women more prone to complications. BAME women report poorer quality of care and lower satisfaction (Henderson 2013 "Experiencing maternity care: the care received and</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>perceptions of women from different ethnic groups”, BMC Pregnancy & Childbirth).</p> <p>Therefore, we do not believe that introduction of an IOL recommendation based on ethnicity alone is the best option. We support the introduction of training and support to reduce institutional racism and promote culturally tailored sensitive care in maternity services. We support the plans and commitment to offer continuity of midwifery care to improve outcomes for these women.</p> <p>We respectfully suggest that this recommendation should be removed.</p> | |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 006 | 010 - 011 | <p>This is not supported by clear evidence. If this recommendation remains, then we might reasonably expect to see the following:</p> <ul style="list-style-type: none"> a. A significant decrease in women experiencing SOL b. A decrease in women going into labour after sweep/mechanical induction c. Increased CTG monitoring d. Decrease in MLU and home births e. Increased use of epidurals f. An increase in caesarean birth (Dahlen et al 2021) g. Increased stillbirth in the next pregnancy, where the reason for caesarean is related to IOL h. An increase in instrumental birth i. An increase in episiotomy linked to h) above j. An increased likelihood of breathing difficulties for the neonate, subsequent to f) above k. Longer length of postnatal stay l. Increased SSI and perineal infection m. Reduced bonding and breastfeeding n. Lower satisfaction levels for women o. Increased incidence of birth trauma p. Significant challenges to maternity services: increased resources directed towards lol, theatres, and postnatal wards | <p>Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | Increase in adverse outcomes due to p) above, as resources are directed towards iol throughput, there is a greater chance of concerns being missed. | |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 006 | 002 onwards | <p>Prevention of Prolonged Pregnancy: All the evidence presented in support of IOL for post-term pregnancy is based on RCTs, which does not represent all of the literature. There is a large body of observational evidence and qualitative evidence that has not been taken into consideration. The committee should complete a broader review of the evidence.</p> <p>Developing NICE Guidelines: The manual states that depending on the topic it can be useful to review a range of different types of evidence including observational and qualitative studies.</p> <p>1.2.2 and 1.2.3 Prevention of prolonged pregnancy 41+0</p> <p>All the evidence cited in support of these recommendations derives from RCTs. While it is essential to include RCT evidence, we believe a more cautious approach is needed when extrapolating “universal” recommendations applicable to all women from these studies. RCTs of labour induction versus expectant management may be subject to biases, namely:</p> <p>Performance bias by providers due to lack of blinding, based on which the committee has correctly downgraded the quality of some of the evidence. This may have led to different management of women in the two arms of the trial. Representativeness of the study population ie, only between one fifth to one third of eligible women were accepted to be part of the ARRIVE, SWEPSIS and INDEPTH trials: although the samples were considered comparable to the general population in SWEPSIS, there may be unmeasured differences between the trial and general populations, especially as far as attitudes towards IOL are concerned. This limits the external validity of RCT findings.</p> | <p>Thank you for your comment. The methodological limitations of the included trials were reflected in the evidence report and taken into consideration by the committee when interpreting the evidence. The committee considered the proportion of women who declined to participate to be within normal parameters and considered this could be due to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal.</p> <p>RCT evidence provides the highest quality level of evidence when comparing the outcomes resulting from different interventions and will always be preferred (when it is available) as a basis for NICE guideline recommendations. However, we recognise that other sources of data can provide additional useful information and have now included Hospital Episode Statistics and MBRRACE data to provide supplementary information in this section of the guideline.</p> <p>In addition, based on stakeholder feedback, we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>It is our belief that the SWEPSIS trial all cases of perinatal mortality were among nulliparous women, and the ARRIVE trial included only nulliparae. In INDEPTH, one case was among a nulliparous woman and the other two among multiparous women.</p> <p>Linked to the above point, we don't know whether IOL was available on request to women who didn't take part in the trials. If not, taking part in the trial would have been the only chance for low-risk women keen to have an IOL of getting this earlier than 42 weeks. Those women subsequently assigned to the expectant management cohort may have felt more stressed about being in the on-intervention group, or anxious about their labour not starting. Stress and anxiety are known to affect the onset and progress of labour and might have adversely impacted these women's outcomes.</p> <p>We request that the committee revisit this recommendation in the view of the above.</p> <p>1.2.3 Prevention of prolonged pregnancy 41+0)</p> <p>We suggest that this recommendation should be reworded as there is no robust evidence available which identifies the gestational age beyond which continuing the pregnancy may pose additional risks to mother and baby.</p> <p>Some recent studies, however, suggest that:</p> <ul style="list-style-type: none"> - Though the risk remains small, the risk of stillbirth or neonatal death in the first week of life may increase with expectant management between 41 and 42 weeks, roughly from less than 1 per 1000 pregnancies to 4 per 1000 - Though the risk remains small, the risk of the baby needing to be admitted to a neonatal unit may increase with | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>expectant management between 41 and 42 weeks, roughly from 30 per 1000 pregnancies to 43 per 1000</p> <p>The SWEPSIS study, informing this recommendation, was not powered for perinatal mortality and the evidence on NICU admission from SWEPSIS, INDEPTH and another two smaller studies is of low quality (due to performance bias).</p> <p>The ARRIVE trial did not show a significant difference in NICU admissions.</p> | |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 006 | 004 | <p>The indication of restrictive timing (38 weeks) for the discussion on preference for birth including expectant/induction/planned caesarean does not take into consideration that the timing and content of antenatal care should be tailored to the woman's needs.</p> <p>As per the RCM Blue Top Guideline on Induction of labour recommendation: Information should be tailored to women's specific circumstances We suggest removing the suggested timing.</p> | <p>Thank you for your comment. We agree that discussions about mode of birth should take place earlier in pregnancy, and we have now moved this recommendation to the section of the guideline on information and decision-making. We have also removed the proscribed weeks at which these discussions must take place so they can fit around current antenatal appointment scheduling. The recommendation already states that a woman's individual circumstances and preferences should be taken into consideration.</p> |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 006 | 010 | <p>The service provision implications of this recommendation are significant and do not seem to have been recognised or considered by the authors.</p> <p>A significant increase in provision of midwifery one-to-one care hours will be required if IOL were to be offered to all healthy 'low' risk women at 41 weeks. The in-patient hospital stay of women will significantly increase affecting service user flow.</p> <p>We believe that there are important safety implications of induction of labour on a large scale that may outweigh benefits and that have not been considered here.</p> <p>We believe that the committee should remove this recommendation.</p> <p>Research by Dahlen et al 2021 has shown that 15% of low-risk women have IoL for non-medical reasons. Their</p> | <p>Thank you for your comment. As a result of stakeholder feedback the guideline no longer recommends induction from 41+0 weeks. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | comprehensive study also shows IoL as leading to more interventions, including caesarean, epidural, episiotomy, instrumental births. Some hospitals currently have induction rates close to 50%. These recommendations will further diminish the opportunities for women to go into labour spontaneously. The small increased risk of stillbirth cannot justify such a fundamental change to maternity service user experience. Gestational age based on due dates are not always accurate, and the draft recommendations risk may risk an increased incidence of premature births. | |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 006 | 014 | <p>The evidence on mode of birth is contradictory, with most studies suggesting that there is no difference between IOL and expectant management.</p> <p>We suggest removing the sentences that refer to these risks. Specifically:</p> <p>a. The evidence on the increased risk of caesarean birth is almost exclusively based on the ARRIVE trial, which compared IOL at 39 weeks versus 40-41, in a very different population and health system from the UK.</p> <p>b. The two large relevant European studies, INDEX and SWEPSIS, comparing IOL at 41 vs 42 weeks, did not find a difference in mode of birth</p> <p>c. The only study showing some evidence of a reduction in instrumental birth is the ARRIVE trial without the difference reaching statistical significance again in a very different population and health system from the UK.</p> | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have now included tables with the estimated risks associated with a pregnancy continuing beyond 41+0 weeks by parity to aid understanding of the evidence reviewed. The supporting information explains how this data was derived, its limitations and how to interpret it. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 006 | 020 | 'Consider induction of labour...' This wording suggests that the HCPs will decide, rather than the woman. This wording is not appropriate. | Thank you for your comment. 'Offer' is the wording used by NICE to reflect a recommendation based on strong evidence, and 'consider' is where there is more uncertainty. Based on stakeholder feedback we have amended the recommendations for earlier induction for certain groups of women and instead included information on increased risks from a national audit (MBRRACE). |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 007 | 006 - 015 | There needs to be a balanced discussion, with the pros and cons of monitoring, and the pros and cons of induction presented in a neutral, balanced way. | Thank you for your comment. This recommendation has been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | This recommendation, as currently drafted, is framed in such a way that women are likely to comply with induction and not opt for monitoring. This needs to be amended in light of the Montgomery - v - Lanarkshire ruling. | limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 007 | 016 - 020 | This statement is problematic and contradicts recommendations from RCM Blue Top Guideline on Induction of labour: "Midwives should ensure women and their families know that they have a choice about having an induction of labour. Unless the clinical situation changes, midwives should not make frequent offers of this intervention." The choice of language implies that women will want to 'revisit' their option, the same assumption is not made about the opposite scenario. Should women be offered to revisit their option during IOL process?? We respectfully suggest removing this recommendation, as it has the potential to pressurise healthcare professionals into 'revisiting' their options with women which in turn will be perceived and interpreted as coercion. | Thank you for your comment. We have reworded the first of these recommendations to emphasise that women can choose whether or not to discuss their decision again. However, the committee agreed that it is important that women are advised to contact their maternity unit if they have concerns about their baby, or that some women may decide that, as they have still not gone into spontaneous labour, they wish to re-discuss their options for birth, and so this recommendation has not been changed. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 007 | 003 - 005 | Women can feel pressurised and indeed coerced into interventions. This section needs to be worded more strongly to address this possibility, particularly in light of the Montgomery v Lanarkshire ruling. The current recommendations have substantial implications for service delivery, including significantly increased length of time at ANC appointments to ensure women are fully informed prior to making decisions about induction of labour. | Thank you for your comment. We have amended the wording to clarify that the decision is the woman's and this should be recorded in her notes. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 007 | 006 - 007 | 1.2.6 Monitoring for women opting for expectant management There seem to be a lack of evidence informing this recommendation - on the impact of fetal monitoring and expectant management from 41 weeks. The impact on service provision does not seem to have been considered, in terms of how the service would implement routine twice-weekly monitoring for women opting for expectant management. This is a potential pressure for both personnel and resources. | Thank you for your comment. Other recommendations (for example 1.2.2 and 1.2.4) have been amended so it is unlikely that the cohort of women being offered and declining induction will change significantly. This recommendation has also been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The options to do CTG and amniotic pool |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | depth are only provided as suggestions, carried over from the previous version of the guideline, and have been in place since 2008, so it is unlikely these recommendations will have an impact on resources. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 007 | 010 | While it is true that monitoring gives a snapshot of the current situation, the inclusion of the statement that adverse effects on the baby cannot be predicted is scaremongering and should be taken out. Women should be encouraged to focus on how they physically feel as well as their baby's movements. We are concerned that this statement would mean that women decide on induction of labour out of fear and not based on decisions that are right for them. | Thank you for your comment. The committee agreed that it was very important to make women aware of the limitations of monitoring so we have not removed this part of the recommendation. However, a later recommendation provides advice on ensuring women know to monitor their baby's movements. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 007 | 013 | If this recommendation is implemented this will lead to service pressures in terms of an increase in number of women requiring cardiotocograph monitoring and ultrasound scanning to calculate amniotic pool depth. | Thank you for your comment. Other recommendations (for example 1.2.2 and 1.2.4) have been amended so it is unlikely that the cohort of women being offered and declining induction will change significantly. This recommendation has also been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The options to do CTG and amniotic pool depth are only provided as suggestions, carried over from the previous version of the guideline, and have been in place since 2008, so it is unlikely these recommendations will have an impact on resources. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 007 | 016 | Once women have made their decision to decline induction, this decision should be respected and supported. By revisiting this at future appointments, we feel that this could be perceived as coercion and women may feel coerced or obliged to agree to induction of labour if regularly asked about it by health care professionals. There is potentially a power imbalance between healthcare professional and woman. This recommendation needs to be reviewed in light of the Montgomery v Lanarkshire ruling. | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again, and have removed the suggested frequency of at least once a week. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | In addition, if this recommendation is implemented this will lead to service pressures in terms of increased appointments with healthcare professionals for women to revisit options. | |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 007 | 018 | If this recommendation is implemented this will lead to service pressures in terms of increased number of phone calls / electronic referrals to Induction of Labour Team requesting Induction of Labour to be arranged. | Thank you for your comment. If a woman decides to decline induction and await spontaneous labour, there may be situations where, a few days or a week later, she wishes to reconsider her decision and her options for birth, or if she has concerns about her baby. In this case the committee agreed that she should be advised to contact her midwife or maternity unit. There is nothing in the recommendation to state that it must be immediate. However, we have amended the recommendation to clarify that there is only urgency to contact the maternity service if the woman has concerns about her baby. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 008 | 021 - 029 | 1.2.12 and 1.2.13 Those two sets of recommendations seem slightly confusing. Women should be offered the option for expectant management OR induction of labour. Expectant management should include 24 hours however some women will opt for longer expectant management. These recommendations should include both risks and benefits of both options (e.g. impact on place of birth). | Thank you for your comment. The management of PPRM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not reviewed the data on the risks and benefits of induction of labour compared to expectant management in prelabour rupture of the membranes, or the risks of expectant management beyond 24 hours, and so have not been able to make the changes you suggest. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 008 | 007 - 012 | It would be helpful to also provide positive framing here e.g. The benefits for the baby in avoiding preterm birth | Thank you for your comment. The management of PPRM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not reviewed the data on the risks and benefits of induction of labour compared to expectant management in prelabour rupture of the membranes, and so have not been able to make the changes you suggest. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 008 | 013 - 017 | 1.2.11 preterm labour rupture of membranes after 34+ but before 37+ The evidence does not indicate any significant harms to the baby from choosing immediate delivery over expectant management. The service implication of immediate IOL should be considered: occupancy and acuity of the neonatal | Thank you for your comment. The evidence for this recommendation is in the evidence review carried out as part of the development of the neonatal infection guideline (NG195), and we agree that the evidence found harms to the baby from expectant management, not from immediate birth. It found increased neonatal infections in the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | unit, midwifery workforce availability for one-to-one care to safely offer immediate IOL and the impact of continuity of midwifery carer. | expectant management group compared to the immediate birth group, and also found that immediate birth was a cost-effective strategy. The neonatal infection guideline also states that as immediate birth is current practice the impact on units will be minimal. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 008 | 003 - 006 | This section should include the benefits of continuing pregnancy not just the risks. Women cannot make informed choices, if they are offered only the risks of one option. This is not a 'shared decision'. The woman decides what happens to her and her baby. This section needs to be reworded to acknowledge women's autonomous decision making, particularly in light of the Montgomery v Lanarkshire ruling. | Thank you for your comment. The management of PPRM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not reviewed the data on the risks and benefits of induction of labour compared to expectant management in preterm prelabour rupture of the membranes, and so have not been able to make the changes you suggest. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 008 | 022 | Instead of 'up to 24h' this should read 'after 24h' | Thank you for your comment. This recommendation relates to the period up to 24 hours after the membranes have broken. The course of action after 24 hours of expectant management is provided in the next recommendation. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 009 | 001 - 003 | Add a further sentence to ensure there is no attempt at persuasion/coercion, in light of the Montgomery-v-Lanarkshire ruling. | Thank you for your comment. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 009 | 022 - 024 | We welcome this recommendation. Women are entitled to decline the offer of treatment such as IOL or caesarean birth, even when it would benefit their or their baby's health. However we believe this applies to all interventions in any situation not just in the instance of women who have had a previous caesarean birth. We respectfully suggest applying the wording in this recommendation across the whole guideline. | Thank you for your comment. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Belfast Health & Social Care Trust Maternity Service | Guideline | 009 | 009 | If this recommendation is implemented this will lead to service pressures in terms of increase in the number of high-risk women having an IOL. Decrease in number of women having a successful VBAC due to number of women with previous caesarean section being advised to have an induction of labour. | Thank you for your comment. We recognise that many women will wish to have a vaginal birth after a previous caesarean birth. However, the stem of this recommendation is 'If birth is indicated.....' so these recommendations would apply where a decision has been made that it is necessary to expedite birth. In order to clarify this, we have amended the wording to 'if birth needs to be expedited.' |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 009 | 017 | The word birth should be used instead of the word "delivery" to be consistent with previous publications. | Thank you for your comment. We have changed this to birth. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 009 | 021 | We welcome the commitment to ensuring women are aware of their right to decline intervention, including IOL. However the caveat 'even when it would benefit their or their baby's health' could be misread. Women sometimes report feeling coerced into agreeing to IOL, even where there is no clear risk to their baby. The word 'would' should not be used as no-one can know the outcome beforehand. | Thank you for your comment. We have amended the wording of this recommendation to say '....when it may benefit their or their baby's health.' to reflect the uncertainty. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 010 | 002 - 004 | Women decide. This needs to be reworded in light of the Montgomery ruling. | Thank you for your comment. This recommendation relates to women requesting an induction of labour and the responsibility of the healthcare professional is therefore to provide them with personalised information on the risks and benefits, which is what this recommendation states. Decision-making about induction of labour is covered in more detail at the beginning of the guideline in the section entitled 'information and decision-making'. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 010 | 009 | The word birth should be used instead of the word "delivery" | Thank you for your comment. We have changed 'delivery' to 'birth'. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 010 | 017 | 1.2.21 Fetal growth restriction needs to be clearly defined-below the 5th or 10th percentile. The agreed definition of fetal compromise should also be clearly defined here. The evidence of relative, absolute risks of each available options should also be given to women and included in this guidance. | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add a definition of confirmed fetal compromise. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Belfast Health & Social Care Trust Maternity Service | Guideline | 010 | 019 onwards | We welcome the admission that NICE are aware of a lack of evidence regarding macrosomia. Is it possible to include absolute risk numbers in this section? | Thank you for your comment. To increase the usefulness of these statements we have included the absolute rates from the evidence. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 010 | 020 | While it is positive that this point does reference discussion of the benefits and risks of both induction and expectant management in women with suspected foetal macrosomia, we feel that this change in recommendation from the previous guidelines (that in the absence of any other indications, induction should not be recommended solely based on suspected large baby) is unnecessary. As is highlighted in this draft, there is lack of evidence around the risks associated with having a larger baby, indicating that induction cannot be recommended based on evidence. Late pregnancy scans are inaccurate, with a 15% error margin for predicting baby's weight, meaning that recommendation of induction based on baby's size could lead to more women being induced for no medical reason. There is the likelihood that once women are told they are potentially having a big baby and are offered induction, they are less likely to consider the lack of evidence and more likely to opt for induction as it is recommended by their healthcare professional and the fear associated with birthing a big baby. Given the evidence listed in the bullet points, there is no valid reason for recommendation 1.2.22 and it should be removed. This was a do not do action in the previous guidance and there a lack of robust evidence to justify changing this. | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 011 | 002 - 004 | This is further confirmation that there is no evidence to support the recommendation in 1.2.22. | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. Thank you for your comment. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 011 | 012 onwards | We very much welcome the thoughtful recommendations for women experiencing intrauterine fetal death. | |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 012 | 001 - 003 | This recommendation should include risk and benefits of immediate offer of IOL or caesarean birth versus expectant management in the event of intrauterine fetal death and SROM. Infection and bleeding should also be better defined here, is the recommendation referring to APH? Is infection referring to signs of sepsis. Could this be divided into separate sections? | Thank you for your comment. It was not within the scope of this guideline to review the risks and benefits of different modes of birth after intrauterine fetal death so we are not able to provide more detail on this, or on the definitions of infection or bleeding. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 013 | 005 - 006 | Numbers should be provided to women. From the Cochrane review on membrane sweeping 1:8 women will go into spontaneous labour after a sweep. There are negatives associated with receiving a sweep as well as benefits, all should be listed for women to make informed choice. This section should reflect the RCM Blue Top Guideline on Induction of labour: •Clear and understandable information should be presented about the risks and benefits of a sweep and the procedure should be explained in detail. •Membrane sweeps should be discussed in an antenatal appointment prior to 40 weeks so that women have time to make considered decisions. •Side effects of membrane sweeps, such as pain during the procedure and light vaginal bleeding and cramps afterwards should be discussed with women prior to consent for the procedure. This will support women to make an informed decision about a sweep and may alleviate worry if women experience these side effects. •If a woman declines membrane sweeping, this decision must be respected and supported. •Unless the clinical situation changes, midwives should not make frequent offers of this intervention. | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps. Thank you for sharing the RCM blue top recommendations with us, which are in-line with the NICE recommendations. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Belfast Health & Social Care Trust Maternity Service | Guideline | 013 | 014 - 015 | <p>There is inadequate evidence to support this recommendation, which is likely to result in a range of unintended consequences, with significant negative impacts on women, babies, and services.</p> <p>These include:</p> <ul style="list-style-type: none"> a. A significant decrease in women experiencing SOL b. A decrease in women going into labour after sweep/mechanical induction c. Increased CTG monitoring d. Decrease in MLU and home births e. Increased use of epidurals f. An increase in caesarean birth (Dahlen et al 2021) g. Increased stillbirth in the next pregnancy, where the reason for caesarean is related to iol h. An increase in instrumental birth i. An increase in episiotomy linked to h) above j. An increased likelihood of breathing difficulties for the neonate, subsequent to f) above k. Longer length of postnatal stay l. Increased SSI and perineal infection m. Reduced bonding and breastfeeding n. Lower satisfaction levels for women o. Increased incidence of birth trauma p. Significant challenges to maternity services: increased resources directed towards lol, theatres, and postnatal wards q. Increase in adverse outcomes due to p) above, as resources are directed towards iol throughput, there is a greater chance of concerns being missed. <p>This would also lead to an increase in the number of women being offered vaginal examination at an earlier gestation meaning it may be more painful. These women should be offered a membrane sweep in the correct environment with adequate analgesia i.e. entonox. The implications of this recommendation would also increase footfall through</p> | <p>Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, nor the need for pain relief. However, we have expanded the recommendation on discussing it with women and obtaining their consent, and this includes for additional sweeps. As the recommendations for membrane-sweeping have been in place since 2008, the committee did not believe the minor changes to the recommendations would be a challenge to maternity services.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>induction of labour service. As mentioned previously, pregnancy length can vary greatly, and research is lacking as to the timing of sweeps.</p> <p>In addition, the wording of any recommendation on sweeps should be changed – Additional membrane sweep can be <i>offered</i>, and it is the woman's decision whether to accept an additional sweep should labour not start spontaneously.</p> | |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 013 | 003 | <p>We welcome the inclusion of discussing the risks of sweeps – discomfort and bleeding.</p> <p>In addition we would suggest that women are informed that there is a lack of evidence around the effectiveness of sweeps as well as the optimal timing and frequency of sweeps (Finucane et al 2020).</p> <p>As many women find having a sweep extremely uncomfortable, so we would recommend adding a requirement to discuss pain relief options available to them.</p> <p>We also feel that women should be informed that they have the option to accept or decline a sweep. This should be added here.</p> <p>The timing of the offer of membrane sweeping should be carefully considered here.</p> <p>If IOL is to be routinely offered at 41 weeks and 39 weeks for some groups of women, is this recommendation stating that most women should be offered a sweep between 38-39 weeks of pregnancy.</p> <p>There are service provision implications to be considered here in terms of offering earlier sweeping of the membranes. There is low quality evidence to suggest an increased risk of pre-labour rupture of membranes for women having a membrane sweep.</p> <p>Avdiyovski H, Haith-Cooper M, Scally A. (2019) Membrane sweeping at term to promote spontaneous labour and reduce the likelihood of a formal induction of labour for post</p> | <p>Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, and so are not able to comment on this in the guideline. We have now added in that pain should be included in the initial discussion with women about membrane sweeps. We have now also emphasised that the option of a membrane sweep should be discussed with women and their consent obtained.</p> <p>The recommendations have been clarified to state that membrane sweeps should be discussed after 39 weeks (as opposed to 'from 39 weeks'), and that this is a discussion and not an offer recommendation. As the recommendations on membrane-sweeping have been in place since 2008 the committee did not think that the minor changes to the wording would impact on services.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | maturity: a systematic review and meta-analysis, Journal of Obstetrics and Gynaecology, | |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 013 | 010 | Obtaining consent before performing a membrane sweep is a basic requirement. However, it would also be beneficial if the guidance referenced ensuring women fully understood the likelihood of a sweep being effective and knew what their Bishop score was before they made a decision. It needs to be explicitly stated that a sweep should not be done during a VE, and should only take place following meaningful discussion and clear agreement from the woman. | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, or the likelihood of success. However, we have now expanded the recommendation on discussing it with women and obtaining their consent. To determine the Bishop score before women made their decision would require a separate vaginal examination and so we have not recommended this. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 014 | 014 - 028 | A Bishop score of 6 or less generally indicates that the cervix is unfavourable. Offering induction by whatever method if the cervix is unfavourable means that it is more likely to affect the birth outcomes, increasing the need for interventions or caesarean section for unsuccessful induction, which can have a subsequent impact on women's perinatal mental health perceive their birth experience was traumatic. | Thank you for your comment. The evidence review carried out for methods of induction analysed the data by the sub-groups of women with a Bishop score of 6 or less and woman with a Bishop score greater than 6. The evidence showed that the recommended methods of induction (dinoprostone, misoprostol and mechanical methods) were all effective at leading to vaginal birth within 24 hours, and did not increase the rate of caesarean birth or instrumental birth compared to placebo, in women with a Bishop score of 6 or less. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 014 | 001 - 010 | This section would be more meaningful with numbers included as information for sharing with women in regard of uterine activity and hyperstimulation. | Thank you for your comment. There was evidence from the systematic review on the rates of hyperstimulation with dinoprostone and misoprostol so this has been added in a table. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 015 | 005 onwards | Women will not generally be aware of the methods listed. Women should be informed of methods used locally in terms of choice and not about methods that are not supported. | Thank you for your comment. We have amended this recommendation to state that it is for information only, and that these methods of induction do not all need to be discussed with women. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 016 | 012 | Repeated vaginal examinations, whether for doing sweeps or for assessing the Bishop score, can potentially lead to an increased risk of infection. The number of internal examinations should be kept to a minimum. | Thank you for your comment. It was not within the scope of this guideline update to consider the evidence for infections with intact membranes therefore we did not make an amendment to the recommendations to minimise the number of vaginal examinations. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Belfast Health & Social Care Trust Maternity Service | Guideline | 017 | 003 | Repeated vaginal examinations, whether for doing sweeps or for assessing the Bishop score, can potentially lead to an increased risk of infection. The number of internal examinations should be kept to a minimum. | Thank you for your comment. It was not within the scope of this guideline update to consider the evidence for infections with intact membranes therefore we did not make an amendment to the recommendations to minimise the number of vaginal examinations. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 024 | 001 - 005 | It is positive that consideration is being given for outpatient induction of labour and we feel this should be encouraged and supported where appropriate. Data from our outpatient IOL with cervical ripening balloon (Foley) will soon be published. | Thank you for your comment and support of this research recommendation. |
| Belfast Health & Social Care Trust Maternity Service | Guideline | 031 | 012 | <p>The deletion of recommendation 1.2.1.1 from the 2008 guideline is deeply concerning. Women with uncomplicated pregnancies should only be offered intervention (including IOL) if there is clear and compelling evidence to support this. The suggested change from the previous guideline version 'women with uncomplicated pregnancies should be given every opportunity to go into spontaneous labour' to 'women with uncomplicated pregnancies should be offered induction' is a complete change in emphasis, that implies that induction of labour is the preferred option, and that spontaneous onset is not.</p> <p>The recommendations in the current draft guideline are not supported by good evidence, and have the potential to cause increased harm. The evidence scope should have included attention to the long term outcomes, and to women's experiences, as well as the immediate intrapartum outcomes. The ARRIVE trial, which the draft guideline seems to rely upon heavily has been criticised by many experts in terms of study design and generalisability. There is clear evidence that long-term outcomes are poorer following induction of labour, and that this is avoidable, iatrogenic harm.</p> <p>The draft guideline suggests that CS is less likely following IOL. However the latest evidence (Dahlen, Thornton, Downe et al) and clinical experience suggests otherwise. InBHSCT, slow progress in labour with IOL is the second most common reason for emergency c section, following abnormal CTG</p> | <p>Thank you for your comment. We will address your points in turn.</p> <ol style="list-style-type: none"> 1. We have reinstated the recommendation that says 'Women with uncomplicated pregnancies should be given every opportunity to go into spontaneous labour'. 2. As you have noted, it was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. 3. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. 4. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>findings. The research by Dahlen et al included almost 475000 births and considered long term outcomes up until CA 16. Almost 15% of these women had IOL for non-medical reasons, and this will likely increase if the current recommendations are implemented. Primiparous women with IOL in this study were less likely to experience a straightforward birth, and more likely to experience c section, epidural, episiotomy, and post-partum haemorrhage. In terms of Obstetric anal sphincter injury, Dahlen et al found that this was less common in women with IOL. However, research by Rygh et al had previously found the opposite – that oxytocin augmentation was associated with a higher OR incidence of OASI.</p> <p>In addition the 'due date' is an estimate, which risks increasing prematurity, if IOL is based solely on EDC. Intervention in the normal physiological onset of labour in a healthy woman having a straightforward pregnancy, requires clear and compelling evidence to support this. The current draft guideline is not supported by such evidence.</p> <p>The RCM Blue Top Guideline on Induction of labour states there is evidence that women can feel pressured into accepting an induction and therefore detailed discussion is essential to support women to make the choices that are right for them. Some women do not understand the process of IOL and do not feel involved in the decision-making process. This can negatively impact on their experience.</p> | mode of birth will not lead to inappropriate interventions or the birth of preterm babies. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | General | General | <p>This draft update has not taken into consideration women's views of induction of labour and the long-term outcomes on women and their babies; it is only focussed on the birth. While induction of labour may be the right decision for some women, routine induction can cause harm, and a small absolute risk of stillbirth does not justify a routine policy of induction without medical indication for healthy uncomplicated pregnancies.</p> <p>Bringing forward the date for recommending induction to 41 weeks for low-risk women based on lacking and debatable</p> | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>evidence, undermines the physiological process of birth and the trust that women have in their bodies and their babies. Recent research (Rydahl et al 2020, Dahlen et al 2021) is showing that women are often being induced for non-medical reasons, but that this has no effect on decreasing stillbirth rates. However, it can lead to poorer outcomes for mothers and their babies, such as increased chance of additional interventions, increased incidence of neonatal birth trauma and need for resuscitation, and increased chance of admission into hospital for infections up to 16 years after birth. Labours that are induced and have increased interventions then affect the establishment of breastfeeding following birth.</p> <p>Research has shown that women who have had induction would not do it again if they had the choice, they felt that they had very little information on which to make a decision, and felt coerced into induction or that they had no choice. When presented with a recommendation of induction without balanced information or information about the risks that are relevant to her, women feel that they cannot disagree or go against what the healthcare professional is saying as they are the 'expert'. During the induction process, many women felt that they were out of control or that the control was taken away from them, and having control of their birth experience is vital for women having a positive birth experience. (Lou et al 2018; Adler et al 2020) This can lead to women feeling as if their birth experience was traumatic, which can affect postnatal mental health, bonding with their baby, and establishing the family unit following birth.</p> <p>In Northern Ireland, a recent survey by BirthWise found that 33% of women described their birth experience as traumatic. 54% of these women were induced, and 69% of the inductions ended in assisted deliveries or emergency caesarean section. Women commented that they felt very uninformed, unsupported, out of control, that they were</p> | <p>by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. The recommendations in the guideline also reflect that decisions, circumstances and preferences may change over the course of a pregnancy and that women should not be bound to a decision made at an earlier time, and that she may wish to change that decision if her circumstances change.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>rushed through the process and their body wasn't ready for labour, or that they would not choose to have induction again in a future pregnancy, statements that concur with the research mentioned above.</p> <p>The views of women and the long-term effects of induction need to be considered. At all points, we feel that it is important that women are given balanced evidence-based information so that they can make the decisions that are right for them and that their decisions should be respected and supported, not revisited regularly which feels very much like coercion.</p> | |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | General | General | The term 'risk' should be replaced with 'chance' throughout the document. | Thank you for your comment. The term risk is mainly used as a synonym for 'harm' in this guideline, as in the term 'risks and benefits', and is also used to imply the probability of a negative outcome, whereas chance could mean a negative or positive outcome. We have therefore not changed 'risk' to 'chance'. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | General | General | The term 'delivery' should be replaced with 'birth' throughout the document. | Thank you for your comment. We have made this change in the 2 recommendations that still used the word 'delivery'. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 004 | 006 – 007 | We feel that a statement should be included regarding respecting and supporting women's decisions about their birth. | Thank you for your comment. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline. We have also included that this decision must be recorded in the woman's notes. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 005 | 011 – 012 | The risks and benefits of induction of labour and the proposed methods should be discussed for everyone, not just in specific circumstances, and individualised discussions for each woman. | Thank you for your comment. The committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth with individual women. |
| Belfast Health and Social Care Trust – | Guideline | 005 | 016 – 025 | We believe that every woman should be given the time, information and chance to discuss their options before | Thank you for your comment. We have added a new section to this recommendation which states: 'Recognise |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Maternity Liaison Committee | | | | making their decision. However, women often do not know that it is their decision or feel under pressure to agree to induction while at an appointment without the chance to discuss with their partner. Women are also often told that their baby may die if they do not go for induction, language which is very emotive and coercive. The guideline needs to make this recommendation clear, and address the issue of coercion. | that some women will decide to proceed with induction and some women will choose not to have an induction. Support women whatever their decision, even if you disagree with it and do not allow your views to influence the care they are given.' |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 006 | 017 | Research around stillbirth and neonatal death is conflicting and debatable – research has been underpowered, not of good quality, and many of the trials lump all women in together so that the data is difficult to interpret. Trials, particularly ones such as the ARRIVE trial, should not be used as a basis for guidelines for a number of reasons: 73% of women declined to take part in the study so this cannot be considered a representative sample of the population, the type of care the women received was highly medicalised for low-risk pregnancies (which is not the usual mode of care in the UK) and most crucially there was no effect on stillbirth or neonatal death rates. Rydahl et al (2020) found that a change to earlier induction of labour had no effect on decreasing stillbirth rates, but did increase the number of women being induced, as well increase tearing and uterine rupture. All of this information needs to be shared with women, not just that there is an increased likelihood of stillbirth and neonatal death, so that they are able to make a fully informed decision. Women should also be informed of what the absolute risks of stillbirth are, not only informed that there is an increased risk or a doubling of risk, to inform their decisions. | Thank you for your comment. We will address your points in turn: 1. The methodological limitations of the ARRIVE trial were reflected in the evidence report and taken into consideration by the committee when interpreting the evidence. The committee considered the proportion of women who declined to participate to be within normal parameters and considered this could be due to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal. 2. The committee acknowledged that although all included studies were from high-income countries, these were conducted in a variety of settings (not just the United Kingdom) where healthcare is mainly accessible through private funding and where there are usually fewer midwives available to support women during birth, such as the US. However the committee agreed that the evidence was broadly applicable to the current UK context as it provided evidence from similar healthcare systems from high income countries. 3. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have now included tables with the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding of the evidence reviewed. The supporting |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | information explains how this data was derived, its limitations and how to interpret it. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 006 | 010 – 011 | <p>The current induction rate in the UK is approximately 32%, with the rates being close to 50% in some hospitals. Research recently published which has not been taken into account here (Dahlen et al 2021) has noted that 15% of low-risk women are having their labours induced for no medical reason, with no subsequent decrease in stillbirth rate. However, it does lead to higher rates of intervention (epidural, emergency caesarean, assisted births, episiotomy) and more adverse neonatal and child outcomes, such as increased incidence of neonatal birth trauma and need for resuscitation, and increased chance of admission into hospital for infections up to 16 years after birth. Labours that are induced and have increased interventions can also increase the incidence of birth trauma, which has a knock-on effect on physical and mental postnatal health, can affect the establishment of breastfeeding after birth and can affect bonding with baby.</p> <p>Due dates are inaccurate as pregnancy length can vary by a range of 38 days (Jukic et al 2013), and term is considered 37 – 42 weeks (this has even been pointed out in the above line that labour usually starts naturally by 42 weeks). Therefore, suggesting induction of labour at 41 weeks for these women is unnecessary, not supported by clear evidence and could potentially lead to increased adverse outcomes for woman and baby.</p> | <p>Thank you for your comment. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. Based on stakeholder feedback we have also amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. The study by Dahlen 2021 is an observational study that compared induction of labour with spontaneous onset of labour, so it is not eligible as it is not a RCT. Evidence report C includes full information on each primary study. For further details regarding inclusion and exclusion criteria of studies, please see the review protocol in appendix A of evidence report C.</p> |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 006 | 012 – 019 | <p>Provide balanced information here, including an explanation of the risks associated with induction of labour and the potential for a cascade of intervention and potential for a more challenging and traumatic birth.</p> | <p>Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------------------|-----------|---------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 006 | 020 – 025 | <p>There is no robust evidence to suggest that women of increased BMI, aged above 35 years, of black, Asian or ethnic minority, or assisted conception pregnancies should be induced at 39 weeks. We are concerned that the recommendation of induction at 39 weeks for women at a higher risk of complications is not evidence based and is being based on the 'knowledge and experience' of the panel. This suggestion will lead to a huge increase of women having inductions for no medical reason, but solely based on the fact that she falls into one of these categories. The recommendation should emphasise that a woman should be treated as an individual and her care should be individualised for her, not based on generalised population-level recommendations.</p> <p>In addition, there is already an existing disparity in maternal mortality of black and brown women in childbirth, due to underlying racial inequalities – this recommendation is discriminatory, does not address the underlying problem and continues to feed in to the disparities that are there.</p> <p>The wording 'consider induction of labour ...' is not appropriate, as this indicates that the decision is being made by the healthcare professional and not the woman as it should be. The wording should be 'consider offering induction...'</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 007 | 003 – 005 | In reality, women often feel pressurised or coerced into interventions. The wording in this section needs to be stronger to address this possibility, particularly in light of the Montgomery ruling. | Thank you for your comment. We have amended the wording to clarify that the decision is the woman's and this should be recorded in her notes. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 007 | 018 | If this recommendation is implemented this will lead to service pressures in terms of increased number of phone calls to Induction of Labour Team requesting Induction of Labour to be arranged. | Thank you for your comment. The committee agreed that it is important that women are advised to contact their maternity unit if they have concerns about their baby, or that some women may decide that, as they have still not gone into spontaneous labour, they wish to re-discuss their options for birth, and so this recommendation has not been changed. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 007 | 006 – 015 | There needs to be a balanced discussion, with the pros and cons of monitoring, and the pros and cons of induction presented in a neutral, balanced way. This recommendation, as currently drafted, is framed in such a way that women are likely to comply with induction and not opt for monitoring. This needs to be amended in light of the Montgomery ruling. | Thank you for your comment. This recommendation has been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 007 | 006 – 015 | The discussion needs to be balanced, and the pros and cons of both monitoring and induction need to be discussion in a balanced way. Women should additionally be encouraged to focus on how they physically feel as well as their baby's movements. We are concerned that this statement is written in a way that would mean that women decide on induction of labour (and not opt for monitoring) out of fear and not based on decisions that are right for them. And while it is true that monitoring gives a snapshot of the current situation, the inclusion of the statement that adverse effects on the baby cannot be predicted is scaremongering and should be taken out. | Thank you for your comment. This recommendation has been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. However, a later recommendation provides advice on ensuring women know to monitor their baby's movements. The committee agreed that it was very important to make women aware of the limitations of monitoring so we have not removed this part of the recommendation. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 007 | 016 – 017 | Once women have made their decision to decline induction, this decision should be respected and supported. By revisiting this at future appointments, we feel that this could be perceived as coercion and women may feel coerced or obliged to agree to induction of labour if regularly asked about it by health care professionals. There is potentially a power imbalance between healthcare professional and woman. A woman can contact her midwife/consultant if she changes her mind. | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 008 | 003 – 006 | Any decision to induce labour at 41+0 is made by the woman – it is not a 'shared decision'. The woman decides what happens to her and her baby. | Thank you for your comment. The NICE definition of shared decision-making is a collaborative process, making sure the person understands the risks and benefits through discussion and we think this applies to decisions about maternity choices, although the final decision is ultimately the woman's. We have reviewed the use of the terminology 'shared decision-making' throughout the guideline and have amended it in a number of places. However, there are some circumstances where there may be factors that relate to the decision that are within the remit of the healthcare professional too - such as their professional responsibility to act in the woman's best interests, and in this example to determine if suitable neonatal facilities are available. In this case we think the decision would therefore be shared, and so have not amended it in this recommendation. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 008 | 022 | This should be 'after 24h' instead of 'for up to 24h'. | Thank you for your comment. This recommendation relates to the period up to 24 hours after the membranes have broken. The course of action after 24 hours of expectant management is provided in the next recommendation. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 009 | 001 – 003 | The wording of this statement should be stronger to ensure that there is no attempt at coercion, whether indirectly or directly, in light of the Montgomery ruling. | Thank you for your comment. We have changed the wording of this recommendation to 'Respect the woman's decision....', in accordance with the language used in other parts of the guideline. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 009 | 021 – 024 | This is a positive recommendation; however, we are very concerned that including the statement that women are entitled to decline the offer of treatment even if it would benefit their baby's health is scare tactics and coercion, and including this does not support a woman's decision making. It should be worded more strongly to ensure that women are not persuaded or coerced in their decision making. | Thank you for your comment. We have amended the wording of this recommendation to say '...when it may benefit their or their baby's health.' to reflect the uncertainty. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 010 | 002 – 004 | If women request an induction, this is her decision to make and should be supported. | Thank you for your comment. This recommendation relates to women requesting an induction of labour and the responsibility of the healthcare professional is therefore to provide them with personalised information on the risks and benefits, which is what this recommendation states. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | Decision-making about induction of labour is covered in more detail at the beginning of the guideline in the section entitled 'information and decision-making' |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 010 | 020 – 029 | <p>While it is positive that this point does reference discussion of the benefits and risks of both induction and expectant management in women with suspected foetal macrosomia, we feel that this change in recommendation from the previous guidelines (that in the absence of any other indications, induction should not be recommended solely based on suspected large baby) is unnecessary. As is highlighted in this draft, there is lack of evidence around the risks associated with having a larger baby, indicating that induction cannot be recommended based on evidence. Late pregnancy scans are inaccurate, with a 15% error margin for predicting baby's weight, meaning that recommendation of induction based on baby's size could lead to more women being induced for no medical reason. There is the likelihood that once women are told they are potentially having a big baby and are offered induction, they are less likely to consider the lack of evidence and more likely to opt for induction as it is recommended by their healthcare professional and the fear associated with birthing a big baby.</p> <p>Ultimately, given that it has been listed that there is a lack of evidence, there is no clear reason for this recommendation and it should be removed.</p> | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 011 | 002 – 004 | This is further confirmation that there is no evidence to support the recommendation in 1.2.22. | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------------------|-----------|---------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 013 | 003 – 009 | <p>We welcome the inclusion of discussing the risks of sweeps – discomfort and bleeding – however, we would suggest that women are informed that there is a lack of evidence around the effectiveness of sweeps as well as the optimal timing and frequency of sweeps (Finucane et al 2020).</p> <p>Many women find having a sweep extremely uncomfortable, so we would recommend that it is included to discuss pain relief options available to them, i.e. Entonox and that a sweep is done in an environment where these options are available.</p> <p>We also feel that women should be informed that they have the option to accept or decline a sweep.</p> | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, the likelihood of success, optimal timing or frequency, or the need for pain relief. However, we have now expanded the recommendation on discussing it with women and obtaining their consent, and included pain in the topics to discuss with women. We have added additional recommendations to the section at the beginning of the guideline on information and decision-making on the right of women to decline or stop induction procedures, so we have not repeated this for every intervention. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 013 | 010 – 011 | It needs to be made absolutely clear that a membrane sweep must not be done during a vaginal examination, and should only be done if you have obtained the woman's informed consent. | Thank you for your comment. We have revised the recommendations to emphasise that membrane sweeping must be discussed with women and only carried out if they give their consent. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 013 | 014 – 015 | The length of pregnancy can vary from woman to woman, with full-term being considered 37 – 42 weeks. There is limited research regarding the timing and effectiveness of membrane sweeps, therefore, there is inadequate evidence to support this recommendation. We feel that 39 weeks is too early to offer women a sweep, as the majority of women's bodies are not ready for labour at this point and it is undermining the woman's trust and connection to her body and her baby. Women could potentially be opting for a sweep/sweeps that are invasive, uncomfortable, and unlikely to work. | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, or the optimal timing. However, the recommendations have now been clarified to state that membrane sweeps should be discussed after 39 weeks (as opposed to 'from 39 weeks') so sweeps will happen from week 40 onwards |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 013 | 016 – 017 | The wording of this should be changed to 'Additional membrane sweep can be offered if labour does not start spontaneously, and it is the woman's decision whether or not to accept this offer. | Thank you for your comment. We have now amended this recommendation to emphasise that additional membrane sweeping should only be considered after a discussion with the woman. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 014 | 014 – 028 | A Bishop score of 6 or less generally indicates that the cervix is unfavourable. Offering induction by whatever method if the cervix is unfavourable means that it is more likely to affect the birth outcomes, increasing the need for interventions or | Thank you for your comment. The evidence review carried out for methods of induction analysed the data by the sub-groups of women with a Bishop score of 6 or less and woman with a Bishop score greater than 6. The evidence |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | caesarean section for unsuccessful induction, which can have a knock-on effect on women's mental health if they feel that their birth experience was traumatic. | showed that the recommended methods of induction (dinoprostone, misoprostol and mechanical methods) were all effective at leading to vaginal birth within 24 hours, and did not increase the rate of caesarean birth or instrumental birth compared to placebo, in women with a Bishop score of 6 or less. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 016 | 012 | Repeated vaginal examinations, whether for doing sweeps or for assessing the Bishop score, can potentially lead to an increased risk of infection. The number of internal examinations should be kept to a minimum. | Thank you for your comment. It was not within the scope of this guideline update to consider the evidence for infections with intact membranes therefore we did not make an amendment to the recommendations to minimise the number of vaginal examinations. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 017 | 003 – 005 | Repeated vaginal examinations, whether for doing sweeps or for assessing the Bishop score, can potentially lead to an increased risk of infection. The number of internal examinations should be kept to a minimum. | Thank you for your comment. It was not within the scope of this guideline update to consider the evidence for infections with intact membranes therefore we did not make an amendment to the recommendations to minimise the number of vaginal examinations. |
| Belfast Health and Social Care Trust – Maternity Liaison Committee | Guideline | 031 | 012 | We are very concerned about the removal of recommendation 1.2.1.1 from the 2008 guideline. An offer of any intervention, including induction of labour, for women with uncomplicated pregnancies, should only be done when there is clear and robust evidence to support it. The recommendations in the current draft guideline are not supported by good evidence, particularly the ARRIVE trial which has been criticised by many experts regarding the study design and generalisability, and widening blanket induction recommendations such as these are likely to cause increased harm. The recommendations must take into consideration women's view and experiences of induction and the long-term health outcomes, both mentally and physically, for women and their babies. Recent evidence (Dahlen et al 2021) found that almost 15% of women having uncomplicated pregnancies had induction for non-medical reasons, and induction leads to an increase in additional interventions; primiparous women were less likely to have a straightforward birth and more likely to have a caesarean section, episiotomy and post-partum haemorrhage. Pregnancy is not an illness and being full term is not a | Thank you for your comment. We will address your points in turn. 1. Based on stakeholder feedback we have reinstated this recommendation into the guideline. 2. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. 3. It was not within the scope of this update to review the risks and benefits of induction of labour compared to expectant management but the committee have updated the section on information and decision-making to include the factors that should be considered by women when making a decision about mode of birth. 5. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the birth of preterm babies. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>disease or medical condition. This is clear and avoidable harm.</p> <p>Additionally, if labour is induced based solely on estimated due date (which is an estimate; pregnancy length varies from woman to woman), there is the risk of increasing prematurity for these babies and the long-term harmful effects that this would have for them. This recommendation should be reinstated, as the current draft guideline is not underpinned by compelling evidence to support induction at 41 weeks. We should not be interfering with the normal physiological onset of labour in women with uncomplicated pregnancies.</p> | |
| BigBirthis | Guideline | General | General | <p>Many women and birthing people report that the offer of induction is presented to them as a demand, and that they are unaware that they can decline this recommendation. Those who try to decline induction report being coerced into accepting it. Any guideline on induction should very clearly reiterate that women and birthing people must be given the option to decline induction, and give guidance to clinicians in how to make a clear recommendation without coercing the woman or birthing person. Simply saying that 'A woman's individual needs and preferences should always be taken into account.' is not sufficient.</p> | <p>Thank you for your comment. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline.</p> |
| BigBirthis | Guideline | 001 | 006 | <p>There is evidence that medical staff and guidelines referring to pregnant trans men and non-binary people as 'women' harms them (Greenfield and Darwin, 2021). Whilst it is probably intended to make the guideline inclusive, it has actually become a form of iatrogenic harm in itself. Also, as no data is captured that specifies the gender of the parent, it cannot be assumed that induction should be recommended at the same times and rates for pregnant non-binary people and trans men. The harm to mental health of a prolonged hospital stay is unknown. The difference that 'top surgery' makes to BMI is unknown. Whether testosterone usage has an effect on rates of uterine rupture is unknown. Without this medical evidence, how can the guideline be safely applied to this cohort?</p> | <p>Thank you for your comment. To ensure consistency between NICE guidelines the NICE editorial team have developed a more inclusive description and rationale for the use of the terminology relating to the intended population for maternity and obstetric guidelines, and this is included in the introductory information at the beginning of the guideline. Part of this rationale is, as you have stated, that the evidence for the recommendations is based on data from studies on women, and while the committee have extrapolated this evidence to other groups of pregnant people, you are correct that there was no evidence on which to base this assumption and further research is needed.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| BigBirthas | Guideline | 004 | 001 | This wording implies that if an induction is recommended, a woman or pregnant person does not have the right to decline it. It also sounds as though carers may consent to medical treatment against a pregnant woman or birthing person's wishes. | Thank you for your comment. We have removed this text referring to carers so it is consistent with standard NICE text at the beginning of other guidelines and makes it clear who should be involved in discussions and making informed decisions about care. |
| BigBirthas | Guideline | 005 | 001 | Add the risk of uterine rupture and damage to perinatal mental health here. Also add the findings from Dahlen et al. (2021) about the negative sequelae for woman/person and the baby: 'Primiparous women with IOL versus spontaneous onset differed significantly for: spontaneous vaginal birth (42.7% vs 62.3%), instrumental birth (28.0% vs 23.9%), intrapartum caesarean section (29.3% vs 13.8%), epidural (71.0% vs 41.3%), episiotomy (41.2% vs 30.5%) and postpartum haemorrhage (2.4% vs 1.5%)'. 'Following induction, incidences of neonatal birth trauma, resuscitation and respiratory disorders were higher, as were admissions to hospital for infections (ear, nose, throat, respiratory and sepsis) up to 16 years' (Dahlen et al., 2021). | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on these outcomes. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| BigBirthas | Guideline | 006 | 012 | Given Dahlen's evidence (Dahlen et al., 2021) that many of these risks are associated with induction, rather than prolonged pregnancy, this evidence needs to be reviewed again. Whilst the correlations are clear, it is unclear whether the intervention of the induction or the length of pregnancy is the causal factor. | Thank you for your comment. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. |
| BigBirthas | Guideline | 006 | 023 | BMI is a very rough tool. Women and birthing people may decline to be weighed, or scales may not be available. Weight is then either given as an estimate, or guessed by the midwife. From our Facebook group we know that women decline being weighed to avoid the pressure and coercion that already exists. If this guideline is implemented, we foresee more women declining to have their BMI/ | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>height/weight recorded as a preventative measure to avoid being coerced into an induction they do not want or need.</p> <p>A significant number (a majority?) of women with a BMI over 30 will have an uncomplicated birth, so why would we want to decrease their chance of an uncomplicated birth by recommending an increase in inductions amongst these women?</p> <p>We know that any medicalisation of birth which deviates from the natural process has the potential to develop into a 'spiral of intervention', potentially ultimately leading to an emergency caesarean section, extended hospital stays, potential for poor wound healing, poor rates of breastfeeding initiation and continuation, and many other adverse outcomes for the mother/baby dyad (Dahlen et al., 2021). To needlessly herd the significant percentage of higher BMI women who would otherwise have had uncomplicated labours and births into an unnecessary induction puts them at increased risk of these outcomes and would have significant implications on costs and staffing for the NHS in both the short and longer term.</p> <p>It is also worth noting the criticisms of BMI as a tool that does not take into account different norms within those of different ethnicities.</p> <p>If people are weighed, they are weighed at booking (by which point they could be nearly into the second trimester), which will mean their recorded BMI is inaccurate.</p> | |
| BigBirthas | Guideline | 006 | 024 | <p>The reason for the higher maternal mortality rate amongst Black and Asian women is structural racism. There is no biological difference that would account for these differences, and they still exist when socio-economic factors are taken into account.</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>Black women are already at a greater risk of birth trauma (Kendall-Tackett, 2014). Experiencing birth as a traumatic event has significant long term negative sequelae, including postnatal depression, postnatal anxiety, PTSD, secondary tokophobia, relationship breakdown and impaired bonds with infants (Greenfield, Jomeen and Glover, 2016). Induction is a risk factor for experiencing birth as a traumatic event (Greenfield, Jomeen and Glover, 2016).</p> <p>The mental health of mothers is not an add-on to obstetric care. Suicide is a leading cause of maternal mortality, and iatrogenic harm to mental health must be recognised.</p> <p>The solution to the higher rates of maternal mortality amongst Black and Asian women should be to change the structures that lead to their having worse outcomes. Recommending these women to have early inductions, risking further harm, rather than address the issues within the system which leads to this disparity is unacceptable, and yet more evidence of structural racism within maternity care.</p> | |
| BigBirthis | Guideline | 006 | 024 | 'Assisted conception' would include most lesbians, and bisexual women in a same-sex relationship. There is no evidence that using donor sperm and IUI increase any risks. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| BigBirthis | Guideline | 007 | 007 - 012 | Agree – monitoring gives only a snapshot of that moment in time. Therefore, why are we offering it? What purpose does it have? If carried out, monitoring at this stage should explicitly exclude estimates of the baby's size, due to the unreliability of said measurements. | Thank you for your comment. This recommendation has been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The recommendation does not imply a baby's size should be estimated so we do not think it is necessary to exclude this. |
| BigBirthis | Guideline | 007 | 006 | We do not have the resources to provide this. | Thank you for your comment. Other recommendations (for example 1.2.2 and 1.2.4) have been amended so it is |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-------------------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | unlikely that the cohort of women being offered and declining induction will change significantly. This recommendation has also been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The options to do CTG and amniotic pool depth are only provided as suggestions, carried over from the previous version of the guideline, and have been in place since 2008, so it is unlikely these recommendations will have an impact on resources. |
| BigBirthas | Guideline | 007 | 013 | We do not have the resources to provide this. | Thank you for your comment. Other recommendations (for example 1.2.2 and 1.2.4) have been amended so it is unlikely that the cohort of women being offered and declining induction will change significantly. This recommendation has also been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The options to do CTG and amniotic pool depth are only provided as suggestions, carried over from the previous version of the guideline, and have been in place since 2008, so it is unlikely these recommendations will have an impact on resources. |
| BigBirthas | Guidelines | 007 | 016 | This will result in women and birthing people experiencing coercion. | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again. |
| BigBirthas | Evidence review D | 008 | 006 | The only study that examined maternal satisfaction was a study where 16,427 women declined to participate (Grobman et al., 2018). The volume of women who declined participation perhaps gives an indication that the majority of people do not want to be induced early? This needs factoring into the recommendation of when to offer induction. | Thank you for your comment. The committee acknowledged the paucity of evidence for the outcome maternal satisfaction in this review, and they agreed that women's choice is key for providing optimal care in maternity services. Based on stakeholder feedback, the recommendations have been amended to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. The committee considered the proportion of women who declined to participate in the trial within normal parameters and noted that this may have been related to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal. |
| BigBirthas | Guideline | 008 | 006 | This displays a misunderstanding, or could lead to a misinterpretation about what 'shared decision making' means. | Thank you for your comment. The NICE definition of shared decision-making is a collaborative process, making sure the person understands the risks and benefits through discussion and we think this applies to decisions about maternity choices, although the final decision is ultimately the woman's. We have reviewed the use of the terminology 'shared decision-making' throughout the guideline and have amended it in a number of places. However, there are some circumstances where there may be factors that relate to the decision that are within the remit of the healthcare professional too - such as their professional responsibility to act in the woman's best interests, and in this example to determine if suitable neonatal facilities are available. In this case we think the decision would therefore be shared, and so have not amended it in this recommendation. |
| BigBirthas | Guideline | 008 | 022 | This implies that women must have an induction within 24 hours. If a woman declines an induction, will expectant management no longer be offered? Why would care be withdrawn if she declines induction? | Thank you for your comment. The course of action after 24 hours of expectant management is provided in the next recommendation, and at this point induction will be offered. As with all healthcare decisions it is the woman's choice whether or not to take up that offer. There is no suggestion that care will be withdrawn. |
| BigBirthas | Guideline | 013 | 004 | Add that a membrane sweep increases the chances of infection | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, including the risk of infection. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|-----------------------------------|---------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| BigBirthas | Evidence review D | 017 | 033 | As no evidence was available it feels that this has been ignored. Induction increases the risks of an instrumental birth, and 3 rd and 4 th degree tears. Iatrogenic perineal trauma is an issue for women and birthing people that can be life changing. It should not be dismissed in this way. While stillbirth & neonatal death are catastrophic (and rare) outcomes, a more widespread increase in harm to the birthing person that can also be significant and life-changing should not be treated as an acceptable consequence. | Thank you for your comment. We are unclear to which section of the guideline your comment makes reference to, but we think it may be relevant for the section on suspected fetal macrosomia. The recommendations have been reworded to clarify that options for birth are expectant management, induction of labour or caesarean birth. In addition we have included more information on the risk of shoulder dystocia and 3 rd and 4 th degree tears to aid understanding. |
| BigBirthas | Prevention of prolonged pregnancy | 019 | 011 | “The committee 9 also noted a possible increase in the need for assisted vaginal birth....this difference was not deemed clinically important.” It is very dismissive of women's wishes and experiences to declare assisted vaginal birth 'not important'. Maternal satisfaction and comfort IS important and should carry more weight in what we recommend with regards to when to offer induction. Instrumental births are often what people wish to avoid, with many birth plans stating that women would rather have a caesarean birth than an instrumental birth to avoid higher risks of 3 rd and 4 th degree tears etc. | Thank you for your comment. The committee agreed that the outcome assisted vaginal birth is relevant for decision making and hence included it as part of the important outcomes in the review. As part of NICE guideline development we use minimally important differences (MIDs) for: 1) defining boundaries for imprecision ratings when applying GRADE to intervention review evidence and 2) defining boundaries for importance ratings for evidence statements/discussions with committees. 'Clinically important' in this context refers to the fact that the intervention did not have an important effect on the outcome (assisted vaginal birth, in this case), not that the committee did not think that the outcome was important for decision-making. We have now included in a table the estimated risks associated with different induction timing strategies to aid understanding. The supporting information explains how this data was derived and how to interpret it. |
| BigBirthas | Guideline | 024 | Whole page | The evidence cited does suggest that there are increased risks of adverse outcomes for these groups, but it does not suggest that induction will reduce these risks. That leap appears to have been made by Committee members based on professional experience. Whilst valuable, professional experience is no substitute for evidence in the making of NICE Guidelines. | Thank you for your comment. The recommendations for women who may be at higher risk of stillbirth have been amended and revised substantially, and so we have updated this rationale section to reflect these changes to the recommendations. |
| Birth Practice and Politics Forum | Guideline | | General | We are concerned that this guideline focuses only on management of labour by induction, it fails to address women's views, their experiences of induction, or the long | Thank you for your comment. The scope for this update of the guideline did not include a review relating to women's experiences of induction of labour, nor the risks and |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>term implications for both women and babies. We consider this to be a serious omission.</p> <p>Furthermore, intermittent auscultation has been shown to be as effective as cardiotocography and that CTGs increase the caesarean rates. In light of the evidence to support intermittent auscultation why is this option not offered; and why are women not advised of the risks of continuous CTG?</p> | <p>benefits of induction of labour compared to expectant management. The committee have amended the information and decision-making recommendations at the start of the guideline and we will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.</p> <p>The recommendations on monitoring state that continuous cardiotocography is only required at the start of induction and after that intermittent auscultation can be used, unless there are concerns.</p> |
| Birth Practice and Politics Forum | Guideline | | General | <p>There is no discussion of the risks of membrane sweeping. At the very least, women should be informed that this is an intervention, it can provoke spontaneous rupture of membrane, or that it increases the risk of an infection, interferes with the normal progression of a normal, physiological labour, and often leading to other interventions..</p> | <p>Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps.</p> |
| Birth Practice and Politics Forum | Guideline | | General | <p>The recommendation to interfere with uncomplicated pregnancies is deeply worrying. The principle of "first do no harm" appears to have been forgotten.</p> <p>If women do not have any existing medical conditions why are they being induced? Induction of labour is a medical intervention and has no place in a home setting where hyper-stimulation of the uterus requires immediate medical intervention which will not be available at home.</p> <p>Furthermore, the justification for outpatient induction appears to be that women can labour at home and this is presented as an attractive option for them.</p> | <p>Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's. The recommendations on outpatient induction have been amended to clarify that this is also something that must be discussed with a woman and her decision respected.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Birth Practice and Politics Forum | Guideline | | General | The offer of outpatient induction is of considerable concern, not least because of the failure to carry out a randomised controlled trial before implementing this intervention. The risk of induction of labour has not changed over the past few years, but what has changed is the productivity and throughput in overly busy, under-staffed, labour wards where there are not enough beds or midwives to support women in labour. The solution is to encourage more fit and healthy women to birth at home without the risk of outpatient induction. | Thank you for your comment. The section of the guideline was not included in the scope of this update, but was amended by the committee based on their knowledge and experience, but we agree that randomised controlled trials in this area would be useful. The committee were aware that many units in urban areas already offer outpatient induction and it is preferred by some women, who can begin their induction process in their own home. We have amended the recommendation to clarify that outpatient induction should be discussed with the woman and it should be her choice. Furthermore, the details of the reasons for a women to contact her midwife or maternity unit have been expanded, to reduce the risk of complications. |
| Birth Practice and Politics Forum | Guideline | 004 | General | Amend <i>"carers have the right to be involved in planning and making decisions"</i> This suggests that the carers have a right to make decisions. Suggest amending it to: "carers have the right to be involved in planning and assisting the woman to make her decision." | Thank you for your comment. We have removed this text referring to carers so it is consistent with standard NICE text at the beginning of other guidelines and makes it clear who should be involved in discussions and making informed decisions about care. |
| Birth Practice and Politics Forum | Guideline | 004 | 008 | <i>Explain to women that induction of labour is a medical intervention that might affect their birth options and their experience of the birth process.</i> This is a vague statement that fails to spell out the reality of induction of labour - the higher intervention rates and more adverse maternal, neonatal and child outcomes. See: Dahlen HG, Thornton C, Downe S et al (2020). Intrapartum interventions and outcomes for women and children following induction of labour at term in uncomplicated pregnancies: a 16-year population-based linked data study, <i>BMJ Open</i> , Vol 11, Issue 6. https://bmiopen.bmj.com/content/11/6/e047040 | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update and so we are unable to provide more detailed data as you suggest. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Birth Practice and Politics Forum | Guideline | 005 | 003 | Add <i>"induction of labour is more painful than a physiological labour"</i> . There is a paucity of research examining how painful induction of labour can be. From our discussions with women who have had both induced and normal, | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>physiological, births they consistently express how very painful induction of labour is.</p> <p>Adler et al (2020) showed that, "The women who underwent labor induction were less satisfied with their birth experience compared to women with spontaneous onset of labor." (</p> <p>Adler K, Rahkonen and Knuit H (2020). Maternal childbirth experience in induced and spontaneous labour measured in a visual analog scale and the factors influencing it, a two-year cohort study, BMC Pregnancy and Childbirth, 20, No 415, 21 July 2020. https://doi.org/10.1186/s12884-020-03106-4</p> <p>A French population based cohort study commented that:</p> <p><i>Determinants of maternal dissatisfaction common to both groups were unbearable vaginal discomfort, inadequate pain relief, lack of attention to requests, caesarean delivery and severe maternal complications.</i> Dupont et al (2020).</p> <p>Dupont C, Blanc-Petitjean P, Cortet M et al (2020). Dissatisfaction of women with induction of labour according to parity: Results of a population-based cohort study. Midwifery 84: 102663.</p> | <p>data on pain or women's experiences. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date.</p> |
| Birth Practice and Politics Forum | Guideline | 006 | General | <p>We consider that the term "risk" should not be used as it gives an impression of certainty instead of being explicit about the actual overall risk and how high or low it is. Having been told that they have a high risk or double the risk many women are shocked when they learn how low the actual overall risk is. Instead of using the term "risk" it should be replaced by "chance"</p> <p>Furthermore, there is no acknowledgment that the length of pregnancy can vary by 37 days (from 37 to 42 weeks) and women should be aware of this fact when approached to agree to a routine induction at 41 weeks.</p> | <p>Thank you for your comment. The term risk is mainly used as a synonym for 'harm' in this guideline, as in the term 'risks and benefits', and is also used to imply the probability of a negative outcome, whereas chance could mean a negative or positive outcome. We have therefore not changed 'risk' to 'chance'. We have, however, amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. The committee agreed that dating scans are</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>Jukic AM, Baird DD, Weinberg CR et al (2013). Length of human pregnancy and contributors to its natural variation. Human Reproduction 2013 Aug 6. [Epub ahead of print]</p> <p>Brenda van der Kooy (1994: 5) noted that, "as elsewhere in nature, normality has a range".</p> <p>van der Kooy B (1994) Calculating Expected Date of Delivery – its accuracy and relevance. Midwifery Matters, 60: 4-7,24.</p> | usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will be based on an accurate estimation of the baby's due date. |
| Birth Practice and Politics Forum | Guideline | 006 | 010 | <p><i>In uncomplicated singleton pregnancies, offer induction of labour at 41+0 weeks, to take place then or as soon as possible afterwards.</i></p> <p>There is no robust evidence to support this recommendation. Furthermore, it is accepted wisdom that a normal pregnancy duration goes from 37 completed weeks to 42 weeks, No account is taken of those who have a naturally occurring longer gestation. (Kay King Women Making Waves Podcast 25 Jan 2021)</p> <p><i>A small absolute increase in risk on its own, without any other medical risks or complications during pregnancy, does not justify a policy of routinely offering induction of labor without strong evidence of the benefits of that policy."</i> Seijmonsbergen-Schermers et al (2019)</p> <p>Seijmonsbergen-Schermers AE, Scherjon S and de Jonge A (2019). Induction of labour should be offered to all women at term AGAINST: Induction of labour should not be offered to all women at term first: do no harm, BJOG Am International Journal of Obstetrics and Gynaecology.</p> <p>Suggest that a table showing the chances of an unexplained stillbirth from 36 weeks to 44 weeks should be included here</p> | Thank you for your comment. Based on stakeholder feedback, we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the birth of preterm babies. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>so that women understand the reasons for routine induction at this time. See Cotzias 1999.</p> <p>Cotzias CS, Paterson-Brown S and Fisk N (1999). Prospective risk of unexplained stillbirth in singleton pregnancies at term population: based analysis, British Medical Journal, Vol 319, p287-8.</p> <p>Furthermore, Rydahl et al's (2019) study looking at the results of induction of labour when it was changed from 42 weeks to 41+3 weeks found increased interventions and an increase in uterine ruptures. The rate of which went from 2.6 per thousand to 4.2 per thousand. Women should be told this.</p> <p>Rydahl E, Declercq E, Juhl M et al (2019). Routine induction in late-term pregnancies: follow-up of a Danish induction of labour paradigm. BMJ Open 9:12. https://bmjopen.bmj.com/content/9/12/e032815</p> <p>A German study found that most women who experienced induction of labour would try to avoid it in a future pregnancy, and many would like to have information on alternative and complementary methods of induction of labour. (Schwarz 2016).</p> <p>Schwarz C, Gross MM, Heusser P et al (2016). Women's perceptions of induction of labour outcomes: Results of an online-survey in Germany. Midwifery. DOI: http://dx.doi.org/10.1016/j.midw.2016.02.002</p> <p>An American prospective cohort study found that self-identified black women were more likely to be unsatisfied than white women (54.0% vs. 37.2%, p=0.037)" women</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>having their first baby were more likely to be unsatisfied compared to women who had already had one or more babies (54.2% vs. 40.9%, p=0.019), and women whose labour resulted in a cesarean delivery were more likely to be unsatisfied than women with a vaginal delivery (67.4 vs. 42.3%, p<0.001). Additionally, increased labour length quartile was associated with decreased satisfaction (p=0.003). This trend held true even for women that had a vaginal delivery." (Hamm et al 2018).</p> <p>Hamm R, Srinivas S, Levine LD (2018). 1032: Can we identify risk factors for decreased birth satisfaction among women undergoing induction of labor? American Journal of Obstetrics and Gynecology 220(1): S662-S663</p> | |
| Birth Practice and Politics Forum | Guideline | 007 | 016 | <p><i>Offer women who decline induction of labour an opportunity to revisit their options with a healthcare professional at least once a week.</i></p> <p>Many women perceive this advice as bullying because they have already made an informed decision.</p> <p>However, If the circumstances have changed i.e. there are clinical signs of possible concern suggest instead: "if there are indications that the health of the woman or her baby has changed and is of concern during this period offer an option for discussion with an appropriate professional."</p> <p>There is no mention of the avoidable harm caused by induction of labour and we recommend that it should be included.</p> | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again. |
| Birth Practice and Politics Forum | Guideline | 009 | 004 | <p><i>If a woman has pre-labour rupture of membranes at term (at or over 37+0 4 weeks) and has had a positive group B streptococcus test at any time in their current pregnancy, offer immediate induction of labour or caesarean birth. [2021]</i></p> <p>Add the following: "Women who decline this advice should be offered a wait and see approach and advised to self-monitor, check their temperature, liquor, fetal movements and ensure close liaison with their midwife."</p> | Thank you for your comment. This recommendation was taken from the NICE guideline on neonatal infection (NG195) and so, to ensure consistency between guidelines, it has not been possible to add in the additional information you suggest. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Birth Practice and Politics Forum | Guideline | 010 | 023 | <p>Add: Inform the woman of the accuracy, or lack of, estimating baby's size by ultrasound. See also research by Ashrafganjooe (20110) which showed that women expecting second or subsequent babies were more accurate at estimating baby's weight.</p> <p>It appears that those women who know the date of conception cannot amend the record because the date in the ultrasound scan is impossible to change, it results in continual arguments throughout the pregnancy. Seijmonsbergen-Schermers AE, Peters LL, Goodarzi B et al (2020). Which level of risk justifies routine induction of labor for healthy women? Science Direct, Sexual and Reproductive Healthcare, Vol 23, 100479.</p> | <p>Thank you for your comment. The review did not look at the accuracy of estimating a baby's due date or size using ultrasound so we are unable to add details about this. Furthermore, the evidence was based on randomised controlled trials in which any inaccuracy would have occurred in both arms of the study and so the committee agreed that the relative risks would still be valid.</p> <p>Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence.</p> |
| Birth Practice and Politics Forum | Guideline | 012 | 013 | <p>Add: in the event of an intrauterine death without evidence of infection discuss the option of awaiting spontaneous labour, not all women are keen to have induction of labour.</p> | <p>Thank you for your comment. Expectant management of IUFD is already covered in recommendations above for all cases of IUFD.</p> |
| Birth Practice and Politics Forum | Guideline | 013 | 010 | <p>There is no discussion of the risks of membrane sweeping. At the very least, women should be informed that this is an intervention, that increases the risk of an infection, can provoke spontaneous rupture of membrane, interferes with the normal progression of a normal, physiological labour, and often leads to other interventions..</p> <p><i>Routine use of sweeping of membranes from 38 weeks of pregnancy onwards does not seem to produce clinically important benefits. When used as a means for induction of labour, the reduction in the use of more formal methods of induction needs to be balanced against women's discomfort and other adverse effects'</i> (Boulvain et al 2005: 2). Boulvain M, Stan CM, Irion O. Membrane sweeping for induction of labour. Cochrane Database of Systematic Reviews 2005, Issue 1. Art. No.: CD000451. DOI:</p> | <p>Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|-----------|---------|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Birth Practice and Politics Forum | Guideline | 016 | 016 | Ensure facilities are available for cardiotocography wherever induction of labour is started. [2008, amended 2021] Intermittent auscultation has been shown to be as effective as cardiotocography and that CTGs increase the caesarean rates. In light of the evidence to support intermittent auscultation why is this option not offered; and why are women not advised of the risks of continuous CTG? | Thank you for your comment. Cardiotocography must be available where induction is carried out, but this recommendation does not state that it must be used continuously. The following recommendations on monitoring include more detailed information on when cardiotocography should be used, and when intermittent auscultation can be used. |
| Birth Practice and Politics Forum | Guideline | 017 | 018 | <i>Consider outpatient induction of labour with vaginal dinoprostone preparations or mechanical methods in women without existing medical conditions or obstetric complications. [2008, amended 2021]</i> If women do not have any existing medical conditions why are they being induced? Induction of labour is a medical intervention and has no place in a home setting where hyper-stimulation of the uterus requires immediate medical intervention which will not be available at home. Furthermore, the justification for this development appears to be that women can labour at home and this is presented as an attractive option for women. The risk of induction of labour has not changed over the past few years, but what has changed is the productivity and throughput in overly busy, under-staffed labour wards where there are not enough beds or midwives to support women in labour. | Thank you for your comment. The existing medical conditions referred to comorbid conditions (for example, high blood pressure, diabetes) so we have clarified this in the recommendation. The committee were aware that many units in urban areas already offer outpatient induction and it is preferred by some women, who can begin their induction process in their own home. We have amended the recommendation to clarify that outpatient induction should be discussed with the woman and it should be her choice. Furthermore, the details of the reasons for a women to contact her midwife or maternity unit have been expanded, to reduce the risk of complications. |
| Birth Practice and Politics Forum | Guideline | 031 | Table 1 1.2.1.1 | <i>1.2.1.1 Women with uncomplicated pregnancies should be given every opportunity to go into spontaneous labour.</i> We are concerned that this recommendation has been dropped on the grounds that the following advice makes it unnecessary. We disagree, the following advice encourages routine intervention on dubious grounds and this advice should be reinstated. | Thank you for your comment. Based on stakeholder feedback we have reinstated this recommendation into the guideline. |
| Birth Practice and Politics Forum | Guideline | 032 | Table 1 1.2.10.1 | <i>In the absence of any other indications, induction of labour should not be carried out simply because a healthcare professional suspects a baby is large for gestational age (macrosomic).</i> We are concerned that this recommendation has been deleted, and particularly because the justification for the new | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | advice acknowledges the lack of evidence to support the change See comments page 16 paras 1.2.2 and 1.2.7. | offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. |
| Birth Trauma Association | Guideline | General | | Overall, there are some excellent new recommendations so the Birth Trauma Association welcomes this update. Induction of Labour is frequently associated with long painful labours that can leave women traumatised and fearful of future childbirth. Equally, prolonged labour – 'doing nothing' – can, albeit rarely, result in one of the most traumatic experiences of all; the birth of a still born baby that was, a few weeks earlier, a live and healthy foetus. We are a long, long way from having undertaken all the necessary research to see what can be done to improve this difficult situation but generally this update has taken a step forward. | Thank you for your comment and for your support for this update. |
| Birth Trauma Association | Guideline | 006 | 003 | 1.2.1 Excellent – real progress. Women should be offered information and choice on all three options – induction, expectant and ELCS. There are 'agendas' in the maternity services and the guidance needs to ensure that the information that health care professionals are giving to women is up to date and evidence based bearing in mind the Montgomery v Lanarkshire judgement. This could be clarified in the recommendations by a reference. One regret is that many women (with hindsight) say that they would have accepted one method of induction but not multiple methods. To subject a woman with a very low bishop score to multiple attempts at induction is barbaric and harmful. It would have been helpful to include information on likely success of induction for the individual woman at each stage. | Thank you for your comment and support of this guideline. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline. We have also included that this decision must be recorded in the woman's notes. The evidence for all the methods of induction recommended for women with a Bishop score of 6 or less showed that they led to successful vaginal birth in 24 hours so we have not included details of their relative success. |
| Birth Trauma Association | Guideline | 006 | 020 | 1.2.4 Very clear on when induction should be offered but not clear on what should happen if ELCS is requested or if a woman gets to 42 weeks. Ultimately the baby is going to die if labour does not commence. So clarification on these two points in terms of information to women would be helpful. | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations for earlier induction for certain groups of women and instead included information on increased risks from a national audit (MBRRACE). |
| Birth Trauma Association | Guideline | 006 | 020 | 1.2.4 Induced labour is often painful and distressing. Imposing a more traumatic experience of childbirth on a group of women already suffering higher rates of adverse | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | outcomes seems counterintuitive. Whilst we would support all women's requests for induction at 39 weeks to be respected, we believe that singling out black, Asian or minority ethnic women to be specifically considered for early induction is wrong. This is likely to lead to increased offers of induction to a group that will have a higher proportion of individuals whose first language is not English. Obtaining full, informed consent can be difficult in these circumstances; women can feel directed rather than offered choice. At worst, this could lead to minority groups being pushed towards induction just to smooth NHS workloads during busy periods. There is no clear evidence that additional induction leads to better outcomes for ethnic minority women nor is there a full understanding of why prolonged labour presents an increased risk. Until there is, a better approach would be to offer enhanced care to those who experience prolonged labour. | with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Birth Trauma Association | Guideline | 007 | 003 | 1.2.5 on Better and more honest information | Thank you for your comment. We understand this to mean that you support this recommendation. |
| Birth Trauma Association | Guideline | 010 | 002 | 1.2.18 Good to see women's requests for induction now being heard. There is an intention and reality gap in practice that perhaps is not reflected in the wording; 'taking women's preferences into account' does not mean 'listen but dismiss'. | Thank you for your comment. There may be women who have no medical indication for induction but who wish to request this, and this recommendation provides advice for healthcare professionals in this scenario. |
| Birth Trauma Association | Guideline | 013 | 003 | 1.3.1 Most women find membrane sweeping more than uncomfortable. Honesty please in the language – 'uncomfortable or painful' | Thank you for your comment. We have added 'pain' to this recommendation. |
| Birth Trauma Association | Guideline | 013 | 016 | 1.3.5 Do not agree with this recommendation. If first induction fails there needs to be a discussion of the option of an ELCS or further induction attempts particularly if the bishops score is low. The word 'barbaric' treatment is used by women subjected to endless induction attempts followed by lengthy painful labour, finishing with a baby in NICU and the mother haemorrhaging. Why do we do this? It is unconscionable and women say they did not give consent. | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, the likelihood of success, optimal timing or frequency. However, we have amended this recommendation to emphasise that additional membrane sweeping should only be considered after a discussion with the woman. |
| Birth Trauma Association | Guideline | 015 | 005 | 1.4.1 Why on earth would a woman in labour be interested in a long list of drugs that don't work? They may have other | Thank you for your comment. We have amended this recommendation to state that it is for information only, and |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------|----------------------------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | things on their mind© By all means respond if they ask, but otherwise stick to useful information. | that these methods of induction do not all need to be discussed with women. |
| Birth Trauma Association | Guideline | 017 | 018 | '1.6.1 Consider outpatient induction of labour with vaginal dinoprostone preparations or mechanical methods in women without existing medical conditions or obstetric complications.' This recommendation needs the words 'if acceptable or suitable for the woman or her circumstances'. It is not suitable for women with no support to be sent home on the bus or tube afterwards (it does happen!). 'Safety and Support' in the next section seems to have been interpreted as support at home. The journey home can be the issue. | Thank you for your comment. We have amended the recommendation to make it clear that it is the woman's decision whether or not to have outpatient induction, and that decision should be supported. |
| Birth Trauma Association | Guideline | 018 | 015 | 1.7.2 Again, are we talking about an unsuccessful first attempt or unsuccessful third or fourth attempt? It isn't clear. After each attempt, the woman should be provided with information and asked whether she wants further attempts at induction. This is not happening and there is a real failure of consent – again particularly with the low bishop score women. Unsuccessful needs defining as 'a failed attempt and the mother declining further offers of attempts'. | Thank you for your comment. Unsuccessful induction is defined in the 'terms used in this guideline' and the definition is hyperlinked from this section of the guideline. It is defined as labour not starting after one cycle of treatment. We have amended the recommendations to clarify that any further attempt or attempts at induction should be discussed with the woman, and the plan for her care agreed with her from that point onwards. |
| Birthrights | Equality Impact Assessment | General | General | The equality impact assessment has not recognised the impact of particular groups of women, namely women over 35, women with a high BMI and black and brown women of being singled out for different treatment on the back of evidence that these groups have worse outcomes in general but with no evidence that induction may improve these outcomes. Evidence submitted to our inquiry on racial injustice suggests that black and brown women already feel they are treated as if their bodies are "different" and more "defective". The impact of this recommendation on the relationship between these groups and maternity services should be explicitly considered in the impact assessment, noting that if the guideline is followed a disproportionate percentage of these women will undergo an induction, potentially resulting in a worse birth experience in general (notwithstanding the fact that some women have a positive experience of induction). | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. We have therefore amended section 4 of the EIA form to represent the changes to the recommendations. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Birthrights | General | General | General | <p>We have grave concerns about the recommendations of this guideline. It adopts a clinical and short term lens, and downplays evidence about women and birthing people's experience of induction, and evidence about long term impacts. Expectant management is a very valid option at 41 weeks given the evidence that most women will go into spontaneous labour and that there is a very low absolute risk of an adverse outcome in most cases. And yet the option of clinical intervention has been prioritised. Decisions where the risks and benefits are not clear cut should be taken by the individual given birth after appropriate counselling by healthcare professionals in line with the Montgomery v Lanarkshire judgement. With this draft guideline, NICE is overstepping its remit and presumes to make the decision about what is right for the average individual in this situation which cannot be justified by the strength of the evidence. Our experience of women and birthing people contacting our advice line is that the quality of the conversation around induction is already extremely poor. If this recommendation proceeds it is highly likely that even more women will feel that they have no choice whether to be induced despite the positive guidance in the draft guideline on what needs to be discussed in order for a woman to make an informed choice. We are particularly concerned about the recommendation to offer induction earlier to black and brown women as well as women over 35 years of age or with a high BMI differently, despite the lack of evidence that this will improve outcomes for these groups. In addition, the guideline fails to take into account whether the recommendations are realistic to implement in practice (ie whether Trusts are able to induce this number of women), and if not, what the consequent impact on women will be. We are aware that it is extremely worrying for women to be told they need to be induced or their baby will die and then have to wait 3 days before the service is able to facilitate this.</p> | <p>Thank you for your comment. The committee used the evidence available, some of which may be based on short-term outcomes, but also took into account women's experience of induction. We will address your specific points in turn.</p> <ol style="list-style-type: none"> 1. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. 2. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. 3. We have also added an additional recommendation to emphasise that it is the woman's choice whether or not to have an induction and that her decision should be respected. 4. We have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report. 5. Due to the changes to the recommendations outlined above, we do not think there will be an impact on Trusts which means they will be unable to care for the number of women being induced appropriately. |
| Birthrights | Guideline | General | General | <p>We have reviewed a complaint report from a Trust where a woman complained that as well as being given a sweep</p> | <p>Thank you for your comment. We have added an additional recommendation to the information and</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | without consent, she also asked for her IV drip to be turned down as she was finding the contractions too much to cope with. The midwife instead turned it up. The Trust argued that the woman had consented to the induction and that the midwife did the right thing by turning the drip up. This guideline needs to make clear that a woman can withdraw her consent to the procedure at any point, at which point a discussion about the risks and the benefit should take place but ultimately her decision must be respected. | decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have also clarified in this section that women can decide at a later stage that they no longer wish to proceed with the induction process, and the section of the guideline on membrane-sweeping already emphasises that consent must be sought. |
| Birthrights | Guideline | General | General | <p>I, and so many others are outraged by the proposed change in guidelines for induction of labour and urge you to reconsider.</p> <p>Particularly recommending induction to BAME women and birthing people at 39 weeks.</p> <p>We know that there are disproportionate disparities in maternal mortality rates for black and brown women and birthing people. We know this is not because black and brown bodies are less able to birth, but that it is the result of systemic racism.</p> <p>The draft guidance is not supported by research and fails to take into account the negative effects of pathologising pregnant people, the risks of induction and intervention and the very real fact that this can increase trauma, fear and injury.</p> <p>These guidelines would cause harm. They have already caused immense harm and hurt, by suggesting this is the way we address these mortality rates in Black and Brown bodies rather than looking at the systemic racism at the heart of our maternity system.</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Birthrights | Guideline | General | | In my opinion, it's an inaccurate guidance, not proven by evidence and would mean (IF it goes ahead) that non-white birthing people could all be put on a pathway to induction after 39 weeks. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>I know as a birthworker since 1997, guidelines are not policy, yet it is easy /convenient to get into the habit of treating guidelines as policy.</p> <p>Birth trauma holds long term implications both physically and mentally and can affect mental health and even relationships between parent and child/ partner for long term.</p> <p>A pathway to induction also removes choice- no more homebirth option, no more birth centre option, no more option for physiological birth.</p> <p>That's a big take, a huge removal of choice, and without evidence to support it, this makes no sense.</p> <p>The very indication for this harmful guideline suggests that black and brown bodied people's bodies don't work and are at risk of harm just for the colour of their skin. This fosters a culture of blame and racism.</p> <p>Racism is a risk factor, not black and brown folks' skin.</p> <p>As a white birthworker unlearning my own racism and leaning into the discomfort of anti racism work, I see first hand the nuances of racial disparities in maternity care, both globally and in the UK.</p> <p>I work with displaced people and families. I see how their choices are limited, often because they are not treated as full humans, not offered choices, not fully seen or heard.</p> <p>A lack of fluency in English, a lack of confidence and autonomy can lead to easy coercion, even if it's not intentional.</p> | <p>report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>I sincerely hope this guideline does not come to pass and that any future guidelines specifically about ethnicity or a specified people group, will have black and brown bodied experts leading in the developments of these policies and guidelines.</p> <p>There are proven, successful models of care such as Jennie Joseph's "The JJ way" and other models of care designed by, and for black women and birthing people. If we get it right for those experiencing the worst outcomes week get it right for everybody.</p> | |
| Birthrights | Guideline | General | | <p>I feel strongly this is not the right course of action to tackle health inequalities.</p> <p>Interestingly, I took this to a few South Asian groups on Facebook to find out other people's views. Over 90% of people are actually in favour of these guidelines. People feel like NICE are doing the right thing and they welcome induction.</p> <p>Some people I heard from had poor experiences in later pregnancy (beyond 40 weeks) and believe that IOL earlier would be a welcome solution. Some people believe the experts know best. Many people hold beliefs that our genes make us higher risk of complications so we need to be induced. I don't know where these beliefs have come from.</p> <p>The issue is - NICE are a respected organisation and people will believe what they say. I don't believe any of these people have a full informed understanding of the risks involved with IOL. People are happy something is being done - and they think it's the right thing but that is down to lack of knowledge around IOL. NICE are taking advantage of this and exploiting people. There is not any strong evidence backing this proposal.</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>I can't understand how the colour of my skin makes me more likely to need a medical intervention during my pregnancy.</p> <p>Also, I know it says 'offer' but we know how much coercion there is in maternity services. An offer doesn't really mean offer - especially if people are already led to believe this is for their own good. So many people will agree to IOL at 39 weeks because they believe it's right (because the experts suggest it is).</p> <p>I think NICE need to re-think this and also consider their position and authoritative status. IOL is not the solution here - and in uncomplicated pregnancies it could cause more harm than good.</p> | |
| Birthrights | Guideline | General | General | <p>This guidance in no way deals with the problems, concerns and risks to women, birthing people and babies. It ignores the systemic racism at play, and the other issues, and just creates more but encouraging induction of labour early. I am saddened to see this and was hoping for more. This guidance should absolutely not be like this, the evidence has not been taken into account and black and brown bodies are being blamed for the outcomes that are actually a result of systemic racism.</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |
| Birthrights | Guideline | General | General | <p>I'm an Antenatal Teacher and Breastfeeding Counsellor and see so many of my clients being induced unnecessarily, usually without any conversation around alternatives, let alone risks and benefits. I sincerely hope the feedback gets listened to and becomes based on the evidence available, not because some people in Westminster think our bodies are broken.</p> | <p>Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | an induction is a woman's choice and that choice should be respected. |
| Birthrights | Guideline | General | | I am very opposed to this guideline. You are placing all birth women within very different categories into the same pathway of suggested intervention when all of their needs will be very different. I am absolutely shocked and disgusted at the implicit racism involved in this draft guideline. There is nothing wrong with black and brown birthing bodies, it is the system that is racist and needs some serious consultation and overhaul in terms of how black and brown birthing bodies are treated. You are pathologising black and brown birthing bodies and suggesting there is something wrong with them by having this guideline. This guideline would then allow midwives and health care professionals to assert induction at 39 weeks for no medical reason and with no evidence (someone's skin colour is NOT a reason). THIS IS RACISM! And you can write in the guidelines as much as you like that this would only be a suggestion and the personal circumstances would also be taken into account but we all know that as soon as this guideline is in place it will become standard practice. The bottom line is that there is NO evidence for such a guidance when it comes to black and brown birthing bodies. I also disagree at this guidance being for birthing people over the age of 35 years old. Where is the evidence???? | Thank you for your comment. The recommendations were made by the committee to try and reduce inequalities in stillbirth rates. However, based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Birthrights | Guideline | General | General | NICE do not seem to take into consideration the need for a positive birth experience. Let's not forget the peculiar oversight that induction is likely to cause a cascade of intervention leading to unnecessary intervention, interference in the human microbiome seeding, life long trauma and very clear racism. As an experienced birth worker specialising in physiological birth, I cannot help but wonder who on earth would make such an awful judgement within NICE. Have they any education on physiological birth at all? To conclude our bodies are broken and birth should be a medicalised process at first thought is insipid. | Thank you for your comment. The committee took into consideration the woman's experience when developing the recommendations. However, we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>NICE are clearly demonstrating the need for an entirely new maternity system. This system works perfectly for THE SYSTEM. The women birthing in it however, are in for a scary ride should guidelines like this continue.</p> <p>Once women are educated in birth physiology, we will begin to see a plethora of court cases for unnecessary intervention resulting in emotional and physical trauma.</p> | <p>include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected.</p> |
| Birthrights | Guideline | General | General | <p>I am a Private Midwife who also works within the NHS. I would like to express my concern regarding the new Induction of labour proposed guidelines.</p> <p>I have worked within Maternity care for 16 years and have seen an increase in intervention without seeing significant improvements in outcomes or women's experiences. More frequently I am witnessing fragmented, complicated care, that is often poor quality, non compassionate and women are birthing feeling increasingly traumatised.</p> <p>I am so disappointed that NICE have taken this course of action, at a time when more than ever women are expressing they want care with a known midwife and more continuity of care, declining unwanted inductions which undermine their ability to birth and their body.</p> <p>In some instances induction of labour is appropriate when there is medical need. However, to apply a guideline which captures such a broad range of birthing people based on demographics and not medical need, will be subjecting them to a cascade of intervention which have long lasting effects physically and emotionally for mother; and impacts which are now becoming more apparent in babies.</p> <p>A true commitment to improving maternity care and outcomes for the included groups of birthing people would include; investment in midwifery training and work place culture to make continuity models of care the norm, tackle systemic racism, investment in antenatal education which is</p> | <p>Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. Based on stakeholder feedback we have also replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>currently very basic if provided at all and projects which directly address inequality, increasing engagement with harder to reach groups. This is the tip of the iceberg, but would be a positive start and NICE are in a key position to influence these changes.</p> <p>As a woman who has birthed 3 children, a midwife and mother of daughters, changes in women's health care that are moving in this direction is very worrying and I urge your team to reconsider the proposal, re-evaluate the evidence and listen to what women want.</p> <p>Many midwives are bewildered by the proposal and I am seeing more midwives than ever looking for a change in career due to the current climate we work in. This proposal is making many birthing people high risk and the added interventions that this will incorporate, is not only harmful to the patients, but the midwives and midwifery profession as a whole.</p> <p>A live mother and baby is not the benchmark of good care- we need to do better!</p> | |
| Birthrights | Guideline | General | General | Also, it would be much appreciated if more inclusive language could have been used, as there is not much difference in saying "women" and "birthing people". | Thank you for your comment. To ensure consistency between NICE guidelines the NICE editorial team have developed a more inclusive description and rationale for the use of the terminology relating to the intended population for maternity and obstetric guidelines, guidelines, and this is included in the introductory information at the beginning of the guideline. |
| Birthrights | Guideline | General | General | These guidelines will reduce women's autonomy and choice in birth and increase risk associated with this intervention. Whilst I recognise the value in interventions at maternal choice or medical indicators, to induce all women after 40 weeks goes against all researched evidence for optimal outcomes and is not considered to impact on stillbirth rates. | Thank you for your comment. The recommendations all offer women a choice and emphasise that decisions should be made by the woman. The recommendations stated that induction should be offered from 41 weeks, not 40 as you state in your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|-----------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>Women who are induced are highly likely to have long labours as they are not given the opportunity to allow their bodies to go through the fluid physiological stages leading up to labour. IOL is associated with haemorrhage, fetal distress and EMLUSCS. Birth trauma is associated with lack of autonomy in decisions around birth and operative deliveries. As most women who have their first baby go post dates, this will reduce choice of birth place and increase the likelihood of emergency c section, rates of which already exceed WHO recommendations and have long-term negative outcomes for babies, and impact breastfeeding rates. This will then ultimately affect choice for subsequent births and homebirths which are evidenced as safer for second babies.</p> <p>With regards to BAME, iol will not address the obstetric racism which is a factor in poor outcomes for this group and the draft guidelines state more research is needed. To my knowledge, there is very little to no research in this group and to place a blanket guideline of this nature is very concerning. Continuity of carer and midwifery care has been previously evidenced to provide better outcomes as carried out by midwifery groups such as the Albany midwives.</p> | <p>later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected.</p> <p>We have also replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report.</p> |
| Birthrights | Guideline | 006 - 007 | 020 - 025 | <p>I think the recommendations that black and brown pregnancies be induced at 39 weeks to combat high maternal morbidity and mortality rates is an overall TERRIBLE idea! As with most responses to systemic racism, it fails to look at the cause and instead puts the onus onto the women themselves. This is not our problem to solve and we should not pay for it with the maternity system pathologising our healthy, uncomplicated black pregnancies.</p> <p><i>[Personal information]</i> Induction is not the answer. They often lead to a cascade of unnecessary interventions, which are more often than not, poorly explained and maternal choice is rarely respected.</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|-----------|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | I urge you to put the onus back onto the system, to educate maternal health workers and make them aware of their potential/actual racism and biases. Provide more information and support for black and brown mothers to uplift and inform them to make the right choices that are best for their specific pregnancy. Please speak to black and brown maternity workers, especially doulas, for guidance. Don't take the easy route as it will be devastating for our community. | |
| Birthrights | Guideline | 004 - 005 | 003 onwards | We really welcome the clear guidance here on the factors to be discussed. Women tell us that they are not told this information consistently and while many women are happy with information they receive at the time, they look back on their induction, and regret they were not told about some of the factors listed here. In addition we know that women/birthing people (I will use women throughout the response, as the draft guideline does, to denote all individuals who give birth however they identify) are often not told how long the process can take and alternatively that it can happen quickly and be very intense. In addition women need to be given evidence based statistics about the likelihood of their baby dying or any other adverse outcome with and without induction. Our experience is that women are simply told that their baby may die or is at increased risk of dying without having any context about the absolute or relative put around that. Finally women need to be told about the current evidence about long term outcomes . Please add these three factors to the list of things to be discussed. (It is worth noting that the Patient Information Forum are currently conducting a survey about the information women receive around induction). | Thank you for your comment. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. Based on stakeholder feedback we have also amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| Birthrights | Guideline | 006 - 007 | 020 - 002 | This is a very concerning recommendation. Women in these categories already feel judged by maternity services and made to feel that their bodies are defective in some way. We are not aware of any evidence that induction improves outcomes for these groups and none has been cited by the guideline committee. Given the evidence we have received in response to our racial injustice inquiry about how | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | particular ethnic groups are stereotyped and “othered” we are very concerned about the impact this could have on the trust black and brown women have in maternity services. Through the inquiry we have also heard numerous examples of black and brown women not being offered any choice at all, having their choices denied or consent overridden, and being ignored or dismissed when they raised questions or concerns about care. We realise the NICE committee is constrained in its terms of reference to look at induction only but the needs of black and brown women, and other groups who have worse outcomes need to be addressed holistically. | |
| Birthrights | Guideline | 005 | 022 | We wholeheartedly support the guidance to “support the woman in whatever decision she makes”, but the guideline as a whole does not show an understanding of the power dynamics of these conversations, about the current culture of “expected compliance” in maternity services(Nicholls et al, EJOG, May 2019) and the evidence about the quality of conversations around induction (see for example Roberts, J. and Walsh, D. (2019) “‘Babies come when they are ready’: Women’s experiences of resisting the medicalisation of prolonged pregnancy’, <i>Feminism & Psychology</i> , 29(1), pp. 40–57. doi: 10.1177/0959353518799386 .) This phrase remains unchanged from the current guideline and yet the evidence suggests that many women do not feel like they have a choice, let alone supported in their choice. Therefore we are pessimistic about the likelihood of women being supported in their choices in reality and NICE need to recognise the part that their guideline will play in contributing to their culture if it does not recognise that induction at 41 weeks is a complex choice that the individual should opine on. | Thank you for your comment. We have added a new section to this recommendation which states: recognise that women can decide to proceed with, delay, decline or halt an induction. Respect a woman’s decision, even if you disagree with it, and do not allow your views to influence the care they are given |
| Birthrights | Guideline | 006 | 014 - 019 | These must be put in context by providing evidence based statistics about the absolute risk of these outcomes with or without induction. This is a minimum requirement for women to make an informed decision. | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| Birthrights | Guideline | 006 | 020 - 025 | <p>They have not taken into account the impact induction may have in the long term in terms of the baby's health and the birthing person's and are also assuming/implying induction is the safest way for labour to begin. There are many studies that dispute this.</p> <p>The fact that NICE have picked 39 weeks as their cut-off point for pregnancy is, in my opinion, a human rights issue. People should be considered full term at 42 weeks but some even go beyond this.</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Birthrights | Guideline | 006 | 020 - 025 | <p>As a coloured woman I am appalled by this proposed change in guideline. The issues affecting coloured women that influence maternal mortality need an overhaul. But bringing forward an unnecessary induction is really not the way forward as that's not really addressing the actual issues.</p> <p>Induction should always be considered on a patient by patient basis and when that particular birthing parent has a higher risk of complications. When a coloured person has an otherwise normal low risk singleton pregnancy, induction only adds risks of a C-section, traumatic birth, necessity of epidurals and related issues with respect to tears/episiotomy/forceps/venture etc. And in a lot of cases an induction before the body is ready to birth ends up in a C Section which should never be taken lightly.</p> <p>This is not even taking into account the negative effects these interventions have on breastfeeding which I witnessed first hand both as a parent who had to be induced and in my role as a breastfeeding mother supporter.</p> <p>I would instead encourage NICE to look into the actual issues affecting women of colour during pregnancy and child birth rather than putting a band aid on the situation.</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Birthrights | Guideline | 006 | 020 - 025 | <p>Strides have been made in starting to recognise the contributing factors that apply to the higher mortality rates for</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>certain ethnic groups in the UK and we are at the beginning of recognising some of the societal and systemic (ie: iatrogenic) factors that influence these mortality figures. It feels like NICE is not recognising the significant contributing factors of racism and systemic/societal issues that are impacting women of colour having babies in the UK. If we are just starting to recognise the potential influence of systemic racism on these figures then how are we already in a position to make guideline recommendations on the care of these women? Should we not be listening and learning at present before we make any recommendations? And if one of the main issues is one of unconscious bias then how does streamlining all brown women sooner into hospital admission help in any way?</p> <p>My recommendation is that NICE remove this suggestion from the guidance and await actual evidence in order to inform their recommendations for brown women in the UK.</p> <p>As much as we operate on the basis that all women provide informed consent for their maternity care, the reality is that, dependent on the setting and the HCP the woman is dealing with, there is often a level of coercion involved in women's decision making during pregnancy - and brown women already report that often they feel they are not taken seriously or are not well listened to.</p> | <p>induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |
| Birthrights | Guideline | 006 | 020 - 025 | <p>I would like it to be noted that I feel that to suggest that induction is a solution to racial disparity in maternity care in the UK is unacceptable.</p> <p>I would urge you to reconsider. This guideline on the basis that first do no harm is being over ridden, the removal of autonomy, the racist undertones. There needs to be more done that doesn't simply shift the blame. Black and Brown bodies are not to blame for our systems failings of them. And I truly believe that a highly medicalised pathway is not the answer here.</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Birthrights | Guideline | 006 | 020 - 025 | <p>Like so many, I am extremely concerned about the proposed changes to the NICE induction guidelines and I feel that, if implemented, we will be taking a huge step back in birthing peoples rights.</p> <p>Many of the changes proposed are without evidence to justify why they are being suggested. While there is clear evidence that inductions lead to further unnecessary interventions which can leave the birthing person with life long traumas.</p> <p>My biggest concern of all is regarding the introduction of inductions for ALL black and brown birthing people regardless of whether their risk is deemed low or high risk. Inducing purely based on skin colour is rotten to the core with racism and there is no place for this, in modern society. If maternal mortality rates are higher for a certain group of birthing people, please for goodness sake investigate this. Spend the time, effort and money it deserves to find the answers and set things right. Don't put a bandaid on it in the form of early inductions.</p> <p>I look forward to hearing positive news that the draft proposal has been withdrawn.</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |
| Birthrights | Guideline | 006 | 020 - 025 | <p>- Melanin is NOT a reason to induce. This does not address the inequalities present within our maternity system that mean that black and brown women are at increased risk in Pregnancy, birth and post birth. This is a clear example of medical racism. This DOES NOT address the dire situation these women face, it DOES NOT address the systemic racism and inequalities, and the implications for the emotional, mental and physical harm these recommendations can cause is highly dangerous.</p> <p>- Concerning that the 2008 recommendation – which stated “Women with uncomplicated pregnancies should be given every opportunity to go into spontaneous labour” is now deemed unnecessary.</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | There is no robust evidence or justification given for inducing older, larger women or after assisted conception – when NO trials or evidence suggests that it is beneficial to induce those who have conceived via IFA or other ARTS. | |
| Birthrights | Guideline | 006 | 020 - 025 | I am myself from BAME community and seeing the fact that NICE is planning to offer induction of labour at 39 weeks compared to 'normal' induction would put myself and this community at more risk. I am not a registered midwife yet, but I am aware of the risks associated with IOL and I also believe that the majority of healthcare differences aren't caused by someone's skin colour or ethnicity- but by constitutional racism that has been going on for many years. That is one of the cause behind the fact that black mother are 5x more likely to die from childbirth and also the fact that health care professionals are taught to provide care to people with white skin. This further causes problems as many things can be misdiagnosed or not even diagnosed- leading to more physical and mental health problems. Furthermore, by offering induction at 39 weeks, the strain will not only cause more health complications to the individual themselves, but it will cause more stress on the already burdened and stretched nhs- as they will need to expand their induction units, which will mean that there will be higher rates of interventions, leading to more assisted births, Caesarean sections and intrapartum or postnatal complications. This could also lead to birth trauma and possible ptsd- leading to mental health problems that will require support from specialist mental health team. All of this can be prevented by treating all birthing people in a equal way, and seeing each pregnancy as an individual case rather than categorising according to skin colour. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Birthrights | Guideline | 006 | 020 - 025 | I was extremely disappointed to hear that your response to the higher numbers of maternal deaths for black and brown people than white people is to penalise black and brown bodies. Our bodies are already over-medicalised and now your guidelines are designed to encourage health | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>professionals to further ignore our voices and force unnecessary procedures on our bodies.</p> <p><i>(Personal information)</i></p> <p>This [recommendation to induce black and brown women at 39 weeks] is insulting and blames us for the NHS's systematic racism. Listen to our voices; do not create guidelines that inflict medicine on us without our consent. This is not good enough.</p> <p>I have worked with Mars Lord, Nicola Goodall and Amy Dignam to design some Play the Race card to challenge health care progression beliefs about the families that they are serving. If you are looking for a way to address the maternal death numbers, please get in touch with us.</p> | report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Birthrights | Guideline | 006 | 010 - 011 | <p>Although other organisations are best placed to comment on the clinical evidence, we do not support this recommendation. Evidence from our advice line suggests that women will experience this as coercive, and that they will feel under pressure to go into labour before 41 weeks, which we know increases anxiety. It is paternalistic and patronising to conclude that although women experience induction as more painful, that it might increase their risk of an operative birth with the potential long term sequelae of that, and that induction means that many women cannot give birth in an environment where they feel safe, this should all be disregarded on the basis of a small absolute and small relative increase in the risk of adverse outcomes for the baby. Of course women should have the option of induction at 41 weeks if that is their informed choice, but on the current evidence expectant management is an equally valid choice. Clinicians should discuss all reasonable options without bias and the decision should be the individual woman's only.</p> | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. |
| Birthrights | Guideline | 006 | 020 | <p>Opening discussion at 38 weeks with this statement - Explain to women that labour usually starts naturally by 42+0</p> | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | weeks – ignores evidence that due dates are INACCURATE and pregnancy length varies. Policy Makers ignore this, in relation to scan dates, even when a woman states that these suggested dates of conception are not possible. Again not women centred, not listening to women's views. | pregnancy to make the focus a discussion of the risks and benefits with the woman so she can make an informed decision. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the birth of preterm babies. |
| Birthrights | Guideline | 007 | 016 - 017 | Whilst this is phrased as an "offer" and an "opportunity" the lived experience of many women contacting our advice line is that this feels like harassment or coercion. We know of cases where threats of social services are made when induction is declined. Whilst it should be clear that this offer is open to women at all times, women should be asked about how often they want to revisit this discussion and their decision should be respected. | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again. |
| Birthrights | Guideline | 010 | 014 | Please remove the word "possible". This tentative language is not used in other recommendations about risk. | Thank you for your comment. We have removed the word 'possible'. |
| Birthrights | Guideline | 013 | 010 - 011 | Strongly welcome the explicit guidance to obtain consent for membrane sweeping as we are aware of a number of cases where explicit consent has not been obtained. | Thank you for your comment. The committee highlighted that lack of consent may be a problem with membrane-sweeping and so added this recommendation. |
| Birthrights | Guideline | 013 | 016 - 017 | This should read "Consider offering". | Thank you for your comment. Offer is the standard NICE terminology used when there is good evidence to support a recommendation. The word 'offer' is also used as it is recognised that decisions are made with or by women, and so it highlights that the offer of treatment or intervention can be accepted or declined. |
| Birthrights | Guideline | 016 | 012 | There should be an acknowledgement here that assessing the Bishop score involves a vaginal examination for which consent needs to be obtained. You may wish to give guidance on whether it is safe to continue with an induction without this examination. | Thank you for your comment. The committee agreed that it would not be possible to safely carry out an induction of labour without doing a vaginal examination. The committee agreed that many of the procedures within the guideline would require consent, this was part of professional practice, and therefore it was not necessary to specify that consent should be obtained in individual recommendations. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Birthrights | Guideline | 024 | 022 - 029 | <p>As a doula and Antenatal educator I work hard to make sure the evidence and information I provide to my clients is evidence based and unbiased.</p> <p>The MBRRACE report revealed the true extent of the risk that black and brown birthing people face when giving birth with rates of adverse outcomes and mortality being significantly higher than for those who are white. The reason for the increased likelihood of morbidity and mortality can only be attributed to systemic racism in care services.</p> <p>In an effort to address this the new draft guidelines for induction suggest that all black and brown birthing people be offered induction at 39 weeks. However, by treating people differently according to the colour of their skin, we would only be confirming - and fuelling that racism.</p> <p>This will not end racism and inequality of care in the NHS - it will exacerbate it. It will reduce access to midwifery led units, home birth, and access to continuity of carer, all known to improve outcomes in many circumstances. It does not address the root cause systemic issues that increase risk it glosses over them. Rather than dealing with the racism that leads to the disparity instead the responsibility is placed on the women rather than the maternity system.</p> <p>We should also be concerned about the impact of long-term outcomes which are poorer after induction of labour. Both the drugs and mechanical methods used in induction and the interventions that may result can have unwanted and potentially harmful consequences. These may be justified where induction will benefit an individual. But when induction is a routine recommendation and information on long-term outcomes is not being offered or considered, we are denying women and families the right to make informed decisions.</p> | <p>Thank you for your comment. We agree that information provided to women should be evidence-based and unbiased. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion of the risks of later versus earlier induction with the woman (and we have included tabulated details of absolute risks), so she can make an informed decision. We have also replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report. It was not within the scope of this update to review the risks and benefits of induction of labour compared to expectant management but the committee have updated the section on information and decision-making to include the factors that should be considered by women when making a decision about mode of birth. We have therefore updated this rationale section to reflect these changes to the recommendations.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>This recommendation is based not on evidence and research but NICE panel members are basing some sweeping statements about these groups of women being at high risk purely on their "knowledge and experience." No evidence is given to justify offering induction of labour to these women at 39 weeks.</p> <p>NICE has rules as to what constitutes robust evidence but it is sometimes difficult to see how these rules are being applied in this particular draft guideline.</p> | |
| Birthrights | Guideline | 024 | 022 - 029 | <p>This is very concerning. Not only is this systemically racist but it's putting a whole group of women into one category. It ignores the fact that every human being is different, that every circumstance is different and takes away the basic women's and human rights of these groups of women. The colour of one's Skin does not automatically mean they're Going to struggle to give birth past 39 weeks. Even being over 35 or overweight doesn't mean this whole group would struggle. By saying they recommend early induction to this whole group they're ignoring the cause of the problem and going straight to trying to solve a problem. By doing this you actually create more risk because there are high risks with induction of needing further intervention. Intervention, which likely wouldn't Be needed if they weren't induced. By offering this to all black and mixed race ethnic groups we will see a huge rise in inductions and then C-sections (seeing as 80% of inductions end in C-sections) because women will often go with what the professional body is recommending because they are scared and uninformed. Instead you need to look at why these groups are struggling to give birth and inform every woman of the best ways to prevent intervention.</p> | <p>Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion of the risks of later versus earlier induction with the woman (and we have included tabulated details of absolute risks), so she can make an informed decision. We have also replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report. It was not within the scope of this update to review the risks and benefits of induction of labour compared to expectant management but the committee have updated the section on information and decision-making to include the factors that should be considered by women when making a decision about mode of birth. We have therefore updated this rationale section to reflect these changes to the recommendations.</p> |
| Birthrights | Guideline | 024 | 022 - 029 | <p>As above. There needs to be a review into why this draft guidelines were put in place and who was making this decision? Was this a room of white people by any chance? I repeat there is no evidence that black and brown birthing bodies have any adverse outcomes for natural term length pregnancies because of the colour of their skin. This is</p> | <p>Thank you for your comment. We have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report. We have therefore updated this rationale section to reflect these changes to the recommendations.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | happening to them because of the systemic racism within the NHS and the way they are treated by the Health Care Professionals they encounter | |
| Birthrights | Guideline | 024 | 022 - 029 | <p>This is blatant racism. It is abhorrent to imply that black and brown bodies are a risk factor in pregnancy/birth.</p> <p>They have not based this on any evidence as stated in the proposal but instead have used their own personal opinions/experiences. This is not good enough for the number of birthing people who will potentially have totally unnecessary medicalised/traumatic births.</p> | Thank you for your comment. We have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report. We have therefore updated this rationale section to reflect these changes to the recommendations. |
| Birthrights | Guideline | 024 | 022 - 029 | <p>I am writing to you as I'm outraged at the new N.I.C.E Guidelines regarding criteria for blanket induction for women who are black, brown, over 35 or over a BMI of 30. After reading the documents it seems the real issue is the lack of evidence that has been gathered to make these guidelines which is really alarming.</p> <p><i>(Personal information)</i> I was treated very badly, spoken to in a derogatory manner, I had several panic attacks in my 5 day ordeal in hospital and experienced a forced scenario where I asked a senior midwife who was breaking my waters to stop as it hurt and she continued to do so and told me to stop crying. And so as I am now <i>(personal information)</i> pregnant today I have refused induction at all costs <i>(personal information)</i> as the pain was awful, contractions every 2 mins for 3.5 days and only to be told I had failed to progress. Unsurprisingly given the awful adrenaline fueled environment. I didn't feel safe, I felt attacked, scared and worried.</p> <p>However I have to add I am a white female, and I know the statistics of how black and brown women are 5 times more likely to die in childbirth and asian women twice as likely in comparison to white women which is an alarming statistic https://www.aims.org.uk/journal/item/mbrance-bame</p> | Thank you for your comment. We have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report. We have therefore updated this rationale section to reflect these changes to the recommendations. We have received a great deal of stakeholder feedback during consultation this guideline - over 3000 comments, of which 1500 were from individuals - and the committee has considered all of these when revising the guideline, so we are confident that the views of service users have been taken into consideration. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>I think these guidelines wash over the deeper issues that are at play here, and as a result may put further women at harm due to the nature of this sticky plaster (induction). I instead recommend that N.I.C.E do some deeper analysis and put in practices that could combat some of these issues. Look at the core institutionalised racism towards black, brown and asian folk and understand why this is happening and put things in place to combat this so all women have an equal shot at a respected and dignified birth and are not forced to go down an induction route - which will lead to more interventions and more harm.</p> <p>I would also recommend that some research is done to actually speak to the community of women involved and find out what could have helped them with medical guidance. This needs to be done in partnership to create change as I fear there will be more women coming away with horrific stories to tell or perhaps not even living to tell that story which would be an atrocity.</p> | |
| Birthrights | Guideline | 024 | 012 - 015 | I am concerned that these guidelines are coming from the committee and not from mother's or professionals who have worked with pregnant women. This risks misunderstanding the view and choices of a pregnant woman or doesn't take into consideration real experience of induced labour and especially induced labour so early on and without actual complications. | Thank you for your comment. This section of the rationale relates to the general recommendations the committee made about discussing induction with women. The committee includes lay members and professional members (for example, midwives, obstetricians, an obstetric anaesthetist and a GP) all of whom work with pregnant women. It is a requirement of membership of a NICE committee to have relevant expertise of the topic under consideration. Details of the committee membership can be found on the NICE website. The recommendations have been updated based on stakeholder feedback, so they have taken further service user experience into consideration. |
| Birthwise | Guideline | General | General | This draft update ignores women's views of induction of labour and the long-term outcomes on women and their babies; focussing on the birth alone. Induction of labour may be the right decision for some women, routine induction can and does cause harm, and the absolute risk of stillbirth is not | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>clearly explained to women when being encouraged into induction. The small absolute does not justify a routine policy of induction without medical indication for healthy uncomplicated pregnancies.</p> <p>Routine induction at 41 weeks for low-risk women is based on lacking and debatable evidence, it undermines the physiological process of birth and the trust that women have in their bodies and their babies. Recent research (Rydahl et al 2020, Dahlen et al 2021) is showing that women are often being induced for non-medical reasons, but that this has no effect on decreasing stillbirth rates. However, it can lead to poorer outcomes for mothers and their babies, such as increased chance of additional interventions, increased incidence of neonatal birth trauma and need for resuscitation, and increased chance of admission into hospital for infections up to 16 years after birth. Labours that are induced and have increased interventions then affect the establishment of breastfeeding following birth.</p> <p>Research has shown that women who have had induction would not do it again if they had the choice, they felt that they had very little information on which to make a decision, and felt coerced into induction or that they had no choice. When presented with a recommendation of induction without balanced information or information about the risks that are relevant to her, women feel that they cannot disagree or go against what the healthcare professional is saying as they are the 'expert'. During the induction process, many women felt that they were out of control or that the control was taken away from them, and having control of their birth experience is vital for women having a positive birth experience. (Lou et al 2018; Adler et al 2020) This can lead to women feeling as if their birth experience was traumatic, which can affect postnatal mental health, bonding with their baby, and establishing the family unit following birth.</p> | <p>limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>In Northern Ireland, our BirthWise survey found that 33% of women described their birth experience as traumatic. 54% of these women were induced, and 69% of the inductions ended in assisted deliveries or emergency caesarean section. Women commented that they felt very uninformed, unsupported, out of control, that they were rushed through the process and their body wasn't ready for labour, or that they would not choose to have induction again in a future pregnancy, statements that concur with the research mentioned above.</p> <p>The views of women and the long-term effects of induction need to be considered. At all points, we feel that it is important that women are given balanced evidence-based information so that they can make the decisions that are right for them and that their decisions should be respected and supported, not revisited regularly which feels very much like coercion. Induction needs to be the exception, a decision made in exceptional circumstances and women being encouraged to trust in the ability of their bodies to grow and birth their babies at the time that is right for them. Medics see and feel the impact of stillbirth in the very small number of cases where this occurs. They do not see the longer term impact that induction (and often unnecessary induction) is having on up to 12,000 women per year in Northern Ireland alone.</p> | |
| Birthwise | Guideline | 004 | 006 | We feel that a statement should be included regarding respecting and supporting women's decisions about their birth. Including highlighting that women can choose to decline any intervention, and recording discussions in women's notes so that they are not repeated unnecessarily. | Thank you for your comment. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline. We have also included that this decision must be recorded in the woman's notes. |
| Birthwise | Guideline | 004 | 008 | Discuss with women that induction can increase the risk of shoulder dystocia. | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | update, therefore we are not able to confirm that induction of labour increases the risk of shoulder dystocia. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Birthwise | Guideline | 005 | 016 - 025 | Women are not presented with induction being a choice. They are first told that their baby is at risk of dying and then they are offered induction. They are not told the risks of induction of labour. Women frequently report being told their baby might die if they do not agree to the induction. It would be helpful if the guideline addressed the issue of direct or indirect coercion, particularly in light of CG138 and the Montgomery ruling. Coercion based on guidelines is not acceptable, the risks relevant to each woman need to be discussed and based in evidence. | Thank you for your comment. We have added a new recommendation to this section to address this issue which states: 'Recognise that some women will decide to proceed with induction and some women will choose not to have an induction. Support women whatever their decision, even if you disagree with it and do not allow your views to influence the care they are given.' |
| Birthwise | Guideline | 005 | 012 - 019 | Clearly identify the risk level for low risk women of each of these occurring in a pregnancy beyond 41 weeks and compare to the risk level of each item during induction of labour. In reality most of these risks are higher with induction of labour and this needs to be clearly indicated. | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on these outcomes. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Birthwise | Guideline | 005 | 011 | Add: 'and the risks and benefits of spontaneous onset of labour' | Thank you for your comment. The committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth so we have not made this change. |
| Birthwise | Guideline | 005 | 011 | The risks and benefits of induction of labour and the proposed methods should be discussed for everyone, not just in specific circumstances, and individualised discussions for each woman. | Thank you for your comment. The committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth with individual women. |
| Birthwise | Guideline | 006 | 012 - 019 | This needs to be balanced with an explanation of the risks of induction which also increases many of these risks, and has long term impacts on women and babies. Medical professionals do not see the long term physical and mental impact of induction of labour, their view is skewed by the fact that they only see the immediate impact of the small number of stillbirths or neonatal deaths that occur. | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. |
| Birthwise | Guideline | 006 | 020 - 025 | It is not acceptable to suggest induction of labour based on race. Black, Asian or women with a minority ethnic family background will be put at further risk if induction takes place at 39 weeks without a medical reason. The systemic racism within the maternity system already puts these women at higher risk, and if they are then being induced early leading to longer in hospital, additional interventions and more contact with services where they are already experiencing poor outcome this will increase the total harm caused by maternity services. For these women we need to focus on interventions that have been proven to improve outcomes - | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | Continuity of carer, doula support, anti-racism training for all health care professionals. | |
| Birthwise | Guideline | 006 | 020 -025 | <p>This may increase the risk for these women, rather than decrease it. Not enough evidence to support this recommendation. This would have significant impacts on services, including:</p> <ul style="list-style-type: none"> a. A significant decrease in women experiencing spontaneous labour b. A decrease in women going into labour after sweep/mechanical induction c. An increase in caesarean birth (Dahlen et al 2021) d. Increased stillbirth in the next pregnancy, where the reason for caesarean is related to iol e. An increase in instrumental birth f. An increase in episiotomy subsequent to c) above g. An increased likelihood of breathing difficulties for the neonate, subsequent to c) above h. Longer length of postnatal stay i. Increased SSI and perineal infection j. Reduced bonding and breastfeeding k. Lower satisfaction levels for women l. Increased incidence of birth trauma m. Significant challenges to maternity services: increased resources directed towards iol, theatres, and postnatal wards n. Increase in adverse outcomes due to m) above, as resources are directed towards iol throughput, there is a greater chance of concerns being missed. <p>In reality, 'consider induction of labour' for these women will quickly lead to rigid enforcement of induction for all of these women similarly to how the 41+6 guidance is currently implemented with very little opportunity for women to deviate from the expected path of intervention.</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | Vulnerable women are already at higher risk of adverse outcomes, and this may well be partly due to increased levels of intervention. This recommendation may reinforce existing vulnerabilities rather than reducing them. | |
| Birthwise | Guideline | 006 | 010 - 011 | <p>This is not supported by clear evidence. If this recommendation remains, then we might reasonably expect to see the following:</p> <ul style="list-style-type: none"> a. A significant decrease in women experiencing spontaneous labour b. A decrease in women going into labour after sweep/mechanical induction c. An increase in caesarean birth (Dahlen et al 2021) d. Increased stillbirth in the next pregnancy, where the reason for caesarean is related to induction e. An increase in instrumental birth f. An increase in episiotomy subsequent to e) above g. An increased likelihood of breathing difficulties for the neonate, subsequent to c) above h. Longer length of postnatal stay i. Increased surgical site infection and perineal infection j. Reduced bonding and breastfeeding k. Lower satisfaction levels for women l. Increased incidence of birth trauma m. Significant challenges to maternity services: increased resources directed towards iol, theatres, and postnatal wards n. Increase in adverse outcomes due to m) above, as resources are directed towards iol throughput, there is a greater chance of concerns being missed. | <p>Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected.</p> <p>Based on these changes, and the fact that 98.9% of women who go into spontaneous labour will have done so by 42+0 weeks, the committee recognised that this may lead to an increase in the number of inductions for some units, depending on their current induction rates at different gestational ages.</p> |
| Birthwise | Guideline | 006 | 010 | <p>The current induction rate in the UK is approximately 32%, with the rates being close to 50% in some hospitals. Research recently published which has not been taken into account here (Dahlen et al 2021) has noted that 15% of low-risk women are having their labours induced for no medical reason, which leads to higher rates of intervention (epidural,</p> | <p>Thank you for your comment. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | emergency caesarean, assisted births, episiotomy) and more adverse maternal, neonatal and child outcomes. Due dates are inaccurate as pregnancy length can vary by a range of 38 days (Jukic et al 2013), and term is considered 37 – 42 weeks (this has even been pointed out in the above line that labour usually starts naturally by 42 weeks). Therefore, suggesting induction of labour at 41 weeks for these women is unnecessary and could potentially lead to increased poor outcomes for woman and baby. | to have an induction. Based on stakeholder feedback we have also amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the birth of preterm babies. |
| Birthwise | Guideline | 006 | 012 | Provide balanced information here, including the risks associated with induction of labour and the potential for a cascade of intervention and potential for a more challenging and traumatic birth. | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. |
| Birthwise | Guideline | 006 | 017 | Research around stillbirth and neonatal death is conflicting and debatable – research has been underpowered, not of good quality, and many of the trials lump all women in together so that the data is difficult to interpret. Trials, particularly ones such as the ARRIVE trial, should not be used as a basis for guidelines for a number of reasons: 73% of women declined to take part in the study so this cannot be considered a representative sample of the population, the type of care the women received was highly medicalised for low-risk pregnancies (which is not the usual mode of care in | Thank you for your comment. We will address your points in turn: 1. The methodological limitations of the ARRIVE trial were reflected in the evidence report and taken into consideration by the committee when interpreting the evidence. The committee considered the proportion of women who declined to participate to be within normal parameters and considered this could be due to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | the UK) and most crucially there was no effect on stillbirth or neonatal death rates. Rydahl et al (2020) found that a change to earlier induction of labour had no effect on decreasing stillbirth rates, but did increase the number of women being induced, as well increase tearing and uterine rupture. All of this information needs to be shared with women, not just that there is an increased likelihood of stillbirth and neonatal death, so that they are able to make a fully informed decision. Women should also be informed of what the absolute risks of stillbirth are, not only informed that there is an increased risk or a doubling of risk, to inform their decisions. | 2.The committee acknowledged that although all included studies were from high-income countries, these were conducted in a variety of settings (not just the United Kingdom) where healthcare is mainly accessible through private funding and where there are usually fewer midwives available to support women during birth, such as the US. However the committee agreed that the evidence was broadly applicable to the current UK context as it provided evidence from similar healthcare systems from high income countries. 3. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have now included tables with the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding of the evidence reviewed. The supporting information explains how this data was derived, its limitations and how to interpret it. |
| Birthwise | Guideline | 006 | 020 | There is no robust evidence to suggest that women of increased BMI, aged above 35 years, of black, Asian or ethnic minority, or assisted conception pregnancies should be induced at 39 weeks. It is not appropriate for the guidelines to be based on the knowledge and experience of the panel and not evidence-based research. We are concerned that the suggestion of induction at 39 weeks for these women will lead to a huge increase of women being induced for no medical reason. The woman should be treated as an individual and her care should be individualised for her, not based on conflicting or debatable generalised population-level recommendations. In addition, the wording 'consider induction of labour ... in women with ...' is not appropriate, as this indicates that the decision is being made by the healthcare professional and not the woman as it should be. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Birthwise | Guideline | 006 | 010 & 020 | The number of women being advised to have an induction of labour will increase meaning more women may be induced. | Thank you for your comment. As a result of stakeholder feedback the guideline no longer recommends induction |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | The impact of induction of labour means more women will be under the care of medical professionals, more women may require artificial hormones to birth their baby. More women will require cardiotocograph monitoring during labour, and require an increase in epidural analgesia. This may also increase the number of women requiring instrumental delivery. | from 41+0 weeks or that induction of labour be considered at 39+0 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. It may be that the new recommendations will encourage some women to have an earlier induction than they would previously, but a substantial change in the number of induced labours is not anticipated with the revised recommendations. |
| Birthwise | Guideline | 007 | 006 - 015 | There needs to be a balanced discussion, with the pros and cons of monitoring, and the pros and cons of induction presented in a neutral, balanced way. This recommendation, as currently drafted, is framed in such a way that women are likely to comply with induction and not opt for monitoring. This needs to be amended in light of the Montgomery ruling. thought needs to be given for information that could arise out of monitoring, for example 'bigger' babies being picked up in late third trimester scans. These scans are known to be inaccurate, but this inaccurate information may cause further coercion from consultants and midwives. | Thank you for your comment. This recommendation has been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. Any information about potential fetal problems picked up on these scans would need to be considered as part of personalised care, in the same way that the woman's reports of reduced fetal movements, or abnormalities in fetal heartbeat on auscultation would be considered. |
| Birthwise | Guideline | 007 | 003 -005 | In reality, women can feel pressurised and indeed coerced into interventions. This section needs to be worded more strongly to address this possibility, particularly in light of the Montgomery ruling. It should also be stressed that discussions and decisions are recorded in a womans notes so that she does not have to repeat the discussions multiple times with different health care professionals. | Thank you for your comment. We have amended the wording to clarify that the decision is the woman's and this should be recorded in her notes. |
| Birthwise | Guideline | 007 | 016 - 017 | This is a recipe for coercion and needs to be reviewed in light of the Montgomery ruling. | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Birthwise | Guideline | 007 | 003 | Increased length of time at antenatal appointment to discuss women's decision if she chooses to not have an induction of labour. | Thank you for your comment. We have not specified in the recommendation that additional time will be needed, as the timing of this appointment may vary, or the decision may be made once a woman is already under maternity care for birth. |
| Birthwise | Guideline | 007 | 010 | This statement is blatant fear mongering. While it is true that monitoring gives a snapshot of the current situation, the inclusion of the statement that adverse effects on the baby cannot be predicted is scaremongering and should be taken out. Women should be encouraged to focus on how they physically feel as well as their baby's movements. We are concerned that this statement would mean that women decide on induction of labour out of fear and not based on decisions that are right for them. | Thank you for your comment. The committee agreed that it was very important to make women aware of the limitations of monitoring so we have not removed this part of the recommendation. However, a later recommendation provides advice on ensuring women know to monitor their baby's movements. |
| Birthwise | Guideline | 007 | 013 | If this recommendation is implemented this will lead to service pressures in terms of an increase in number of women requiring cardiotocograph monitoring and ultrasound scanning to calculate amniotic pool depth. | Thank you for your comment. Other recommendations (for example 1.2.2 and 1.2.4) have been amended so it is unlikely that the cohort of women being offered and declining induction will change significantly. This recommendation has also been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The options to do CTG and amniotic pool depth are only provided as suggestions, carried over from the previous version of the guideline, and have been in place since 2008, so it is unlikely these recommendations will have an impact on resources. |
| Birthwise | Guideline | 007 | 016 | If this recommendation is implemented this will lead to service pressures in terms of increased appointments with healthcare professionals for women to revisit options. This will also be used as a coercion tool as women will be made to feel they must revisit these discussions, even if they have already made an informed decision. | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again, and have removed the suggested frequency of at least once a week. |
| Birthwise | Guideline | 007 | 016 | Once women have made their decision to decline induction, this decision should be respected and supported. By revisiting this at future appointments, we feel that this could | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | be perceived as coercion and women may feel coerced or obliged to agree to induction of labour if regularly asked about it by health care professionals. There is potentially a power imbalance between healthcare professional and woman. A woman can contact her midwife/consultant if she changes her mind. | |
| Birthwise | Guideline | 007 | 018 | If this recommendation is implemented this will lead to service pressures in terms of increased number of phone calls to Induction of Labour Team requesting Induction of Labour to be arranged. | Thank you for your comment. If a woman decides to decline induction and await spontaneous labour, there may be situations where, a few days or a week later, she wishes to reconsider her decision and her options for birth, or if she has concerns about her baby. In this case the committee agreed that she should be advised to contact her midwife or maternity unit. There is nothing in the recommendation to state that it must be immediate. However, we have amended the recommendation to clarify that there is only urgency to contact the maternity service if the woman has concerns about her baby. |
| Birthwise | Guideline | 008 | 007- 012 | It would be helpful to also provide positive framing here eg. The benefits for the baby in avoiding preterm birth | Thank you for your comment. The management of PPRM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not reviewed the data on the risks and benefits of induction of labour compared to expectant management in prelabour rupture of the membranes, and so have not been able to make the changes you suggest. |
| Birthwise | Guideline | 008 | 003 - 006 | This is not a 'shared decision'. The woman decides what happens to her and her baby. This section needs to be reworded to acknowledge women's autonomous decision making, particularly in light of the Montgomery ruling. | Thank you for your comment. The NICE definition of shared decision-making is a collaborative process, making sure the person understands the risks and benefits through discussion and we think this applies to decisions about maternity choices, although the final decision is ultimately the woman's. We have reviewed the use of the terminology 'shared decision-making' throughout the guideline and have amended it in a number of places. However, there are some circumstances where there may be factors that relate to the decision that are within the remit of the healthcare professional too - such as their professional responsibility to act in the woman's best |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | interests, and in this example to determine if suitable neonatal facilities are available. In this case we think the decision would therefore be shared, and so have not amended it in this recommendation. |
| Birthwise | Guideline | 008 | 004 - 005 | This should allow for expectant management up to the onset of labour. Women may wish to wait until 38, 39 or even 42 weeks before intervention for pprom. Having until 37+0 included here will without doubt result in coercion of women to accept intervention as soon as the are 37 weeks. | Thank you for your comment. The management of PPRM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not reviewed the data on the risks and benefits of induction of labour compared to expectant management in preterm prelabour rupture of the membranes, or the risks of managing expectantly beyond 37 weeks, and so have not been able to make the changes you suggest. |
| Birthwise | Guideline | 008 | 003 | Any decision to induce labour at 41+0 is made by the woman – it is not a 'shared decision'. | Thank you for your comment. The NICE definition of shared decision-making is a collaborative process, making sure the person understands the risks and benefits through discussion and we think this applies to decisions about maternity choices, although the final decision is ultimately the woman's. We have reviewed the use of the terminology 'shared decision-making' throughout the guideline and have amended it in a number of places. However, there are some circumstances where there may be factors that relate to the decision that are within the remit of the healthcare professional too - such as their professional responsibility to act in the woman's best interests, and in this example to determine if suitable neonatal facilities are available. In this case we think the decision would therefore be shared, and so have not amended it in this recommendation. |
| Birthwise | Guideline | 008 | 022 | Instead of 'up to 24h' this should read 'after 24h' or indeed for as long as the women should wish to wait. Bodily autonomy allows a women to wait for labour to start spontaneously for whatever duration she is happy with. | Thank you for your comment. This recommendation relates to the period up to 24 hours after the membranes have broken. The course of action after 24 hours of expectant management is provided in the next recommendation, at which point induction of labour will be offered. As with all healthcare decisions it is the woman's choice whether or not to take up that offer. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Birthwise | Guideline | 009 | 021 - 024 | We welcome this recommendation. It could perhaps be worded more strongly, to make it clear that women should not be persuaded, unduly influenced, or coerced when making their decisions. | Thank you for your comment. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline. |
| Birthwise | Guideline | 009 | 001 - 003 | Add a further sentence to ensure there is no attempt at persuasion/coercion, in light of the Montgomery ruling. | Thank you for your comment. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline. |
| Birthwise | Guideline | 009 | 009 | If this recommendation is implemented this will lead to service pressures in terms of increase in the number of high-risk women having an Induction of Labour. Decrease in number of women having a successful VBAC due to number of women with previous caesarean section being advised to have an induction of labour. | Thank you for your comment. We recognise that many women will wish to have a vaginal birth after a previous caesarean birth. However, the stem of this recommendation is 'If birth is indicated.....' so these recommendations would apply where a decision has been made that it is necessary to expedite birth. In order to clarify this, we have amended the wording to 'if birth needs to be expedited.' |
| Birthwise | Guideline | 009 | 021 | We are very concerned that including the statement that women are entitled to decline the offer of treatment even if it would benefit their baby's health is scare tactics and coercion, and including this does not support a woman's decision making. Remove 'even if it would benefit' as this is speculation and has not place in a clinical guideline. | Thank you for your comment. We have amended the wording of this recommendation to say '....when it may benefit their or their baby's health.' to reflect the uncertainty. |
| Birthwise | Guideline | 010 | 020 - 029 | Given the evidence listed in the bullet points, there is no valid reason for this recommendation and it should be removed. | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. |
| Birthwise | Guideline | 010 | 002 - 004 | Women decide. This needs to be reworded in light of the Montgomery ruling. | Thank you for your comment. This recommendation relates to women requesting an induction of labour and the responsibility of the healthcare professional is therefore to provide them with personalised information on the risks and benefits, which is what this recommendation states. Decision-making about induction of labour is covered in more detail at the beginning of the guideline in the section entitled 'information and decision-making'. |
| Birthwise | Guideline | 010 | 008 | Requirement for policies to be written. Will midwives be able to perform induction of women for these women? At present breech presentation is outside midwives' remit. | Thank you for your comment. The exact responsibilities of individual staff groups with respect to induction of labour for specific groups is not covered by NICE guidelines, and would be a matter of professional responsibility. |
| Birthwise | Guideline | 010 | 020 | While it is positive that this point does reference discussion of the benefits and risks of both induction and expectant management in women with suspected foetal macrosomia, we feel that this change in recommendation from the previous guidelines (that in the absence of any other indications, induction should not be recommended solely based on suspected large baby) is unnecessary. As is highlighted in this draft, there is lack of evidence around the risks associated with having a larger baby, indicating that induction cannot be recommended based on evidence. Late pregnancy scans are inaccurate, with a 15% error margin for predicting baby's weight, meaning that recommendation of induction based on baby's size could lead to more women being induced for no medical reason. There is the likelihood that once women are told they are potentially having a big baby and are offered induction, they are less likely to consider the lack of evidence and more likely to opt for induction as it is recommended by their healthcare professional and the fear associated with birthing a big baby. Reinstate the recommendation that induction of labour should not be offered on the basis of big baby alone. Also need to consider that shoulder dystocia occurs in smaller babies, and induction of labour can increase the risk of | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | instrumental delivery subsequently increasing the risk of shoulder dystocia. | |
| Birthwise | Guideline | 011 | 002 - 004 | This is further confirmation that there is no evidence to support the recommendation in 1.2.22. | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. |
| Birthwise | Guideline | 013 | 010 - 011 | It needs to be explicitly stated that a sweep should not be done during a VE, and should only take place following meaningful discussion and clear agreement from the woman. | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps. However, we have expanded the recommendation on discussing it with women and obtaining their consent. |
| Birthwise | Guideline | 013 | 014 - 015 | There is inadequate evidence to support this recommendation, which is likely to result in a range of unintended consequences, with significant negative impacts on women, babies, and services. These include: <ul style="list-style-type: none"> a. A significant decrease in women experiencing spontaneous labour b. A decrease in women going into labour after sweep/mechanical induction c. An increase in caesarean birth (Dahlen et al 2021) d. Increased stillbirth in the next pregnancy, where the reason for caesarean is related to induction e. An increase in instrumental birth f. An increase in episiotomy subsequent to c) above g. An increased likelihood of breathing difficulties for the neonate, subsequent to c) above h. Longer length of postnatal stay i. Increased SSI and perineal infection | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps. However, we have expanded the recommendation on discussing it with women and obtaining their consent. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <ul style="list-style-type: none"> j. Reduced bonding and breastfeeding k. Lower satisfaction levels for women l. Increased incidence of birth trauma m. Significant challenges to maternity services: increased resources directed towards lol, theatres, and postnatal wards n. Increase in adverse outcomes due to m) above, as resources are directed towards lol throughput, there is a greater chance of concerns being missed. | |
| Birthwise | Guideline | 013 | 003 | <p>We welcome the inclusion of discussing the risks of sweeps – discomfort and bleeding – however, we would suggest that women are informed that there is a lack of evidence around the effectiveness of sweeps as well as the optimal timing and frequency of sweeps (Finucane et al 2020).</p> <p>Many women find having a sweep extremely uncomfortable, so we would recommend that it is included to discuss pain relief options available to them.</p> <p>We also feel that women should be informed that they have the option to accept or decline a sweep.</p> | <p>Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, and so are not able to comment on this in the guideline. We have now added in that pain should be included in the initial discussion with women about membrane sweeps. We have now also emphasised that the option of a membrane sweep should be discussed with women and their consent obtained.</p> |
| Birthwise | Guideline | 013 | 010 | <p>Obtaining consent before performing a membrane sweep is excellent. However, it would also be beneficial if the guidance referenced ensuring women fully understood the likelihood of a sweep being effective and knew what their Bishop score was before they made a decision.</p> | <p>Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, or the likelihood of success. To determine the Bishop score before women made their decision would require a separate vaginal examination and so we have not recommended this.</p> |
| Birthwise | Guideline | 013 | 014 | <p>Increase in number of women being offered vaginal examination at an earlier gestation meaning it may be more painful. These women should be offered a membrane sweep in the correct environment with adequate analgesia i.e. entonox. This would increase footfall through induction of labour service.</p> | <p>Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, the likelihood of success, optimal timing or frequency, or the need for</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | pain relief. However, the recommendations have now been clarified to state that membrane sweeps should be discussed after 39 weeks (as opposed to 'from 39 weeks') so sweeps will happen from week 40 onwards. |
| Birthwise | Guideline | 013 | 014 | As mentioned in above comments, pregnancy length can vary greatly, and research is lacking as to the effectiveness and timing of sweeps. We feel that 39 weeks is too early to offer women a sweep, as the majority of women's bodies are not ready for labour at this point, it is undermining the woman's trust and connection to her body and her baby, and women could potentially be opting for a sweep/sweeps that are invasive, uncomfortable, and unlikely to work. Sweeps should not be offered any earlier than 40 weeks. | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, the likelihood of success, optimal timing or frequency, or the need for pain relief. However, the recommendations have now been clarified to state that membrane sweeps should be discussed after 39 weeks (as opposed to 'from 39 weeks') so sweeps will happen from week 40 onwards. |
| Birthwise | Guideline | 013 | 016 | Increase of risk of infection with multiple sweeps needs to be made clear. Also risk of accidental rupture of membranes during a sweep and what the implications of this would be. | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, the likelihood of success, optimal timing or frequency. However, we have amended this recommendation to emphasise that additional membrane sweeping should only be considered after a discussion with the woman. |
| Birthwise | Guideline | 013 | 016 | The wording of this should be changed – Additional membrane sweep can be offered, and it is the woman's decision whether to accept an additional sweep should labour not start spontaneously. | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, the likelihood of success, optimal timing or frequency. However, we have amended this recommendation to emphasise that additional membrane sweeping should only be considered after a discussion with the woman. |
| Birthwise | Guideline | 014 | 014 - 028 | A Bishop score of 6 or less generally indicates that the cervix is unfavourable. Offering induction by whatever method if the cervix is unfavourable means that it is more likely to affect the birth outcomes, increasing the need for interventions or caesarean section for unsuccessful induction, which can | Thank you for your comment. The evidence review carried out for methods of induction analysed the data by the sub-groups of women with a Bishop score of 6 or less and woman with a Bishop score greater than 6. The evidence showed that the recommended methods of induction |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | have a knock-on effect on women's mental health if they feel that their birth experience was traumatic. | (dinoprostone, misoprostol and mechanical methods) were all effective at leading to vaginal birth within 24 hours, and did not increase the rate of caesarean birth or instrumental birth compared to placebo, in women with a Bishop score of 6 or less. |
| Birthwise | Guideline | 016 | 012 | Repeated vaginal examinations, whether for doing sweeps or for assessing the Bishop score, can potentially lead to an increased risk of infection. The number of internal examinations should be kept to a minimum. | Thank you for your comment. It was not within the scope of this guideline update to consider the evidence for infections with intact membranes therefore we did not make an amendment to the recommendations to minimise the number of vaginal examinations. |
| Birthwise | Guideline | 017 | 003 | Repeated vaginal examinations, whether for doing sweeps or for assessing the Bishop score, can potentially lead to an increased risk of infection. The number of internal examinations should be kept to a minimum. | Thank you for your comment. It was not within the scope of this guideline update to consider the evidence for infections with intact membranes therefore we did not make an amendment to the recommendations to minimise the number of vaginal examinations. |
| Birthwise | Guideline | 024 | 001 - 005 | It is positive that consideration is being given for outpatient induction of labour and we feel this should be encouraged and supported where appropriate. | Thank you for your comment and support of this research recommendation. |
| Birthwise | Guideline | 031 | 012 | The deletion of recommendation 1.2.1.1 from the 2008 guideline is deeply concerning. Women with uncomplicated pregnancies should only be offered intervention (including IOL) if there is clear and compelling evidence to support this. The recommendations in the current draft guideline are not supported by good evidence, and are likely to cause increased harm. The evidence scope should have included attention to the long term outcomes, and to women's experiences, as well as the immediate intrapartum outcomes. The ARRIVE trial which the draft guideline seems to rely upon heavily has been criticised by many experts in terms of study design and generalisability. There is clear evidence that long-term outcomes are poorer following induction of labour, and that this is avoidable, iatrogenic harm. The draft guideline suggests that CS is less likely following IOL. However the latest evidence (Dahlen, Thornton, Downe et al) and clinical experience suggests otherwise. In our trust, slow progress in labour with IOL is the second | Thank you for your comment. We will address your points in turn. 1. We have reinstated the recommendation that says 'Women with uncomplicated pregnancies should be given every opportunity to go into spontaneous labour'. 2. As you have noted, it was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. 3. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>commonest reason for emergency c section, following abnormal CTG.</p> <p>The research by Dahlen et al included almost 475000 births and considered long term outcomes up until CA 16. Almost 15% of these women had IOL for non-medical reasons, and this will likely increase if the current recommendations are implemented. Being full term is not a disease.</p> <p>Primiparous women with IOL in this study were less likely to experience a straightforward birth, and more likely to experience c section, epidural, episiotomy, and post-partum haemorrhage.</p> <p>In terms of Obstetric anal sphincter injury, Dahlen et al found that this was less common in women with IOL. However, research by Rygh et al had previously found the opposite – that oxytocin augmentation was associated with a higher OR incidence of OASI.</p> <p>In addition the 'due date' is an estimate, and we risk increasing prematurity, with lifelong harm for the infant, if we induce labour on the basis of EDC.</p> <p>If we are to interfere with the normal physiological onset of labour in a healthy woman having a straightforward pregnancy, then we need clear and compelling evidence to support this. The current draft guideline is not supported by such evidence.</p> | <p>compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction.</p> <p>4. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the birth of preterm babies.</p> |
| Black Beetle Health | Guideline | General | General | <p>It is disappointing to see a guideline that removes the recommendation that "uncomplicated pregnancies should be given every opportunity to go into spontaneous labour." This appears to be part of a systematic undermining of the natural, physiological process of labour and birth.</p> | <p>Thank you for your comment. This recommendation has been replaced back into the guideline.</p> |
| Black Beetle Health | Guideline | 001 | Box | <p>The guideline acknowledges that not all birthing people refer to themselves as women yet proceeds to erase those people by choosing to use 'woman' and 'women' to describe anyone than can and has given birth. Using inclusive language affirms and empowers people, helping service users to feel accepted, listened to and safe. Addressing people in the way that they wish to be known is the bare minimum. A caveat is not acceptable.</p> | <p>Thank you for your comment. To ensure consistency between NICE guidelines the NICE editorial team have developed a more inclusive description and rationale for the use of the terminology relating to the intended population for maternity and obstetric guidelines, and this is included in the introductory information at the beginning of the guideline.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Black Beetle Health | Guideline | 004 | 008 | Rec 1.1.2 – Caesarean section should also be listed here as a possible outcome. | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on caesarean birth rates. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Black Beetle Health | Guideline | 006 | 002 | Clarity is required on what is considered to be a 'prolonged pregnancy'. Pregnancy length varies and the earlier offer of inductions means that more babies will be born before they are ready. Many birthing people report that their 'due date' was changed following the result of a scan. In some cases, they are certain that they couldn't possibly have conceived within the timeframe that scanning technology suggests. The accuracy of due dates or the varying length of gestation is not acknowledged in this guideline. | Thank you for your comment. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the birth of preterm babies. |
| Black Beetle Health | Guideline | 006 | 012 | Rec 1.2.3 Any discussion of 'risks' should be presented in a way that is specific to the individual circumstances. Rather than saying that something 'increases the risk, the absolute risk should be presented. Without this information they cannot make an informed decision. | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| Black Beetle Health | Guideline | 006 | 020 | Rec 1.2.4 – We have grave concerns that in an otherwise uncomplicated singleton pregnancy people with a BMI 30 kg/m ² 23 or above, age 35 years or above, with a black, Asian or minority ethnic family background are being pathologised. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Black Beetle Health | Guideline | 006 | 022 | BMI is an antiquated system that was not designed as a referendum for individuals. The original creator, an academic not a medic, based his calculations on European, white, male bodies to calculate the ideal body based on the mean | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | population. This system has been used to justify eugenics, the systemic sterilization of disabled people, poor people, and people of colour. Black people are disproportionately affected by the use of BMI by health professionals who perpetuate body weight stigma. Body size is not a proxy for health. | report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Black Beetle Health | Guideline | 006 | 023 | A policy that uses skin colour as a sole factor to determine care provision is racist. That is, that it seeks to discriminate against a whole people group or multiple populations in this case, purely on the colour of their skin. To use race as a useful biological category is to ignore the fact that race is a social construct. Routinely ending the pregnancies of black and brown people at 39 weeks, as an attempt to reduce poor health outcomes, is a failure to recognise the systemic oppression, inequitable care and consistent failure of care providers that is responsible for these poorer outcomes. To have a guideline released into the public domain which divides people purely based on the colour of their skin speaks to a deep-seated racism which is inherent in healthcare provision | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Black Beetle Health | Guideline | 006 | 024 | Clarity is required as to which types of assisted conception carries increased risks and the specific complications associated with these. In circumstances where families are using IUI for conception because they do not have the anatomy required to make a baby, where is the increased risk? When assisted conception in the main way that LGBTQ+ families are created, we are concerned that they will be inappropriately labelled high risk and lose their right to wait for spontaneous labour. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Black Beetle Health | Guideline | 007 | 016 | 1.2.7. Once someone has made an informed decision, revisiting this decision "at least once a week" is a tactic of coercion. | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again, and have removed the suggested frequency of at least once a week. |
| Black Beetle Health | Guideline | 010 | 020 | 1.2.22 When there is "little evidence" of benefit. Why is the guideline preference to intervene, rather than allow spontaneous birth to occur? | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------|----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. |
| Black Beetle Health | Evidence | 019 | 022 | It is a concern the study which has had the greatest impact on the gestational age at which induction of labour is to be offered is a study that did not come to completion. | Thank you for your comment. The committee discussed the quality of the evidence from the SWEPIIS study (Wennerholm 2019). The strengths of this study include its large size and relevance to this question. However, the fact that the study was terminated early due to ethical concerns and never reached the sample size intended to power its primary endpoint was a limitation, which may have led to an overestimation of the treatment effect in the intervention group and decrease the precision of the results. These limitations were acknowledged by the committee and were reflected in the overall quality of the evidence of this study. The committee discussed the fact that as such a study was initiated and was terminated on the grounds of perinatal mortality differences, it is unlikely that future research into this specific question will be conducted. Taking this into consideration the committee considered what recommendations could and should be made on the basis of this study, and agreed that the results should be considered with the results of the other studies reviewed. |
| Black Beetle Health | Evidence | 019 | 051 | If the committee is a reference to the MBRRACE report, then it should be acknowledged that there are different outcomes for different racialised groups. Non-white people are not a monolith. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. In addition, we have now included the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding of the evidence reviewed. The supporting information explains how this data was derived and how to interpret it. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Black Beetle Health | Evidence | 019 | 053 | The increased risk needs to be quantified based on the best available evidence. Opinion or "knowledge and experience" is not enough of a reason to be intervening in uncomplicated singleton pregnancies. | Thank you for your comment. We have now included the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding. The supporting information explains how this data was derived and how to interpret it. The recommendations are based on a systematic review of the evidence. However, where there is a lack of evidence the committee do use informal consensus to make recommendations and this is a standard part of the NICE process. |
| Black Beetle Health | Guideline | 024 | 028 | Prolonged beyond term? What does this mean? Is 37 weeks being used a 'term'? | Thank you for your comment. In the context of this guideline the committee took term as 37 weeks. However, based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report. We have therefore updated this rationale section to reflect these changes to the recommendations. |
| Black Beetle Health | Guideline | 025 | 005 | There is little doubt that these recommendations will increase the number of people who are offered inductions. It is disappointing to see that there is no discussion of the wider impact such as birth experience, mental wellbeing or the long-term health implications of induced labour and failed inductions or negative outcomes for families. | Thank you for your comment. It was not within the scope of this guideline update to review the risks and benefits of induction of labour compared to expectant management so we have not been able to include details of the outcomes of induction here. However, due to changes in the recommendations for induction in pregnancies lasting longer than 41 weeks and the removal of the recommendation relating to earlier induction in some high risk groups, there may be an increase in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| British Intrapartum Care Society | Guideline | General | General | The proposed earlier timing of IOL described in this draft document will have a significant impact on units' capacity to manage IOL. BICS members are concerned with current IOL capacity issues (as evidenced by the IOL workshop attendance at our national meetings in 2019). Issues with delays in the IOL | Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>process have been highlighted by BICS members as key areas of risk and complaints.</p> <p>BICS considers NICE needs seriously to consider the impact these guidelines will have on workforce and unit acuity, especially the impact on larger maternity services.</p> <p>BICS considers any increase in the percentage of women having IOL will require services to re-configure prior to the implementation of any change in national guidance. This will require significant investment in both staffing and infrastructure.</p> <p>BICS members are seriously concerned regarding the impact that this draft document will have on the experience of women and birthing people and this is demonstrated in complaints, de-briefing services and requests for caesarean birth in second pregnancies due to the negative experiences in the first pregnancy of induction of labour. This will link to the increased number of inductions of labour and the impact on the workforce and unit acuity.</p> | <p>weeks and variations in populations giving birth in the unit and this may have resource implications.</p> |
| British Intrapartum Care Society | Guideline | General | General | BICS considers a section on reduced fetal movements with proposed timings of IOL would be beneficial. | Thank you for your comment. We are not sure which particular section of the guideline this comment refers to, but timing of induction in relation to reduced fetal movements was not a topic included in the scope of this update so the committee have not been able to make recommendations on this topic. |
| British Intrapartum Care Society | Guideline | General | General | BICS considers NICE should review their writing style about ethnicity and follow the UK Government advice to capitalise all ethnic groups - https://www.ethnicity-facts-figures.service.gov.uk/style-guide/writing-about-ethnicity | Thank you for your comment. We will keep this under review, but current NICE style is not to capitalise black or white. Please see the NICE style guide here: https://www.nice.org.uk/corporate/ecd1/chapter/talking-about-people-including-deaf-and-blind-age-faith-family-background-gender |
| British Intrapartum Care Society | Guideline | General | General | BICS would prefer replacing risk with chance throughout the guideline. | Thank you for your comment. The term risk is mainly used as a synonym for 'harm' in this guideline, as in the term 'risks and benefits', and is also used to imply the probability of a negative outcome, whereas chance could |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-----------|-----------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | mean a negative or positive outcome. We have therefore not changed 'risk' to 'chance'. |
| British Intrapartum Care Society | Guideline | General | General | BICS would prefer replacing delivery with birth | Thank you for your comment. We have replaced 'delivery' with 'birth'. |
| British Intrapartum Care Society | Guideline | 013 - 015 | 018 – 002 | <p>BICS shares the following with the committee.</p> <p>As shown in the NICE network meta-analysis (NMA) evidence review¹ (figure 9, pg 21) not all induction methods cause equal amounts of hyperstimulation. With the common induction agents, statistically significant increases over placebo are seen with the withdrawn Misodelle (OR 8.87), vaginal PGE2 pessary slow release (OR 4.64), vaginal PGE2 normal release (OR 4.29), and vaginal misoprostol (<50mcg; OR 3.85). There is no significant increase in hyperstimulation with FHR changes over placebo with a cervical ripening balloon (CRB), oral misoprostol (dose <50mcg or titrated), iv oxytocin or vaginal PGE2 (tablet).</p> <p>Whilst this is clearly all on a continuum, it is clear that the highest rates are with PGE2 and vaginal misoprostol and the lowest with oral misoprostol and CRBs.</p> <p>The lower rate of hyperstimulation with oral misoprostol is supported by direct comparison studies in both the old² and recently updated³ Cochrane reviews. The latest oral misoprostol Cochrane review shows oral misoprostol to have significantly lower rates of hyperstimulation (with FH changes) than both dinoprostone (RR 0.49, 95% CI 0.40 to 0.59) and vaginal misoprostol (RR 0.69, 95% CI 0.53 to 0.92).³</p> <p>BICS considers that the interpretation of the evidence as shown in the draft NICE guidance, and the inclusion of oral misoprostol as the 'second choice' to dinoprostone is potentially biased, and possibly based on the MHRA</p> | <p>Thank you for your comment. The MHRA had advised the committee to include warnings about the use of misoprostol, based on previous warnings about the hyperstimulation seen with the vaginal insert, and the committee therefore included warnings about hyperstimulation, monitoring uterine activity and fetal condition, and a possible reduced response to tocolysis. The recommendations have now been amended to recommend low dose oral misoprostol as an alternative to dinoprostone (and not just when dinoprostone has failed to work) but the committee have continued to follow the MHRA advice to provide warnings about its use. In addition, we have provided some information on the relative rates of hyperstimulation with different pharmacological options.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-----------|-----------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>notification on Misodelle, which relates only to Misodelle and not all misoprostol.</p> <ol style="list-style-type: none"> 1. NICE guideline CG70 (update); Inducing Labour. [B] Methods for the induction of labour. Evidence review underpinning recommendations 1.3.2 and 1.3.6 to 1.3.12 in the NICE guideline, May 2021. Draft for consultation. 2. Alfirevic Z, Aflaifel N, Weeks A. Oral misoprostol for induction of labour. Cochrane Database of Systematic Reviews 2014, Issue 6. Art. No: CD001338. 3. Kerr RS, Kumar N, Williams MJ, Cuthbert A, Aflaifel N, Haas DM, Weeks AD. Low-dose oral misoprostol for induction of labour. Cochrane Database of Systematic Reviews 2021, Issue 6. Art. No.: CD014484. | |
| British Intrapartum Care Society | Guideline | 010 - 011 | 019 – 004 | <p>BICS notes that many women are fearful if they are told they are having a 'big baby' and that conversations around the size of their baby with clinicians can lead to anxiety and fear about their birth. Clinicians need to be aware of this, and they require support from this guidance to enable them to explain the current evidence [and lack of evidence where there is none] so that women can make decisions based on evidence and not fear.</p> <p>BICS considers reference to the Cochrane review (Boulvain, 2016) should be included.</p> <p>BICS considers the wording 'limited' and 'very limited' requires defining here.</p> <p>BICS considers this section requires the addition of guidance regarding the timing of IOL for a woman who choses this in the context of suspected fetal macrosomia.</p> | <p>Thank you for your comment. We appreciate that women may have fears about having a large baby but the evidence about the risks and benefits of induction is very unclear. However, the uncertainty about the evidence has been emphasised in the recommendations.</p> <p>The Cochrane review (Boulvain, 2016) was used as a source of evidence for this review, and how this evidence was used is detailed in the accompanying evidence review A. However, it is not normal practice to include individual references in the recommendations in NICE guidelines.</p> <p>The words 'limited' and 'very limited' are used to indicate that there was a small quantity of low or very low quality evidence and the details of this evidence are included in the accompanying evidence review A. However, it is not normal practice to include technical details of the evidence quality or quantity in the recommendations in NICE</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | BICS wonders if the evidence base is strong enough to 'offer' IOL currently, would 'consider' IOL be better language? | <p>guidelines. However, to increase the usefulness of these statements we have included the absolute rates from the evidence.</p> <p>The committee discussed whether it was possible to define the best time to induce labour in suspected fetal macrosomia but the evidence included induction at a range of gestational ages and it was not possible to identify the preferred gestational age. The committee also considered this would be an individualised decision based on the estimated size of the baby, the woman's clinical circumstances and her preferences.</p> <p>The recommendation did not state 'offer induction of labour', it said 'offer a choice of induction of labour or expectant management', but we have amended the wording to make it clearer that this a discussion about risks and benefits, not a recommendation to always offer an induction.</p> |
| British Intrapartum Care Society | Guideline | 004 | 009 | <p>BICS considers it would be beneficial to expand on the effect of induction of labour on women's experience of the birth process.</p> <p>Hilingsson (2011) describes how women having an IOL are more likely to have a less positive birth experience than women in spontaneous labour (OR 1.5; 1.01—3). Discussion of the number of women who declined to participate in the large RCTs used as evidence for this update should be explored here.</p> <p>BICS considers there is a need to need to take women's views and experience of induction of labour into account, and the long-term outcomes and impact for women and babies, both mentally and physically. Recent research which hasn't been considered (Rydahl et al 2020, Dahlen et al 2021) has shown that women are often induced for non-medical reasons, which does not decrease stillbirth rates but</p> | <p>Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on these outcomes, nor to look at the qualitative data relating to women's experiences. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. We have also added further recommendations to emphasise that the decision to have an induction or not, rests with the woman and that decision must be respected.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>does increase the chance of additional interventions, neonatal birth trauma and the need for resuscitation. This can affect the establishment of breastfeeding, bonding with their baby, and have postnatal mental health impacts.</p> <p>Women who have had induction often feel as if they had very little information on which to base their decision, did not know that they had a choice, felt a lack of control of decisions and the birth, and/or felt coerced into it, and would not choose to do it again (Lou et al 2018, Adler et al 2020). At all points, it is important that women are given balanced evidence-based information, meaning not only the benefits/risks of not inducing but also the benefits and risks of induction, so that they can make their own decisions and then be supported and respected in their decisions. Unfortunately, women are often told that their baby might/will die or that there is an increased risk of 'XYZ' without the supporting data and evidence, and this is coercive and does not support their decision making.</p> | |
| British Intrapartum Care Society | Guideline | 006 | 012 - 019 | BICS considers it would be beneficial to quantify the 'increased likelihood' of these events to support a woman to make an informed choice. | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| British Intrapartum Care Society | Guideline | 006 | 020 - 025 | <p>BICS considers this is a significant recommendation based on the committee's experience and knowledge, and that the evidence to inform this recommendation is limited.</p> <p>The audit data from MBRRACE-UK supports the fact that women from Black, Asian and minority ethnic groups, those with a BMI >30 and those aged >35 do have an increased chance of adverse perinatal outcomes. The committee do not explore potential reasons for these increases.</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-----------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>BICS considers efforts are urgently required to explore the underlying reasons for this disparity in outcomes and has concerns that offering an intervention (with its associated potential complications) to women from Black, Asian and minority ethnic groups is not the best way to address this inequity. BICS is concerned that this approach will widen the disparity rather than reduce it.</p> <p>Implementing this guidance in its current form could mean that units (especially those serving large multi-ethnic cities) could have an IOL rate of almost 80%. BICS considers that the suggestion from the committee that this recommendation will not have a substantial resource impact at national level is likely to be dangerously erroneous.</p> | |
| British Intrapartum Care Society | Guideline | 006 | 018 - 019 | BICS considers it would be beneficial to include the associated increase in OASI injury with the increased use of instrumental births in this section. | Thank you for your comment. The evidence review for this update did not include OASI injury as an outcome so we are unable to provide any data on this. |
| British Intrapartum Care Society | Guideline | 006 | 021 & 026 | BICS would prefer replacing risk with chance | Thank you for your comment. The term risk is mainly used as a synonym for 'harm' in this guideline, as in the term 'risks and benefits', and is also used to imply the probability of a negative outcome, whereas chance could mean a negative or positive outcome. We have therefore not changed 'risk' to 'chance'. |
| British Intrapartum Care Society | Guideline | 007 | 018 | BICS considers 'maternity unit' is too vague. Could this be reworded to say - give women a specific point of contact (named MW, maternity helpline etc...) so they can contact the maternity service as soon as possible ... | Thank you for your comment. We have amended this recommendation to include midwife as well as maternity unit. |
| British Intrapartum Care Society | Guideline | 009 | 004 - 007 | <p>BICS considers this section needs to be clearer for women who have previous carriage of GBS and have decided to have IAP in this labour rather than screening for GBS at 35-37 weeks [as per RCOG GTG] – could this be clearer to offer them immediate IOL as well?</p> <p>Also clearer guidance is needed that this applies to women who have previously had a baby affected by GBS infection and are planning to receive IAP during labour.</p> | Thank you for your comment. This guideline focuses on induction of labour to reduce the risk of neonatal infection with ruptured membranes, but advice on the use of intrapartum antibiotic prophylaxis during labour would still apply and is not covered in this guideline, but is covered in the NICE guideline on neonatal infection (NG195) and we have added a link to this from the recommendation. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| British Intrapartum Care Society | Guideline | 009 | 017 | BICS would prefer replacing delivery with birth | Thank you for your comment. We have changed this to birth. |
| British Intrapartum Care Society | Guideline | 010 | 005 - 015 | <p>BICS suggests the section on 'Breech Presentation' is re-written to reflect the ethos of informed choice and discussion, in a similar manner to the section on 'Previous caesarean birth.'</p> <p>A guideline on IOL with breech presentation is only applicable to women who have chosen to plan a vaginal breech birth. The guideline should reflect and respect this, using neutral, non-judgemental language.</p> <p>For example:</p> <p>1.2.19 Advise women with a baby in the breech position, who have chosen to plan a vaginal breech birth, that:</p> <ul style="list-style-type: none"> induction of labour could lead to an increased risk of emergency caesarean birth, compared to spontaneous breech labour induction of labour could lead to an increased risk of neonatal intensive care unit admission for the baby, compared to spontaneous breech labour the methods used for induction of labour will be guided by the need to reduce these risks. See the recommendations on methods for inducing labour. <p>1.2.20 If birth is indicated, offer women who have a baby in the breech position a choice of:</p> <ul style="list-style-type: none"> an attempt at external cephalic version, immediately followed by induction of labour if successful caesarean birth or induction of labour in breech presentation <p>Take into account the woman's circumstances and preferences. Advise women that they are entitled to decline</p> | Thank you for your comment. Induction of labour with breech presentation was not included in the scope of this guideline update and so we have not been able to add more detail about the risks and benefits of induction, compared to a spontaneous labour and so we have not made the changes you suggest to these recommendations. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | the offer of treatment such as external cephalic version, induction of labour or caesarean birth. | |
| British Intrapartum Care Society | Guideline | 010 | 017 - 018 | <p>BICS notes there is no definition of fetal growth restriction or fetal compromise.</p> <p>Is this referring to babies <10th, <5th <3rd centiles with fetal compromise based on CTG or Dopplers?</p> <p>BICS requests that both fetal growth restriction and fetal compromise are clearly defined here.</p> | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add a definition of confirmed fetal compromise. |
| British Intrapartum Care Society | Guideline | 010 | 006 | <p>1.2.19 Induction of labour is not generally recommended if a woman's baby is in the breech position. [2008, amended 2021]</p> <p>BICS would recommend the evidence behind this statement is included.</p> | Thank you for your comment. Induction of labour with breech presentation was not included in the scope of this guideline update and so there is no direct link to the evidence for these recommendations. However, the evidence is available on the NICE website as part of the 2008 guideline evidence. |
| British Intrapartum Care Society | Guideline | 010 | 009 | BICS would prefer replacing delivery with birth | Thank you for your comment. We have changed 'delivery' to 'birth'. |
| British Intrapartum Care Society | Guideline | 010 | 014 | <p>BICS considers that this systematic review may inform the discussion about the risks and benefits of IOL when a baby is in a breech presentation.</p> <p>https://www.ejog.org/article/S0301-2115(17)30578-X/fulltext</p> | Thank you for your comment and for supplying details of this paper. Induction of labour for babies in the breech position was not included in the scope of this update, but we will forward this information to the NICE surveillance team who ensure guidelines are up to date. |
| British Intrapartum Care Society | Guideline | 012 | 021 - 022 | <p>BICS acknowledges that the SPCs for these medications include them being contraindicated in women who have a uterine scar. BICS members would benefit from guidance here of alternative options for women in this situation. Is NICE recommending that medication cannot be used in this situation? If so, will they be making a clearer recommendation for birth by CS in this situation? BICS is concerned about the potential impact of this statement of the woman's current clinical care and any future pregnancies she may have.</p> <p>BICS notes this is one of the areas highlighted in the guideline that requires further research (p22, lines 14-16).</p> | Thank you for your comment. In order to make the recommendation more helpful, we have used the same wording as that used for women who are giving birth to a live baby and who have had a previous caesarean birth, which suggests that methods used for induction will need to take into account the risk of uterine rupture, for example by using mechanical methods. However, as you have noted, the committee made a research recommendation as they agreed that more research was required. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-----------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| British Intrapartum Care Society | Guideline | 014 | 017 - 022 | <p>BICS shares the following with the committee.</p> <p>The NICE NMA¹ shows clear benefits of oral misoprostol over dinoprostone, but for unknown reasons (maybe due to the MHRA warning about the Misodelle misoprostol vaginal delivery system which has been mistakenly believed to also relate to low dose oral misoprostol preparations) it is placed as second line in the draft guidance.</p> <p>The NMA shows that low dose oral misoprostol (whether titrated or fixed dose) has a 30% lower rate of CS than placebo, unlike PGE2 or CRB which show no significant difference (figure 15, pg 31). This is supported by direct comparison evidence contained within the oral misoprostol Cochrane review³ and a very large recent RCT.⁴</p> <p>The same is true for uterine hyperstimulation with FHR changes which is lower in oral misoprostol (and CRB) than dinoprostone in both the NMA¹ and direct comparisons in Cochrane analysis.^{2,3}</p> <p>BICS considers that the evidence for the benefits in terms of CS and hyperstimulation is supported by both the NMA¹ and the oral misoprostol Cochrane reviews^{2,3} and suggest that low dose oral misoprostol should be the first choice for labour induction.</p> <ol style="list-style-type: none"> 1. NICE guideline CG70 (update); Inducing Labour. [B] Methods for the induction of labour. Evidence review underpinning recommendations 1.3.2 and 1.3.6 to 1.3.12 in the NICE guideline, May 2021. Draft for consultation. 2. Alfirevic Z, Afraifel N, Weeks A. Oral misoprostol for induction of labour. Cochrane Database of Systematic Reviews 2014, Issue 6. Art. No: CD001338. | <p>Thank you for your comment. The MHRA had advised the committee to include warnings about the use of misoprostol, based on previous warnings about the hyperstimulation seen with the vaginal insert, and the committee therefore included warnings about hyperstimulation, monitoring uterine activity and fetal condition, and a possible reduced response to tocolysis. The recommendations have now been amended to recommend low dose oral misoprostol as an alternative to dinoprostone (and not just when dinoprostone has failed to work) but the committee have continued to follow the MHRA advice to provide warnings about its use.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-----------|---------|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <ol style="list-style-type: none"> 3. Kerr RS, Kumar N, Williams MJ, Cuthbert A, Aflaifel N, Haas DM, Weeks AD. Low-dose oral misoprostol for induction of labour. Cochrane Database of Systematic Reviews 2021, Issue 6. Art. No.: CD014484. 4. Wang X, Zhang C, Li X, Qi H, Liu Q, Lei J. Safety and efficacy of titrated oral misoprostol solution versus vaginal dinoprostone for induction of labor: A single-center randomized control trial. Int J Gynaecol Obstet. 2020 Dec 17. doi: 10.1002/ijgo.13546. Epub ahead of print. | |
| British Intrapartum Care Society | Guideline | 014 | 009- 010 | <p>BICS considers it is strange that the committee should note the MHRA warning about Misodelle (the withdrawn high dose, but slow release, preparation), and then use it to justify warnings about the low dose misoprostol preparations.</p> <p>The warnings related to hyperstimulation, which is the result of too high a dose. The lower dose does not have this effect (see the NICE evidence NMA¹ and the Cochrane review^{2,3}) and so should not be subject to the MHRA ruling. Indeed, the MHRA, by recently approving Augusta, is clear that the ruling is specific for the Misodelle dosage and delivery system and does not apply to all formulations of misoprostol.</p> <ol style="list-style-type: none"> 1. NICE guideline CG70 (update); Inducing Labour. [B] Methods for the induction of labour. Evidence review underpinning recommendations 1.3.2 and 1.3.6 to 1.3.12 in the NICE guideline, May 2021. Draft for consultation. 2. Alfirevic Z, Aflaifel N, Weeks A. Oral misoprostol for induction of labour. Cochrane Database of Systematic Reviews 2014, Issue 6. Art. No: CD001338. | <p>Thank you for your comment. The MHRA had advised the committee to include warnings about the use of misoprostol, based on previous warnings about the hyperstimulation seen with the vaginal insert, and the committee therefore included warnings about hyperstimulation, monitoring uterine activity and fetal condition, and a possible reduced response to tocolysis. The recommendations have now been amended to recommend low dose oral misoprostol as an alternative to dinoprostone (and not just when dinoprostone has failed to work) but the committee have continued to follow the MHRA advice to provide warnings about its use.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-------------------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | Kerr RS, Kumar N, Williams MJ, Cuthbert A, Aflaifel N, Haas DM, Weeks AD. Low-dose oral misoprostol for induction of labour. Cochrane Database of Systematic Reviews 2021, Issue 6. Art. No.: CD014484. | |
| British Intrapartum Care Society | Guideline | 015 | 023 | BICS supports highlighting the need for further evidence for the use of osmotic dilators in IOL. | Thank you for your comment. We have now amended the recommendations to include osmotic cervical dilators, based on a re-review of the data and stakeholder feedback. |
| British Intrapartum Care Society | Guideline | 016 | | BICS thanks the committee for clarifying guidance on when to switch from AN to IP CTG interpretation | Thank you for your comment and for your support for this recommendation. |
| British Intrapartum Care Society | Guideline | 016 | 019 - 021 | It is common practice to conduct a CTG before and immediately after the insertion of a pessary for induction. This seems to have originated when the early prostaglandins could cause immediate hypotension. This is not the case with modern pharmacological preparations, but the practice continues. BICS considers that members would benefit from the guidance specifically stating that this is not necessary. | Thank you for your comment. Assessment and monitoring were not included in the scope of this update so it was not possible to make changes to the monitoring required relating to pessary insertion. |
| British Intrapartum Care Society | Guideline | 031 | 012 | BICS is concerned that recommendation 1.2.1.1 has been removed. Although it is clear from the new recommendations when IOL might be offered, BICS considers the principle of supporting women planning a vaginal birth to await spontaneous labour until 41+0 weeks remains true. | Thank you for your comment. Based on stakeholder feedback we have reinstated this recommendation into the guideline. |
| British Intrapartum Care Society | Evidence review B | 077 | 030 - 046 | BICS considers it is strange that the committee should note the MHRA warning about Misodelle (the withdrawn high dose, but slow release, preparation), and then use it to justify warnings about the low dose misoprostol preparations. The warnings related to hyperstimulation, which is the result of too high a dose. The lower dose does not have this effect (see the NICE evidence NMA ¹ and the Cochrane review ^{2,3}) and so should not be subject to the MHRA ruling. Indeed, the MHRA, by recently approving Augusta, is clear that the | Thank you for your comment. The MHRA had advised the committee to include warnings about the use of misoprostol, based on previous warnings about the hyperstimulation seen with the vaginal insert, and the committee therefore included warnings about hyperstimulation, monitoring uterine activity and fetal condition, and a possible reduced response to tocolysis. The recommendations have now been amended to recommend low dose oral misoprostol as an alternative to dinoprostone (and not just when dinoprostone has failed to |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------------|-------------------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>ruling is specific for the Misodelle dosage and delivery system and does not apply to all formulations of misoprostol.</p> <p>3. NICE guideline CG70 (update); Inducing Labour. [B] Methods for the induction of labour. Evidence review underpinning recommendations 1.3.2 and 1.3.6 to 1.3.12 in the NICE guideline, May 2021. Draft for consultation.</p> <p>4. Alfrevic Z, Aflaifel N, Weeks A. Oral misoprostol for induction of labour. Cochrane Database of Systematic Reviews 2014, Issue 6. Art. No: CD001338.</p> <p>Kerr RS, Kumar N, Williams MJ, Cuthbert A, Aflaifel N, Haas DM, Weeks AD. Low-dose oral misoprostol for induction of labour. Cochrane Database of Systematic Reviews 2021, Issue 6. Art. No.: CD014484.</p> | <p>work) but the committee have continued to follow the MHRA advice to provide warnings about its use.</p> |
| British Intrapartum Care Society | Evidence review B | 077 | 046 - 050 | <p>BICS considers whilst a recommendation to try a different induction agent makes sense, there is minimal evidence to support this.</p> <p>If a change in preparation is justified, then it would seem reasonable for it to be from dinoprostone to misoprostol or the reverse. There is no logic in having it one way and not the other, especially given the lower rates of CS and uterine hyperstimulation with oral misoprostol.</p> | <p>Thank you for your comment. The MHRA had advised the committee to include warnings about the use of misoprostol, based on previous warnings about the hyperstimulation seen with the vaginal insert, and the committee therefore included warnings about hyperstimulation, monitoring uterine activity and fetal condition, and a possible reduced response to tocolysis. The recommendations have now been amended to recommend low dose oral misoprostol as an alternative to dinoprostone (and not just when dinoprostone has failed to work) but the committee have continued to follow the MHRA advice to provide warnings about its use.</p> |
| British Maternal & Fetal Medicine Society | Evidence review B | | | <p>Whole document – only studies considering balloon catheters as mechanical methods are included</p> | <p>Thank you for your comment. There were additional mechanical methods of induction included: 15 included trials assessed the effectiveness of osmotic cervical dilators, 15 included trials assessed the effectiveness of double balloon or Cook's Catheter and 3 included trials assessed the effectiveness of amniotomy. Please see further details regarding the intervention and comparison</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | groups, outcomes reported, setting and funding in the evidence tables (supplement 3). |
| British Maternal & Fetal Medicine Society | Guideline | 006 | 020 - 023 | Concerned regarding the lack of evidence to support the recommendation to consider IOL from 39 weeks for women otherwise low risk uncomplicated singleton pregnancies with a black, Asian or minority ethnic family background- strongly suggest this is a research recommendation. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. There is already a research recommendation in the guideline to support further research in this area. |
| British Maternal & Fetal Medicine Society | Guideline | 006 | 010 | Pleased to see IOL is recommended from 41 weeks but concerned re capacity of maternity services to deliver this | Thank you for your comment. As a result of stakeholder feedback the guideline no longer recommends induction from 41+0 weeks. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| British Maternal & Fetal Medicine Society | Guideline | 006 | 010 | Pleased to see IOL is recommended from 41 weeks but concerned re capacity of maternity services to deliver this | Thank you for your comment. As a result of stakeholder feedback the guideline no longer recommends induction from 41+0 weeks. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| British Maternal & Fetal Medicine Society | Guideline | 007 | 013 | Pleased to see 'might' as this highlights the lack of evidence regarding frequency or components of monitoring post dates | Thank you for your comment and appreciating the uncertainty which surrounds this monitoring. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------------|-------------------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| British Maternal & Fetal Medicine Society | Guideline | 007 | 013 | Pleased to see 'might' as this highlights the lack of evidence regarding frequency or components of monitoring post dates | Thank you for your comment and appreciating the uncertainty which surrounds this monitoring. |
| British Maternal & Fetal Medicine Society | Guideline | 015 | 023 | Laminaria and Dilapan-S are grouped under osmotic dilators but they are different products. While Laminaria is not available in the UK due to risks of introducing infection, there is now growing evidence supporting the use of Dilapan-S (SOLVE RCT, COMRED RCT, DILAFOL RCT) - most suggest this method is not inferior to Dinoprostone and actually carries increased patient satisfaction | Thank you for your comment. The committee agreed that osmotic cervical dilators was the over-arching term that included all devices that worked by absorbing fluid and swelling in the cervix, and were also aware that there were both naturally-derived and synthetic products included in this category. The DILAFOL trial was included in the evidence review but there was no data on vaginal birth in 24 hours. We are also aware that the COMRED and SOLVE trials have been completed but has not been fully published yet. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date. However, based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour, so they have been removed from this list. |
| British Maternal & Fetal Medicine Society | Guideline | 016 | 019 - 021 | Misoprostol is used in the UK only in the context of intra-uterine fetal death and in these circumstances cardiotocography is not usually employed. Cardiotocography is routinely used to monitor live fetuses in all scenarios of induction of labour | Thank you for your comment. Oral misoprostol is now recommended as an option for induction with a live baby, so the recommendations on CTG monitoring apply to both dinoprostone and misoprostol. CTG can also be used to monitor uterine contractions and this would apply in both situations. |
| British Maternal & Fetal Medicine Society | Evidence review C | 021 | 004 - 006 | As Guideline the committee had identified the lack of evidence for the optimal gestational age at which to offer induction for higher risk groups (ie black, Asian and minority ethnic) they made a research recommendation to identify this and yet this group is explicitly mentioned in the recommendations themselves- this should only be a research recommendation. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| British Maternal & Fetal Medicine Society | Guideline | 028 | 026 - 030 | Good evidence (SOLVE, COMRED, DILAFOL) that Dilapan rather than osmotic dilators as a group is not inferior to Dinoprostone in achieving vaginal birth within 24 hours (80% success rate with both) and patient satisfaction if greater as no concerns of hyperstimulation | Thank you for your comment. Based on stakeholder feedback, the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour. The DILAFOL trial was included in the evidence review but |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------|-----------|-----------|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | there was no data on vaginal birth in 24 hours. We are also aware that the COMRED and SOLVE trials have been completed but has not been fully published yet. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date. |
| Caesarean Birth | General | General | General | Thank you for the opportunity to comment on this guideline draft. As stated earlier, the effort NICE has made to incorporate planned caesarean birth into this guideline, alongside expectant management and induction of labour options, is much appreciated. | Thank you for your comment. |
| Caesarean Birth | Guideline | 007 - 008 | 022 - 023 & 001 - 006 | Planned caesarean birth is not referred to in this section, though "caesarean birth" is listed as a risk beneath "When making a shared decision, take into consideration the following factors:". Did NICE consider including planned caesarean birth in 1.2.9 and/or 1.2.10? | Thank you for your comment. The management of PPRM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not added caesarean birth as an option. |
| Caesarean Birth | Guideline | 004 | 004 - 005 | <p>Re: This section should be read in conjunction with the NICE guidelines on antenatal care and intrapartum care.</p> <p>Please add a link to the NICE NG192 on Caesarean birth here too. It is equally relevant in the context of providing information to support decision making during pregnancy, especially as the very next two lines in this draft guideline state: "Discuss preferences about mode of birth with women early on in their pregnancy."</p> <p>As per the 2015 Montgomery Supreme Court judgment, more than six years ago: Once a woman is pregnant, the foetus has somehow to be delivered. ...The principal choice is between vaginal delivery and caesarean section. ...the risks to both mother and child from a caesarean section are so low that the National Institute for Health and Clinical Excellence (NICE clinical guideline 132, [new 2011] [para 1.2.9.5]) clearly states that "For women requesting a CS, if after discussion and offer of support (including perinatal mental health support for women with anxiety about</p> | Thank you for your comment. We have added a link to the NICE guideline on Caesarean birth as we agree that early discussions about mode of birth would need to include this option as well. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------|-----------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | childbirth), a vaginal birth is still not an acceptable option, offer a planned CS". It is important that the option of a planned caesarean birth, and information on the risks and benefits of both modes of birth, is not available only to those with knowledge and/or professional contacts prior to beginning their NHS antenatal care. | |
| Caesarean Birth | Guideline | 004 | 009 | Re: might affect their birth options Suggest: might affect their plan birth options | Thank you for your comments. We have added further detail to these recommendations to clarify how a woman's options for birth may be affected, such as their planned place of birth. |
| Caesarean Birth | Guideline | 004 | 009 | Re: their experience of the birth process Suggest (or similar): their birth process and birth outcome experiences. It is important to communicate that induction of labour may affect birth outcome/s as well as the birth process. | Thank you for your comments. We have added further detail to these recommendations to clarify how a woman's options for birth may be affected, such as their birth outcomes. |
| Caesarean Birth | Guideline | 004 | 010 | Re: This could include that: This list focuses on induction comparisons with expectant management (awaiting spontaneous labour), but does not include comparisons with a planned caesarean birth. The need for an emergency caesarean birth is lower, for example, with a planned caesarean birth. | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on the relative risks of expectant management or caesarean birth. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Caesarean Birth | Guideline | 005 | 009 - 010 | Re: the alternative options if the woman chooses not to have induction of labour This should be very specific in naming "planned caesarean birth" as an alternative option to induction of labour. | Thank you for your comment. We have not added caesarean birth to this recommendation as the committee considered this would need to be an individualised discussion, depending on the indication of induction, and could include expectant management or caesarean birth. |
| Caesarean Birth | Guideline | 005 | 013 - 014 | Re: and what the woman's options would then be. Suggest: and how this would affect the woman's options. | Thank you for your comment. We have amended this wording as you suggest. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Caesarean Birth | Guideline | 005 | 018 - 019 | Re: encourage women to look at other information about induction (for example, information on the NHS website) Suggest: encourage women to look at other information about induction (for example, information on the NHS website), and the alternatives to induction (add relevant link here) | Thank you for your comment. The committee agreed that this recommendation related to information about induction (not about considering modes of birth in general) so we have not made this change. |
| Caesarean Birth | Guideline | 005 | 022 | Re: support the woman in whatever decision she makes. This is an excellent, and most welcome, inclusion in the guideline. Thank you | Thank you for your comment and support of the increased focus on woman's decision-making. |
| Caesarean Birth | Guideline | 006 | 020 - 024 | Re: Consider induction of labour from 39+0 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications associated with continued pregnancy (for example, BMI 30 kg/m ² or above, age 35 years or above, with a black, Asian or minority ethnic family background, or after assisted conception). This section could be better communicated as a description of women who have been identified in research evidence as having a higher risk of complications. If mode of birth is discussed with all women early in pregnancy (as per 1.1.1, above), and their preferences confirmed at 38 weeks, by 39+0 weeks, all women would understand their birth plan choices. They would know the offer of induction of labour or planned caesarean birth is there, alongside the option of awaiting spontaneous labour, and understand they can make their own decision. Knowing that all women are being offered these same options, and all free to make their own choice based on their own birth preferences and tolerances, this reduces the problem of some women feeling targeted or pressured to do one thing or another (mode of birth pressure can be experienced both ways: too much too soon, too little too late). Providing information and all options, then listening to and supporting all women, would go a long way to reducing the current inequities in birth choices and health outcomes. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Caesarean Birth | Guideline | 006 | 010 - 011 | Re: In uncomplicated singleton pregnancies, offer induction of labour at 41+0 weeks, to take place then or as soon as | Thank you for your comment. The majority of stakeholders who responded to the consultation have stated that they |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>possible afterwards. Why is this not offered sooner, at 39 +0 weeks?</p> <p>I understand there may be concerns by some that the word "offer" could make some women feel pressured into having an induction (or planned caesarean birth), but far stronger verb emphasis has been used in the context of other birth plan choices in maternity care (e.g. home birth, midwifery-led units, VBAC), such as "suggest", "recommend", "advise". It is very important that women <i>are</i> offered different mode and place of birth choices.</p> <p>Also, NICE is recommending the inclusion of planned caesarean birth during discussions about induction of labour, and caesarean birth is usually scheduled closer to 39+0 weeks than 41+0 weeks, so how would this work here? The logic is unclear, and could be challenging to communicate and manage in clinical practice. My organisation suggests the earlier offer (or at least clear information about the option) of induction of labour and planned caesarean, emphasising that this offer does not need to be decided or acted on at 39+0 weeks, and the woman can absolutely decide she wants to await spontaneous labour.</p> <p>Alternatively, change "offer" to "inform women about" these options/ their choices.</p> | <p>feel that even offering induction at 41 weeks is too early. Based on this feedback, we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based.</p> |
| Caesarean Birth | Guideline | 006 | 012 - 013 | <p>Re: Explain to women that the risks associated with a pregnancy continuing beyond 41+0 weeks increase over time For balance, could NICE include some information here about the reported benefits of expectant management too?</p> | <p>Thank you for your comment. it was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Caesarean Birth | Guideline | 006 | 002 | Prevention of prolonged pregnancy Suggest: Managing risks with prolonged pregnancy (or) Managing prolonged pregnancy Or Managing risks with continued pregnancy (see #19 below) | Thank you for your comment. We have changed the title of this section to 'Pregnancy lasting longer than 41 weeks'. |
| Caesarean Birth | Guideline | 006 | 004 | Re: reconfirm a woman's preferences for birth Suggest: confirm the woman's preferences for birth, which may or may not have changed. The current wording (reconfirm) may not be ideal here. It's important to strike a balance between acknowledging that women's preferences can change as their pregnancy progresses (e.g. particularly if their level of concern has changed, perhaps due to differences in fetal movements, for example), and not making the woman feel as though she has to re-explain/ defend/ request her preferences again at such a late stage in pregnancy. It is also important that the 38-week antenatal visit is not interpreted by maternity care staff as the time when a 'final' decision about mode of birth is made (given recommendation 1.1.1., above: "Discuss preferences about mode of birth with women early on in their pregnancy"). This can happen in practice. | Thank you for your comment. We agree that discussions about mode of birth should take place earlier in pregnancy, and we have now moved this recommendation to the section of the guideline on information and decision-making. We have also removed the proscribed weeks at which these discussions must take place so they can fit around current antenatal appointment scheduling. We have also amended the wording to say 'confirm a woman's preferences for birth, which may have changed since earlier discussions.' |
| Caesarean Birth | Guideline | 006 | 009 | Re: planned caesarean birth Thank you for including this here. In previous NICE consultations, my organisation has emphasised the importance of offering women this birth plan alongside induction of labour, and its inclusion is much appreciated. | Thank you for your comment and support of this addition to this recommendation. |
| Caesarean Birth | Guideline | 006 | 010 | Re: uncomplicated singleton pregnancies One important lesson learned from maternity litigation cases is the number of pregnancies and births that were managed differently because they were deemed "low risk" (uncomplicated), and went on to become "high risk" (with serious adverse health outcomes) very quickly. Every life precious, however the pregnancy is labelled, and my organisation's concern is that "offer induction of labour at | Thank you for your comment. We appreciate that complications can occur in pregnancies that were originally defined as low risk. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------|-----------|---------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>41+0 weeks" may be interpreted (and managed) in some NHS hospitals as "do not offer induction of labour before 41+0 weeks".</p> <p>What if the current pregnancy is uncomplicated, but a previous pregnancy and/or birth was traumatic? What if the current pregnancy is uncomplicated, but the woman has expressed preferences and/or concerns that fall within staff definitions of 'normal' in pregnancy? There are many reported cases where it is only <i>after</i> problems have occurred that the woman becomes knowledgeable about the birth plan options she could/should have been offered sooner.</p> | which these tables are based. We have therefore removed the text about 'uncomplicated singleton pregnancies'. |
| Caesarean Birth | Guideline | 006 | 014 & 018 - 019 | <p>Re: increased likelihood of caesarean birth Re: a possible increased likelihood of assisted vaginal birth (using forceps or ventouse).</p> <p>Could these two be combined, to include the possibility of both occurring? Suggest: increased likelihood of emergency caesarean birth a possible increased likelihood of assisted vaginal birth (using forceps or ventouse), or both.</p> <p>Or if kept separate, at least appear next to each other in the list.</p> | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. These outcomes have therefore remained separate as the risks differ. |
| Caesarean Birth | Guideline | 006 | 014 | <p>Re: increased likelihood of caesarean birth Please change to: increased likelihood of emergency caesarean birth</p> | Thank you for your comment. Some of the studies included in the evidence review did not specify whether the caesarean was planned or emergency and in one study both types were included, so we have not specified 'emergency' here. |
| Caesarean Birth | Guideline | 006 | 020 | <p>Re: Consider induction of labour Suggest: Offer induction of labour</p> <p>The language used here has changed, and it is not clear why. "Consider" may be interpreted as though the decision lies with the health provider rather than the woman, and it will only be offered/ discussed after their professional consideration.</p> | Thank you for your comment. 'Offer' is the wording used by NICE to reflect a recommendation based on strong evidence, and 'consider' is where there is more uncertainty. Based on stakeholder feedback we have amended the recommendations for earlier induction for certain groups of women and instead included information on increased risks from a national audit (MBRRACE). |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | Alternatively, change to: Consider and offer/discuss induction of labour... | |
| Caesarean Birth | Guideline | 006 | 022 | Re: continued pregnancy The section is titled "prolonged pregnancy"; suggest consistency by choosing one. | Thank you for your comment. This recommendation was replaced with information from the most recent MBRRACE report and so no longer uses the terminology 'continued'. |
| Caesarean Birth | Guideline | 006 | 026 | Re: the risk of complications If this is kept in, and not edited as suggested in previous comment, could this read: the risks and benefits | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Caesarean Birth | Guideline | 007 | 018 - 020 | Re: Advise women to contact their maternity unit as soon as possible if they change their mind before their next appointment, or have concerns about their baby, for example reduced fetal movements. The language here ("if they change their mind") could be improved. Suggest: Advise women to contact their maternity unit as soon as possible if their decision changes before their next appointment, or if they have any concerns about their baby (especially reduced or unusual fetal movements). | Thank you for your comment. The committee agreed that it is important that women are advised to contact their maternity unit if they have concerns about their baby, or that some women may decide that, as they have still not gone into spontaneous labour, they wish to re-discuss their options for birth, and so this recommendation has not been changed. However, we have amended the description of fetal movements to include reduced or altered fetal movements, as you suggest. |
| Caesarean Birth | Guideline | 007 | 004 - 005 | Re: Discuss the woman's care options from this point on with her. It is not clear what this means or refers to, and seems superfluous following the previous sentence. Suggest deleting. | Thank you for your comment. We have amended the wording to clarify that care options refers to options for birth (expectant management or caesarean birth). |
| Caesarean Birth | Guideline | 007 | 011 - 012 | Re: prevented even with monitoring Suggest: prevented, even with monitoring | Thank you for your comment. We have added the comma as you suggest. |
| Caesarean Birth | Guideline | 007 | 003 | Re: Support the woman's decision, including her choice of place of birth, Please change to: Support the woman's decision, including her choice of place and mode of birth, | Thank you for your comment. We have amended this recommendation to that mode of birth should be discussed if women decline induction of labour. |
| Caesarean Birth | Guideline | 007 | 006 | Re: Offer increased fetal monitoring Is the word "increased" necessary here? Do you mean "additional"? Suggest: Offer fetal monitoring | Thank you for your comment. We have changed this to 'additional' as you suggest. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Caesarean Birth | Guideline | 007 | 009 | Re: deterioration after monitoring ends Could NICE change the word "deterioration" here? Collectively, some of the language in this guideline does not appear appropriately balanced in the context of communicating genuine birth plan choices with women, including expectant management. | Thank you for your comment. We have changed 'deterioration' to 'changes'. |
| Caesarean Birth | Guideline | 007 | 014 | Re: ultrasound estimation of maximum amniotic pool depth Could this be rewritten using lay language? | Thank you for your comment. This is a term used to define a particular measurement obtained using ultrasound and so the committee agreed that it was necessary to use this terminology. |
| Caesarean Birth | Guideline | 007 | 016 | Re: Offer women who decline induction of labour an opportunity Suggest rewording/reframing with more positive/affirmative language: Offer women who decide to await spontaneous labour/ choose expectant management the opportunity | Thank you for your comment. We have reworded this recommendation to use the more positive framing you suggest, and to emphasise that women can choose whether or not to discuss their decision again. |
| Caesarean Birth | Guideline | 008 | 018 - 029 | Re: Prelabour rupture of membrane at term (sections 1.2.12 and 1.2.13) Why is planned caesarean birth not included in this section as a third option? | Thank you for your comment. The management of PROM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not added caesarean birth as an option. |
| Caesarean Birth | Guideline | 009 | 001 - 002 | Re: Support the woman's decision if she chooses not to have induction of labour after 24 hours. Suggest instead: Support the woman's decision if she chooses continued expectant management or planned caesarean birth | Thank you for your comment. We have amended the text to discuss options for birth if the woman chooses to wait for the spontaneous onset of labour. |
| Caesarean Birth | Guideline | 009 | 002 - 003 | Re: Discuss the woman's care options from this point on with her. See comment #22 above. | Thank you for your comment. We have amended the text to discuss options for birth if the woman chooses to wait for the spontaneous onset of labour. |
| Caesarean Birth | Guideline | 009 | 023 - 024 | Re: even when it would benefit their or their baby's health Suggest: even when advised it would benefit their or their baby's health | Thank you for your comment. We have amended the wording of this recommendation to say '...when it may benefit their or their baby's health.' to reflect the uncertainty. |
| Caesarean Birth | Guideline | 009 | 020 | Re: caesarean birth Suggest: planned caesarean birth | Thank you for your comment. We have added the word 'planned' as you suggest. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Caesarean Birth | Guideline | 010 | 002 - 004 | Re: Consider requests for induction of labour only after discussing the benefits and risks with the woman, taking into account the woman's circumstances and preferences. Suggest: Discuss the benefits and risks with the woman, taking into account the woman's circumstances and preferences. Or change to: Agree to/ Support requests...only after... | Thank you for your comment. The committee agreed that the current order of wording in this recommendation highlighted better that requests for induction should only be considered in specific circumstances. |
| Caesarean Birth | Guideline | 010 | 002 - 004 | Also suggest including gestational age in this recommendation. | Thank you for your comment. Gestational age would be covered under 'woman's circumstances' so we have not added this to the recommendation. |
| Caesarean Birth | Guideline | 010 | 020 - 022 | Re: Offer women with suspected fetal macrosomia, and without diabetes, the choice of induction of labour or expectant management after a discussion of the benefits and risks of both options. It is imperative that "planned caesarean birth" is included in these options. Again, thinking about Montgomery (2015), and the principle that all women should be informed about the risks and benefits of both birth modes (vaginal and caesarean), planned caesarean birth is conspicuous by its absence here in the context of macrosomia. Particularly if NICE considers research evidence showing the birth plan choices doctors make for the births of their own children when fetal macrosomia is suspected; it is unethical to withhold this information and option from the lay population. This shocking case is an example of how macrosomia is managed in some NHS hospitals in 2021: https://www.dailymail.co.uk/femail/article-9520151/Mum-astonished-gave-birth-13lbs-baby-girl-second-biggest-UK.html | Thank you for your comment. We have added caesarean birth into this recommendation as an option for birth. |
| Caesarean Birth | Guideline | 010 | 027 - 029 | Re: there is evidence showing no difference in the risk of perinatal death, brachial plexus injuries in the baby, or the need for caesarean birth between the 2 options. There is evidence that planned caesarean birth (the 3 rd option) does reduce this risk. | Thank you for your comment. We have added caesarean birth into this recommendation as an option for birth, and have also amended the wording of the recommendation relating to risks to emergency caesarean birth. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------|-----------|---------|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | Also please change to: the need for emergency caesarean birth | |
| Caesarean Birth | Guideline | 010 | 023 - 024 | Re: there is limited evidence that induction of labour could reduce the risk of shoulder dystocia There is evidence that planned caesarean birth does reduce this risk. | Thank you for your comment. The review carried out for this question compared the risks of induction of labour with expectant management, so we are unable to add detail about the risks of these outcomes for caesarean birth (although logically of course, planned caesarean would negate this particular risk, it does carry other risks). |
| Caesarean Birth | Guideline | 010 | 025 - 026 | Re: there is very limited evidence that induction of labour could increase the risk of third- or fourth-degree perineal tears There is evidence that planned caesarean birth does reduce this risk. | Thank you for your comment. The review carried out for this question compared the risks of induction of labour with expectant management, so we are unable to add detail about the risks of these outcomes for caesarean birth (although logically of course, planned caesarean would negate this particular risk, it does carry other risks). |
| Caesarean Birth | Guideline | 010 | 008 | Re: Consider induction of labour for babies in the breech position if: Should this list also include "the woman does not want expectant management"? | Thank you for your comment. We agree that many women will choose to await spontaneous labour if their baby is breech, but the first bullet of this recommendation was 'birth is indicated' so this recommendation applies when the decision has been made that birth needs to be expedited. To clarify this we have now changed the wording in the recommendation to 'If birth needs to be expedited...' |
| Caesarean Birth | Guideline | 010 | 012 | Re: the woman chooses not to have an elective caesarean birth. Please change to: the woman chooses not to have a planned caesarean birth. | Thank you for your comment. We have 'elective' to 'planned' here. |
| Caesarean Birth | Guideline | 011 | | Re: Base the choice of care It is not clear what this means. Does NICE mean that the healthcare provider makes the choice of care for the woman? It should be the woman who makes the decision about her maternity care birth plan, and again, this can only be a truly informed decision if the offer of a planned caesarean birth is available for all women (not just those with information and knowledge gathered outside their antenatal visits). | Thank you for your comment. This recommendation has been reworded to make it clear that this is a discussion with women about their options for birth, and that these options include caesarean birth. |
| Caesarean Birth | Guideline | 011 & | 017 -021 001 - 003 | Re: Intrauterine fetal death (1.2.26) Can NICE make this recommendation clearer please: which | Thank you for your comment. There are no options in brackets which are not recommended. The first of these 2 |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------|-----------|--------------|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | 012 | | of the three options in brackets are not recommended for discussion with each of the three conditions? For example, if membranes are not intact, is NICE suggesting here that the option of a caesarean birth should not be discussed? In the next line (1.2.27), it says: "if there is evidence of ruptured membranes, infection or bleeding, offer immediate induction of labour or caesarean birth." | recommendations state that if the woman has intact membranes then the options to be discussed are expectant management, induction or caesarean. In the second recommendation (where there is evidence of ruptured membranes, infection or bleeding), induction or caesarean birth are suggested as options. We think this is clear and so have not amended these recommendations. |
| Caesarean Birth | Guideline | 011 | 003 - 004 | Re: Support recruitment into clinical trials, if available. Can the NICE guideline group please explain the reason for this inclusion, and also whether it has knowledge of any specific (current or planned) trials in this context? Thank you Given the absence of "planned caesarean birth" in many parts of this draft guidance, my organisation is concerned that proposed trials seeking recruitment in NHS hospitals (with NICE's recommendation for participation) may only include two options: expectant management and induction of labour. | Thank you for your comment. This group was highlighted for inclusion in clinical trials as the committee were aware of an ongoing clinical trial (Big Baby) which will provide specific data on the role of induction in suspected fetal macrosomia, compared to expectant management. |
| Caesarean Birth | Guideline | 013 | 010 | Re: Obtain consent from the woman before carrying out membrane sweeping. An important recommendation, thank you. | Thank you for your comment. |
| Caesarean Birth | Guideline | 013 | 016 | Re: Consider additional membrane sweeping Suggest: Offer additional membrane sweeping (or) Consider and offer additional membrane sweeping | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, the likelihood of success, optimal timing or frequency. However, we have amended this recommendation to emphasise that additional membrane sweeping should only be considered after a discussion with the woman. |
| Caesarean Birth | Guideline | 017 & 018 | 017 - 027 & 001 - 007 | Re: Outpatient induction There are no recommendations in this section about communicating the risks and benefits to women when offering this option. This is an important omission. | Thank you for your comment. The recommendations have been amended to clarify that the discussion with the woman should include the risks and benefits. |
| Caesarean Birth | Guideline | 017 | 009 - 010 | Re: Explain to women being offered induction of labour that induced labour is likely to be more painful than spontaneous labour | Thank you for your comment. We have amended the recommendation to state that induced labour may be more painful than spontaneous labour, but have not included a |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | Suggest: Explain to women being offered induction of labour that induced labour is likely to be more painful when compared to spontaneous labour. I suggest this as planned caesarean birth has not been included in the section on pain relief. It would be helpful to reference NG192 on Caesarean birth here too. | reference to the caesarean birth guideline here, as pain experiences and pain relief used in caesarean birth would be very different. |
| Caesarean Birth | Guideline | 018 | 019 - 021 | Re: taking into account the clinical circumstances Suggest: taking into account the clinical circumstances and her preferences | Thank you for your comment. We have added in this text as you suggest. |
| Caesarean Birth | Guideline | 018 | 005 | Re: such as reduced fetal movements Suggest: such as reduced or unusual fetal movements | Thank you for your comment. We have amended this recommendation to state 'reduced or altered fetal movements' as the committee agreed that 'altered' was more commonly used than 'unusual'. |
| Caesarean Birth | Guideline | 019 | 001 | Re: Cord prolapse Can NICE explain why an ultrasound scan is not advised to assess cord complications (including, but not only prolapse)? Also, is offering a planned caesarean birth not also considered a precaution in this context (and particularly if an ultrasound scan identified any potential cord complications)? | Thank you for your comment. The recommendations on assessment before induction have been amended to include that an ultrasound scan should be carried if there are concerns about the position of the baby, and the option to offer a caesarean birth have been added to the recommendation on cord prolapse. |
| Caesarean Birth | Guideline | 021 | 014 - 016 | Re: At what gestational age should induction of labour be offered in the subgroups of women who may be more likely to experience adverse outcomes if pregnancy continues? [2021] Given that induction of labour is to be offered together with the option of planned caesarean birth, and as maternity care moves towards a more balanced approach to antenatal education and communication (discussing mode of birth options as well as place of birth options, early in pregnancy), it is unclear how this research question would be implemented/tested in practice? My organisation has provided comments in previous NICE publications related to the problem of having all these separate guidelines, designed at a time when vaginal birth for all women was the default option in maternity care, and interventions tended to be something considered and | Thank you for your comment. Further details of how this research could be conducted have been drafted by the committee and are available in Appendix L of Evidence Review C. Thank you for raising the issue of separate guidelines for different aspects of maternity care. This topic has already been considered by NICE as part of its 5-year strategy to develop living guidelines that reflect pathways of care, and we will ensure your comments are passed on to the appropriate team at NICE. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------|-----------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | decided by the healthcare team (the exception, rather than the rule) rather than the woman herself. It is vitally important that NICE's recommendations for research provide answers that will inform maternity care education and decision making of today, and the future. | |
| Caesarean Birth | Guideline | 021 | 017 - 019 | <p>Re: Based on individual patient data meta-analysis, what is the optimal timing of induction of labour? As above; a research study focusing on this question (at least in the present time) is very unlikely to include and compare the three options available to women in reality (and if they are informed about them): expectant management, induction of labour, and planned caesarean birth.</p> <p>This was a comment I made following the results of the ARRIVE trial, published in August 2018: <i>I propose a new 'THRIVE' trial that measures mortality and morbidity outcomes (incl. stillbirth and pelvic floor injuries) for babies and mothers following THREE pathways at 39 weeks: 1) expectant management, 2) IOL, 3) planned #caesarean 2/2</i> https://twitter.com/PaulineMHull/status/1027721549002854400</p> | <p>Thank you for your comment. Research recommendations are made in NICE guidelines when a search for evidence has been carried out and no or inadequate evidence has been found. In this update an evidence review was carried out to determine the optimal time to induce labour in longer pregnancies and as limited evidence was found research recommendations were made to determine the optimal time for induction in all women, and to determine if this differs in certain sub-groups of women. An evidence review was not carried out to compare the risks and benefits of induction of labour with expectant management and caesarean birth (including outcomes such as those you have mentioned) so it was not possible to create a research recommendation on this topic. However, the need for this review has been highlighted by several stakeholders and so this will be passed to the NICE surveillance team who are responsible for ensuring that NICE guidelines are up to date.</p> |
| Caesarean Birth | Guideline | 021 | 013 | <p>Re: Prevention of prolonged pregnancy Suggest title change, as above. "Prevention" may suggest that this is the aim or goal rather than one option for women to be informed about and make a decision on.</p> | <p>Thank you for your comment. We have removed the wording 'Prevention of..' as the committee agreed this may imply that prolonged pregnancy is a specific pathology.</p> |
| Caesarean Birth | Guideline | 022 | 024 - 027 | <p>Re: Is it safe, effective and cost effective to carry out induction of labour in an outpatient setting? What are the advantages and disadvantages of such an approach, taking into account women's views?</p> <p>This research recommendation reinforces my concern earlier (#49) that communicating risks of this option to women needs to be added. Especially as this is cited as a key driver: "there is an increasing desire to reduce the time women spend in hospital".</p> | <p>Thank you for your comment and support for this research recommendation, which has been carried forward from 2008. We have also amended the recommendations to emphasise that the risks and benefits of outpatient induction should be discussed with the woman, and more detail has been added to lists of reasons for contacting the maternity unit or midwife,</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Caesarean Birth | Guideline | 022 | 015 - 016 | Re: How should labour be induced in women with intrauterine fetal death who have had a previous caesarean birth? Can NICE confirm that this research recommendation is based on women who have chosen induction of labour and do not want a caesarean birth? Thank you | Thank you for your comment. Yes, this is based on women who have elected to be induced and not have a caesarean birth. We have clarified this in the research recommendation tables (in Evidence review D). |
| Caesarean Birth | Guideline | 022 | 018 | Re: maternal satisfaction This would be an important outcome to consider as an alternative research recommendation in the "Prevention of prolonged pregnancy" section, above. | Thank you for your comment. As you have identified the evidence on timing of induction was limited, and hence we have made 2 research recommendations relating to timing, and have added to the research recommendation tables (in Evidence review C) that longer term outcomes such as maternal satisfaction should be measured in this research. |
| Caesarean Birth | Guideline | 024 | 016 | Re: There was evidence that caesarean birth Please change to: There was evidence that emergency caesarean birth | Thank you for your comment. The evidence was for 'caesarean birth' and it was not specified if this was always emergency so this has not been changed, |
| Caesarean Birth | Guideline | 026 | 008 - 011 | Re: As there was not enough evidence to recommend one method over another, the committee recommended that women should be provided with information about both methods so they can make an informed decision Why did the committee not consider evidence on planned caesarean birth outcomes with macrosomia? | Thank you for your comment. The aim of this review was to determine whether induction of labour was beneficial compared to expectant management in suspected fetal macrosomia. Caesarean birth removes the risk of adverse events such as shoulder dystocia, brachial plexus injury or perineal injury, and so the committee did not wish to consider this in the same comparison. However, caesarean birth has now been added as an option for birth in this recommendation. |
| Caesarean Birth | Guideline | 026 | 014 | Re: Currently, there is variation in clinical practice Agreed; part of this variation is seen in the birth plan decisions made by doctors (for their own children's births) compared to women and their families who are not medical professionals. | Thank you for your comment. This view on the variation in practice was discussed by the committee but they did not agree that this reflected their experience, so we have not included this in the guideline. |
| Caesarean Birth | Guideline | 029 | 020 | Re: including caesarean birth, Please change to: including emergency caesarean birth, | Thank you for your comment. We have made this change and included the word emergency. |
| Caesarean Birth | Guideline | 030 | 008 - 009 | Re: when making decisions about induction of labour This emphasises the early point about these separate guidelines and research recommendations. If antenatal education and communication is working effectively in maternity care, women won't be 'making a decision about induction of labour' in isolation. | Thank you for your comment and support of the recognition that this the woman's decision. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------------|----------------------------|-----------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Caesarean Birth | Guideline | 030 | 001 | Re: (such as caesarean birth) Please change to: (such as emergency caesarean birth) | Thank you for your comment. We have made this change and included the word emergency. |
| Caesarean Birth | Guideline | 030 | 010 | Re: is appropriate Suggest: may be suggested | Thank you for your comment. We have changed the text to 'may be appropriate'. |
| Cambridge University Hospitals NHS Foundation Trust | Comments form | Q1 and Q2 | | In answer to question 1 and 2: Offering IOL for indications listed within this guidance will require large scale reorganisation of maternity services and has associated cost implications and capacity, staffing and flow implications. Consideration needs to be given to the capacity of services to undertake the increase in IOL to ensure that service users are not delayed during / throughout the process where they have been informed that IOL is clinically indicated. IOL numbers within our organisation would increase by a quarter to a third i.e. >2000 women a year instead of 1500 (approximately). | Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| Cambridge University Hospitals NHS Foundation Trust | Equality Impact Assessment | General | | The equality assessment does not demonstrate any engagement with groups representing those documented as being affected in coming to the conclusion that no differences in access to services would occur. When the recommendations (such as offer of induction at 39 weeks) are without a clear or strong evidence base yet are a universal offer based on characteristics including ethnicity then there is clear potential for less access to options (specifically the right to have a spontaneous onset to birth without additional coercion). There cannot be an effective equalities assessment without service user involvement from the documented groups. | Thank you for your comment. The committee included 2 lay members with lived experience of induction of labour and wider experience of representing people using maternity services. The consultation process is the additional method we use to obtain input into the guideline from a wide range of stakeholders and individuals, and to ensure that the guideline is fit for purpose. This guideline received over 3000 comments in this way, and each one was read and considered by the committee in order to amend and improve the guideline, and supporting documents such as the Equality Impact Assessment. Based on this stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. We have therefore amended section 4 of the EIA form to address these issues. |
| Cambridge University Hospitals NHS Foundation Trust | Evidence Review C | General | | Our service users commented that lack of evidence in the maternal quality of life and maternal satisfaction categories highlights lack of service user input, consultation and choices within these guidelines. (Lou et al, 2018, Keulen et | Thank you for your comment. The committee acknowledged the paucity of evidence for the outcome maternal satisfaction in this review, and they agreed that women's choice is key for providing optimal care in |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------------|----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | al. 2020). <i>Service User voice: "My primary concern is that it seems to be a move away from individualised care towards general categories."</i> | maternity services. Based on stakeholder feedback, the recommendations have been amended to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. |
| Cambridge University Hospitals NHS Foundation Trust | General | General | General | Definition / clarity in use of the term 'offer' as this may be interpreted differently across organisations implementing the guidance. Especially regarding the management once and 'offer' is declined. | Thank you for your comment. Offer is the standard NICE terminology used when there is good evidence to support a recommendation. The word 'offer' is also used as it is recognised that decisions are made with or by women, and so it highlights that the offer of treatment or intervention can be accepted or declined. |
| Cambridge University Hospitals NHS Foundation Trust | General | General | | Absolute statistics about items such as maternal or neonatal death should be included within the document by gestation, to support informed discussions. | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. |
| Cambridge University Hospitals NHS Foundation Trust | General | General | General | There is potential conflict between this proposed guidance and other NICE guidance, for example, in NICE intrapartum care guidance BMI 30-35kg/m2 indicates individual assessment when planning place of birth and birth on an obstetric led unit with BMI >35kg/m2. In the IOL guidance BMI >30kg/m2 alone is an indication for IOL, would IOL be indicated but possible to be conducted as an MLU IOL in these circumstances? Current NICE guidance on indications for CTG in labour does not cover ethnicity based risk or | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a conflict with other NICE guidance. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------------|-----------|---------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | assisted conception, or place these risk factors into factors that require individual assessment when planning place of birth. | |
| Cambridge University Hospitals NHS Foundation Trust | Guideline | 006 | 020 - 025 | The current guideline defines prolonged pregnancy as $\geq 42+0$ weeks gestation, and that induction prior to that gestation is for the prevention of prolonged pregnancy. We are concerned that the unstated effect of this recommendation is to redefine prolonged pregnancy as beginning two weeks earlier for a sub-group of women based on ethnicity, age, BMI and use of assisted conception. MMBRACE-UK reports increased perinatal mortality suffered by Black and Asian women and their babies, with ongoing investigation into the contribution of systemic racism in these poorer outcomes (Birthrights Inquiry into racial injustice in UK maternity services). The committee notes that evidence on timing of induction of labour is underpowered in relation to subgroups. The term 'assisted conception' is vague (implying the same risks apply to pregnancies conceived by donor insemination and in vitro fertilisation, not supported by the evidence), and may disproportionately affect the birth choices of service users with same sex partners. Women with higher BMI and advanced maternal age already have enhanced fetal monitoring in pregnancy which may prompt intervention. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Cambridge University Hospitals NHS Foundation Trust | Guideline | 006 | 014 - 018 | Provide absolute risks (1 in XXXX compared to 2 in XXXX) as well as relative risks ('increased likelihood') to better support informed decision making by women. Consider inclusion of immediate IOL risks and benefits as well as longer term health implications. | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------------|-------------------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. |
| Cambridge University Hospitals NHS Foundation Trust | Guideline | 006 | 020 | The use of the term 'consider' here would be better expressed as 'consider offering' in line with the use of 'offer' elsewhere in the guideline, and supporting women's choice. (also p. 10, line 8; page 12, line 16; page 14, lines 17 & 23 and page 17, line 18) | Thank you for your comment. 'Offer' is the wording used by NICE to reflect a recommendation based on strong evidence, and 'consider' is where there is more uncertainty. Based on stakeholder feedback we have amended the recommendations for earlier induction for certain groups of women and instead included information on increased risks from a national audit (MBRRACE). |
| Cambridge University Hospitals NHS Foundation Trust | Guideline | 007 | 006 - 007 | Clarity is needed here about whether this offer of increased fetal monitoring means that CTG should then be used in labour. Many women decline IOL in order to retain the option of labour on an MLU (as per p. 4 line 11-14). As it stands it is unclear whether NICE is recommending increased intrapartum fetal monitoring for women who decline IOL and whether MLU birth would be contraindicated if an offer of IOL or of enhanced fetal monitoring was declined. | Thank you for your comment. Women who go into spontaneous labour (after declining induction of labour and/or additional monitoring) would be cared for as recommended in the NICE guideline on Intrapartum care, and this would include guidance on appropriate place of birth. |
| Cambridge University Hospitals NHS Foundation Trust | Guideline | 007 | 006 | Our service users asked why offer increased monitoring if it is not able to predict deterioration or adverse events and whether consideration has been given to the potential negative outcomes of increased monitoring? The AFFIRM study did not find significant difference in outcome with increased surveillance. | Thank you for your comment. This recommendation has been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find this reassuring. Suggestions of what monitoring could be offered is provided but there is no evidence to confirm that monitoring can improve outcomes. |
| Cambridge University Hospitals NHS Foundation Trust | Evidence Review C | 013 | 004 | Give clarity that membrane sweeping is itself a form of induction and the risks involved eg accidental rupture of membranes. Whilst 20/28 defines it as an adjunct to induction of labour this downplays the intervention itself. What is the evidence base for offering sweeps prior to 40 weeks? There is a Cochrane review which noted the low evidence base for this intervention which is suggested in the proposed guidance to become routine and frequent pre-EDD (Finucane et al, 2020). | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, the likelihood of success, optimal timing or frequency, or the need for pain relief. However, the recommendations have now been clarified to state that membrane sweeps should be discussed after 39 weeks (as opposed to 'from 39 weeks') so sweeps will happen from week 40 onwards. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------------|-------------------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cambridge University Hospitals NHS Foundation Trust | Evidence Review C | 013 | 016 | 'Consider offering' not 'consider' | Thank you for your comment. This recommendation has been amended to state that the option of additional sweeps should be discussed with women. |
| Cambridge University Hospitals NHS Foundation Trust | Evidence Review C | 015 | 001 - 002 | This recommendation does not take into account the implications of IOL with amniotomy and IVI oxytocin on maternal experience, including in relation mode of fetal monitoring (precluding IA), the opportunity to labour in water and/or in an MLU and the need for IV access. The strong recommendation appears motivated in part by the economic evidence that there is a small cost saving in avoiding the use of vaginal prostaglandins (Evidence B). | Thank you for your comment. Based on stakeholder feedback, the recommendations have been amended to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. These also reflect the fact that induction of labour will affect women's birth options and their experience of the birth process. |
| Cambridge University Hospitals NHS Foundation Trust | Evidence Review C | 016 | 018 | Monitoring – this section provides no guidance on monitoring before and after amniotomy, nor on monitoring with oxytocin. The implications of method of induction for fetal monitoring (and therefore choices in labour). | Thank you for your comment. Details of monitoring following the use of dinoprostone or misoprostol are provided, due to the risk of hyperstimulation. Monitoring following the use on amniotomy and/or oxytocin is covered in the NICE guideline on intrapartum care, and this is referenced and linked from the recommendation.' |
| Cambridge University Hospitals NHS Foundation Trust | Guideline | 024 | 022 - 029 | Without a secure evidence base of benefit, this rationale, problematises large groups based on skin colour and BMI, reducing their access to spontaneous birth. Being at a higher risk of adverse effects in pregnancies that are post-term cannot be seen to justify induction pre EDD. The evidence tables (Evidence Review C, Appendix E) do not include any comparison of outcomes from 39-41 weeks. The comparison on P12 of the Evidence Review notes no clinically important difference between 39 weeks and 40-42 weeks in maternal and neonatal mortality. (documented in Dahlen et al, 2020).The committee have not taken account of the reasons why different ethnic groups may experience adverse outcomes in pregnancy. <i>Service User voice: "Being Black is not a medical reason for induction."</i> | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion of the risks of later versus earlier induction with the woman (and we have included tabulated details of absolute risks), so she can make an informed decision. We have also replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report. It was not within the scope of this update to review the risks and benefits of induction of labour compared to expectant management but the committee have updated the section on information and decision-making to include the factors that should be considered by women when making a decision about mode of birth. We have therefore updated this rationale section to reflect these changes to the recommendations. |
| Cambridge University Hospitals | Guideline | 024 | 012 - 015 | Our service users were disappointed that recommendations were made based on 'knowledge and experience' rather | Thank you for your comment. This section of the rationale relates to the general recommendations the committee made about discussing induction with women. The |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------------|----------------------------------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| NHS Foundation Trust | | | | than seeking an evidence base drawing on voices of service user relating to maternal experience and satisfaction. | committee has lay members and professional members who are mothers, and the recommendations have been updated based on stakeholder feedback, so they have taken service user experience into consideration. |
| Cambridge University Hospitals NHS Foundation Trust | Guideline | 024 | 028 | Use of term 'a pregnancy that was prolonged beyond term' has potential to confuse. Do they mean a pregnancy that continues beyond 41+6 (the upper limit of 'term', (37+0-41+6 inclusive) as usually defined). Or a pregnancy that continues beyond the EDD? | Thank you for your comment. In the context of this guideline the committee took term as 37 weeks. However, based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report. We have therefore updated this rationale section to reflect these changes to the recommendations. |
| Cardiff & Vale University Health Board | Key recommendations for research | General | General | This should include; Mechanical methods for induction of labour using synthetic osmotic dilators. Is it safe, effective and cost effective to carry out induction of labour with this method. Randomised controlled trials comparing with established pharmacological methods are needed as is an economic evaluation and studies exploring maternal satisfaction with the available induction options available. | Thank you for your comment. The committee were aware of a number of ongoing trials, many due to complete soon, relating to the use of osmotic cervical dilators compared to other methods of induction, so they did not make a research recommendation. |
| Cardiff & Vale University Health Board | Guideline | 004 | 019 | <p>This should be clarified to specify; Hormonal methods of induction can cause the uterus to contract too frequently. This risk is solely attributed to hormonal methods and is not a risk with mechanical methods of induction. It is important that clinicians counsel patients regarding this increased risk of undergoing hormonal methods of induction.</p> <p>The Cochrane review below set out to determine the effectiveness and safety of vaginal prostaglandins for third trimester cervical ripening and induction of labour (the cervix softens, shortens and opens, the uterus starts to contract regularly). Eight different comparisons were made, different vaginal prostaglandins were compared with placebos or no treatment, or other vaginal prostaglandins (PGE2, PGF2a, except misoprostol) and different preparations and dosages were compared. 70 studies were identified involving a total of 11,487 women. Vaginal prostaglandins increase the likelihood of vaginal birth within 24 hours, but they can also</p> | <p>Thank you for your comment. We have amended the recommendation to specify that this warning applies to pharmacological methods only.</p> <p>Thank you for informing us of the Cochrane review. The systematic review on methods of induction carried out for this guideline also looked at the benefits and harms of prostaglandins in a network meta-analysis and these results are reported in evidence review B.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>stimulate the uterus to contract too much and this may cause the baby's heart to slow, however they did not increase the caesarean section rate and may reduce it.</p> <p>Thomas J, Fairclough A, Kavanagh J, Kelly AJ. Vaginal prostaglandin (PGE2 and PGF2a) for induction of labour at term. Cochrane Database of Systematic Reviews 2014, Issue 6. Art. No.: CD003101. DOI: 10.1002/14651858.CD003101.pub3</p> | |
| Cardiff & Vale University Health Board | Guideline | 005 | 006 | <p>This should be clarified to state that women are likely to find induced labour with hormonal methods more painful than spontaneous labour. In a review of 169 women in our unit who received a synthetic osmotic dilator, only 1 woman required opioid based analgesia, with 147 women requiring no analgesia at all.</p> <p>One cohort study in Italy compared the effects of spontaneous (n = 31) and prostaglandin-induced labour (n = 30) on the minimum analgesic dose (MAD) of epidural sufentanil in the first stage of labour in women (at or after 37 weeks of gestation with cervical dilation 2–4 cm) requesting epidural pain relief in labour. The initial dose was sufentanil 25 micrograms and analgesic effectiveness was assessed using 100 mm visual analogue scale (VAS) pain scores. The MAD of sufentanil in spontaneous labour was 22.2 micrograms (95% CI 19.6 to 22.8 micrograms) and 27.3 micrograms (95% CI 23.8 to 30.9 micrograms) in induced labour, and the latter was significantly greater than that in spontaneous labour (P = 0.0014) by a factor of 1.3 (95% CI 1.1 to 1.5). Reported sedation/drowsiness effects were significantly higher in the induced group (P = 0.024). This suggests that prostaglandin induction of labour produces a greater analgesic requirement than does spontaneous labour.</p> <p>Capogna G. Minimum analgesic dose of epidural sufentanil for first-stage labor analgesia: a comparison between</p> | <p>Thank you for your comment. The review on methods for induction included an outcome of 'need for epidural' and the results of the NMA showed there was variation in the need for an epidural for different interventions but no clear pattern suggesting mechanical methods were less painful than pharmacological methods. We have therefore not made this change to the recommendation.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>spontaneous and prostaglandin-induced labors in nulliparous women. <i>Anesthesiology</i>. 2001;94(5):740–4.</p> <p>Schwarzc RL, Belizan JM, Cifuentes JR, et al. Fetal and maternal monitoring in spontaneous labors and in elective inductions. A comparative study. <i>American Journal of Obstetrics and Gynecology</i>. 1974;120(3):356–62.</p> | |
| Cardiff & Vale University Health Board | Guideline | 009 | 012 | <p>This should be clarified to specify hormonal induction of labour could lead to an increased risk of uterine rupture. In our unit, all women with a scarred uterus are offered induction with a synthetic osmotic dilator to mitigate against the risk of uterine rupture.</p> <p>In a large retrospective population-based study, Lydon-Rochelle 2001 evaluated the risk of uterine rupture among women with a prior caesarean birth, comparing the risks following the spontaneous onset of labour, as well as following induction of labour (using both prostaglandin and other methods to induce labour). Where labour occurred spontaneously, the risk of uterine rupture was reported to be 5.2 per 1000 women (56 of 10,789 women), increasing to 7.7 per 1000 women (15 of 1960 women) where labour was induced with “non-prostaglandin” methods, and further increasing to 24.5 per 1000 women (nine of 366 women) where labour was induced with prostaglandin preparations. When expressed as a risk ratio (RR) comparing the chance of uterine rupture among women who had a repeat elective caesarean section, spontaneous labour increased the chance of rupture by three-fold (RR 3.3, 95% confidence interval (CI) 1.8 to 6.0), induction with non-prostaglandin methods by almost five-fold (RR 4.9, 95% CI 2.4 to 9.7), and induction with prostaglandin preparations by over 15.5-fold (RR 15.6, 95% CI 8.1 to 30.0). Specific information was not presented for different prostaglandin preparations (for example, PGE2, or misoprostol)</p> | <p>Thank you for your comment and for sharing these study results with us. The recommendations on methods of induction state that mechanical methods of induction should be used in women who have had a previous caesarean birth, so are in-line with these findings.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cardiff & Vale University Health Board | Guideline | 010 | 017 | <p>This recommendation takes away all patient choice. Our clinical experience is that women with fetal growth restriction who wish to experience a vaginal delivery, may be safely offered induction of labour with synthetic osmotic dilators. In a review of 169 women who received a synthetic osmotic dilator in our unit, no women had an abnormal cardiotocography assessment post insertion. 161 women had an Apgar score of 7 or more at 1 minutes and 168 women had an Apgar score of 7 or more at 5 minutes. Only 8 babies required Neonatal Intensive Care Unit admission. A Cochrane review on mechanical methods of induction of labour concluded that there is low- to moderate-quality evidence that shows mechanical induction with a balloon is probably as effective as induction of labour with vaginal PGE2. However, a balloon seems to have a more favourable safety profile. More research on this comparison does not seem warranted.</p> <p>Moderate-quality evidence shows a balloon catheter may be slightly less effective as oral misoprostol, but it remains unclear if there is a difference in safety outcomes for the neonate. When compared to low-dose vaginal misoprostol, low-quality evidence shows a balloon may be less effective, but probably has a better safety profile.</p> <p>de Vaan MD, Ten Eikelder ML, Jozwiak M, et al. Mechanical methods for induction of labour [published online ahead of print, 2019 Oct 18]. Cochrane Database Syst Rev. 2019;10(10):CD001233. doi:10.1002/14651858.CD001233.pub3</p> | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add more details about induction methods for this indication. |
| Cardiff & Vale University Health Board | Guideline | 012 | 017 | <p>A safer alternative would be to offer mechanical methods of induction with a synthetic osmotic dilator or balloon catheter to avoid the risk of uterine rupture.</p> | Thank you for your comment. In order to make the recommendation more helpful, we have used the same wording as that used for women who are giving birth to a live baby and who have had a previous caesarean birth, which suggests that methods used for induction will need to take into account the risk of uterine rupture, for example by using mechanical methods. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------|---------------------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cardiff & Vale University Health Board | Guideline | 015 | 023 | This is potentially misleading for patients and healthcare providers. Greater and immediate clarity is required to explain that osmotic cervical dilators are not analogous to synthetic osmotic dilators, which are being used with increased frequency in an increased number of maternity units. . | Thank you for your comment. The committee agreed that osmotic cervical dilators was the over-arching term that included all devices that worked by absorbing fluid and swelling in the cervix. |
| Cardiff & Vale University Health Board | Guideline | 017 | 009 | This should be re-phrased to; explain to women being offered induction of labour that pharmacological induced labour is likely to be more painful than spontaneous labour. | Thank you for your comment. The committee did not make this change to the recommendation as even induction of labour which commences with a mechanical method may later require the use of an oxytocin infusion, which may increase the strength of contractions and associated pain. |
| Cardiff and Vale University Health Board | Guideline | 006 | 010 | The recommendation to offer Induction of labour to uncomplicated pregnancies at 41+0 needs to be reconsidered in light of evidence published by Dahlen et al 2021, showing that induction of labour leads to more intervention and more adverse maternal, neonatal and child outcomes. Dahlen HG, Thornton C, Downe S, et al Intrapartum interventions and outcomes for women and children following induction of labour at term in uncomplicated pregnancies: a 16-year population-based linked data study BMJ Open 2021;11:e047040. doi:10.1136/bmjopen-2020-047040 | Thank you for your comment. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. |
| Care Quality Commission (CQC) | Guideline - General | General | General | CQC has a concern about the blanket recommendation around the induction of labour for women from Black, Asian and minority ethnic backgrounds on the basis of race. Whilst there is evidence of a higher risk of poor outcomes for women from these backgrounds, we feel that this should be part of the information that supports women to make informed decisions and have concerns about such a blanket recommendation. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Care Quality Commission (CQC) | Guideline - General | General | General | We know from our work with www.fivexmore.com that Black women already do not currently feel well-heard or well-informed about birth choices and options. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------|---------------------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>Five x more are leading the Black Maternity Survey 2021. In consultation work for the maternity safety enquiry last year, Five x more found 33% of Black women did not feel confident in maternity staff being committed to ensuring safe birth and did not feel well-informed about birth choices and options.</p> <p>For example;</p> <ul style="list-style-type: none"> • 45% of Black women surveyed did not feel informed about vaginal birth, • 78% did not feel informed about home birth, • 70% did not feel informed about water birth, • 73% did not feel informed about c-section, • 85% did not feel informed about assisted birth. | with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Care Quality Commission (CQC) | Guideline - General | General | General | <p>We also know from other recent research (which NICE may already be aware of) that;</p> <ul style="list-style-type: none"> • 78% of Black women surveyed in the UK do not believe their health is equally protected by the NHS compared to white women (Research by the Joint Committee on Human Rights, Sept 2020). • Black and minority ethnic women can be unheard and under-valued by maternity services, as staff, women and families who use services during the pandemic (Turning the Tide report, Oct 2020). • Poor care was identified as a factor in perinatal deaths during COVID-19 period, including poor communication, follow up and personalised care on the part of staff (MBRRACE Rapid Review March-May 2020). | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|------------------------|---------|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Care Quality Commission (CQC) | Guideline - General | General | General | It would also be helpful to know how NICE has considered equality and human rights impacts in drafting this guideline update. | Thank you for your comment. The equality impacts of the updated guideline are described in the Equality Impact Assessment form that is provided on the NICE website, with the other supporting documents. |
| Care Quality Commission (CQC) | Guideline Guideline | 6 6 | 12 (1.2.3) 20 (1.2.4) | <p>The paragraph that refers to ethnicity is unclear.</p> <p>Paragraph 1.2.3 (in relation to induction of women at 41+0 weeks) starts "Explain to women...."</p> <p>But paragraph 1.2.4 (in relation to induction of women at 39+0 weeks in specific circumstances - including ethnicity and age 35+) starts "Consider induction..."</p> <p>This could be read that relating to the factors in para 1.2.4; it is the clinician's decision, rather than the woman's decision.</p> <p>Having re-read the paragraph, this is not only a potential blanket decision on race, but also on age. Both of these are protected characteristics under the Equality Act 2010.</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | General | General | given language is of 'consider' IOL, decline might be better replaced with 'women who choose not to have IOL' etc.. | Thank you for your comment. We have changed decline to 'chose not to' as you suggest, except in the recommendations for breech birth where it made the wording extremely unwieldy. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | General | General | There appears no evidence that Black and Brown women are physically less able to maintain a pregnancy beyond 39 weeks, but rather they are impacted by societal problems of racism and discrimination. It is surprising that a medical intervention is provided to a solution to the multifactorial factors of these issues, especially as it exposes them to the risks of poorly conducted induction of labour (ignoring hyperstimulation, poor interpretations of CTGs etc which may be higher in this group) | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from certain ethnic family groups. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | General | General | An audit of our cases over the last twelve months suggests that implementation of these guidelines would to an increase of 1176 hours work in the antenatal period for counselling women on their choices, and if the offer was taken up by all women, 2689 additional inductions of labour, resulting in 4.5 | Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | additional inductions across both of our sites per day. Women who have their labours induced have twice the length of stay as those that go into labour spontaneously. Therefore this guideline would result in 3369 days additional length of stay in our unit. We could not implement this guideline without a very large estates and staffing investment, and we suggest NICE discusses the impacts with NHSE about the funding issues. | there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | General | General | Implementation of these guidelines could have potentially prevented five stillbirths in the last 12 months within our organisation. (1 ethnicity, 2 BMI, 2 aged over 35). We are not sure if the blanket suggestion of offering inductions for all women in these groups at 39 weeks will fix the problem, especially with the current evidence base | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | General | General | The unintended consequences to implementing these guidelines appear large. For those who accept the offer of an induction, this includes increased risk of OASI tear rates, emergency CS during labour which could increase their risk for pre-term birth in subsequent pregnancies, public health impact of decreased breastfeeding rates. For those not in the at risk groups who labour spontaneously there is a risk that units will be too busy to facilitate their births and cases incorrectly triaged due to the business of the unit, which could have catastrophic consequences. | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. Based on these changes, and the fact that 98.9% of women who go into spontaneous labour will have done so by 42+0 weeks, the committee recognised that this may lead to an increase in the number of inductions for some units, depending on their current induction rates at different gestational ages. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | General | General | Consideration will need to be made on whether we counsel women and birthing people using national or local data when the offer of an induction of labour is made and adequate time and resources allocated to appointments where these discussions take place using appropriately designed | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update and so we are unable to provide data tables as you suggest. However, the committee have expanded the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|--------------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | decision aids to ensure we meet the requirements of Montgomery. We suggest you provide data tables to aid these discussions, as was done with the intrapartum care guidelines for place of birth choice. | recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also added in tables which provide risk data for earlier versus later induction which we hope will be helpful for discussions between healthcare professionals and women. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 004 | 016 - 018 | Where is the evidence that assisted vaginal birth might increase? Maybe better to write: there may be a need for an assisted vaginal birth, with the associated increased risk oftears) – but not to write an “increase” in assisted vaginal birth | Thank you for your comment. We have amended the wording of this recommendation as you have suggested. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 004 | 019 | Current: some methods of induction can cause the uterus to contract too frequently, called hyperstimulation, and that these too-frequent contractions can lead to changes in fetal heart rate and result in concerns about fetal wellbeing. Suggested amendment: Some methods of induction can cause the uterus to contract too frequently and that these too- frequent contractions can lead to changes in fetal heart rate and result in concerns about fetal wellbeing (called hyperstimulation). | Thank you for your comment. We have amended this sentence to make it clear what hyperstimulation is, and have also added a definition of hyperstimulation to the 'terms used' section and the separate glossary supplement. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 005 | 006 - 008 | Where is the evidence that women “are likely” to find induced labour more painful? Maybe better to write: recognise that some women may find induced labour more painful | Thank you for your comment. We have made the change to 'may be more painful'. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 006 1.2.1 | | The practicalities of offering all women planned CS birth at 38/40 would create huge challenges around accommodating not only the in depth conversations around this as a mode of birth, but also counselling and scheduling those that choose this option. As we know our CS lists are booked weeks, | Thank you for your comment. We agree that discussions about mode of birth should take place earlier in pregnancy, and we have now moved this recommendation to the section of the guideline on information and decision-making. We have also removed the proscribed weeks at which these discussions must take place so they can fit around current antenatal appointment scheduling. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|--------------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>sometimes months in advance. This would impact both capacity and safety enormously.</p> <p>Secondly, as part of routine shared antenatal care with GP practices, we do not see women at 38/40. This appointment is routinely done by the GP. A change such as this would see an extra appointment for the 6000+ women who have a baby with us each year. <u>This appointment would also not be feasible in 20 minutes should we need to discuss CS birth as an option for 'prolonged' pregnancy.</u></p> | |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 006 | 012 - 019 | Would be useful to quantify the 'increased likelihood' of these events to support a woman to make an informed choice. | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 006 1.2.1 | 003 | Comment: A 38/40 appointment is too late to reconfirm a woman/s preference for birth. This should be done earlier at 36 weeks. From experience most women want a level of certainty and 2 weeks is not enough. It also does not provide adequate time to plan for IOL or planned ELCS. | Thank you for your comment. We agree that discussions about mode of birth should take place earlier in pregnancy, and we have now moved this recommendation to the section of the guideline on information and decision-making. We have also removed the proscribed weeks at which these discussions must take place so they can fit around current antenatal appointment scheduling. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 006 1.2.3 | 012 | Comment: NICE needs to provide data in terms of simple risk stratification of the increased likelihood of Caesarean birth, admission to neonatal unit, stillbirth and neonatal death and assisted vaginal birth compared to women who labour spontaneously at 41+0. Women will want to know this data. How can we as clinicians therefore advise? | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 006 1.2.4 | 020 | We already offer IOL at term for babies conceived with assistance due to the independent risk factor IVF conveys. We already offer IOL at term for maternal age and the evidence is clear this risk is doubled from age of 40. Could NICE consider making the point about offering IOL from 39 | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | weeks if a woman has multiple risk factors associated with an increased risk of stillbirth and if so consideration of induction of labour from 39 weeks should be discussed and offered. Again NICE needs to provide data with simple risk stratification. | report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 006 | 021 | Replace risk with chance | Thank you for your comment. The term risk is mainly used as a synonym for 'harm' in this guideline, as in the term 'risks and benefits', and is also used to imply the probability of a negative outcome, whereas chance could mean a negative or positive outcome. We have therefore not changed 'risk' to 'chance'. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 006 | 026 | Replace risk with chance | Thank you for your comment. The term risk is mainly used as a synonym for 'harm' in this guideline, as in the term 'risks and benefits', and is also used to imply the probability of a negative outcome, whereas chance could mean a negative or positive outcome. We have therefore not changed 'risk' to 'chance'. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 008 | 018 - 029 | Thank you for making this guidance clearer. | Thank you for your comment. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 008 1.2.11 | 013 | Could we clarify the option for women who have previous GBS and have decided to have IAP in this labour rather than screening for GBS at 35-37 weeks [as per RCOG GTG] – could NICE be clearer on their management. | Thank you for your comment. This guideline focuses on induction of labour to reduce the risk of neonatal infection with ruptured membranes, but advice on the use of intrapartum antibiotic prophylaxis during labour would still apply and is not covered in this guideline, but is covered in the NICE guideline on neonatal infection (NG195). |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 009 1.2.15 | | In this section the guidance states that women who rupture their membranes at term and have a hx of GBS should be offered immediate IOL or CS birth. From what I can see this is based upon 'the committees knowledge and experience of the risks of GBS' as opposed to evidence on the benefit of such an intervention. This concerns me as we are greying the area of GBS colonisation as an indication for CS birth. I would be interested to see the evidence on this, as it would impact the counselling we give to women with GBS on mode of birth significantly | Thank you for your comment. This recommendation was based on the fact that induction of labour or caesarean birth were recommended for women with a history of GBS with preterm (between 34 and 37 weeks) prelabour rupture of the membranes in the new NICE guideline on neonatal infection (NG195). This was based on evidence for increased neonatal infections with expectant management compared to immediate birth. The committee noted that there was no equivalent recommendation for women with PROM at term (at or after 37 weeks) but that babies were |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|-----------------------------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | likely to be at the same risk of increased infection with expectant management, and so added a recommendation to cover this situation. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 009 | 004 - 007 | What about women who have previous GBS and have decided to have IAP in this labour rather than screening for GBS at 35-37 weeks [as per RCOG GTG] – could this be clearer to offer them immediate IOL as well. | Thank you for your comment. This guideline focuses on induction of labour to reduce the risk of neonatal infection with ruptured membranes, but advice on the use of intrapartum antibiotic prophylaxis during labour would still apply and is not covered in this guideline, but is covered in the NICE guideline on neonatal infection (NG195) and we have added a link to this from the recommendation. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 009 | 017 | Replace delivery with birth | Thank you for your comment. We have changed this to birth. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 010 1.2.21 | | Here it states that women should not be induced if there is fetal growth restriction with confirmed fetal compromise, but instead be offered CS birth. I believe this needs expanding upon as to what exactly is meant by 'confirmed fetal compromise' as it reads ambiguously to me. We often induce women with SGA babies so this is another big consideration. | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add a definition of confirmed fetal compromise. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 010 1.2.19 and 1.2.20 | | We suggests the section on 'Breech Presentation' is re-written to reflect the ethos of informed choice and discussion, in a similar manner to the section on 'Previous caesarean birth.' A guideline on IOL with breech presentation is only applicable to women who have chosen to plan a vaginal breech birth. The guideline should reflect and respect this, using neutral, non-judgemental language. For example: 1.2.19 Advise women with a baby in the breech position, who have chosen to plan a vaginal breech birth, that: <ul style="list-style-type: none"> induction of labour could lead to an increased risk of emergency caesarean birth, compared to spontaneous breech labour | Thank you for your comment. Induction of labour with breech presentation was not included in the scope of this guideline update and so we have not been able to add more detail about the risks and benefits of induction, compared to a spontaneous labour and so we have not made the changes you suggest to these recommendations. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <ul style="list-style-type: none"> induction of labour could lead to an increased risk of neonatal intensive care unit admission for the baby, compared to spontaneous breech labour the methods used for induction of labour will be guided by the need to reduce these risks. See the recommendations on methods for inducing labour. <p>1.2.21 If birth is indicated, offer women who have a baby in the breech position a choice of:</p> <ul style="list-style-type: none"> an attempt at external cephalic version, immediately followed by induction of labour if successful caesarean birth or induction of labour in breech presentation <p>Take into account the woman's circumstances and preferences. Advise women that they are entitled to decline the offer of treatment such as external cephalic version, induction of labour or caesarean birth, even when it may benefit their or their baby's health.</p> | |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 010 | 017 - 018 | Fetal compromise – as assessed by what means? CTG? Dopplers? | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add a definition of confirmed fetal compromise. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 010 | 007 | A breech presentation | Thank you for your comment. We have amended the title of this section to 'position' to ensure continuity of terminology |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 010 | 008 | In breech presentations | Thank you for your comment. We have amended the title of this section to 'position' to ensure continuity of terminology |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 010 | 009 | Replace delivery with birth | Thank you for your comment. We have changed 'delivery' to 'birth'. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 010 1.2.21 | 017 | Could we have definition of what entails 'fetal growth restriction with confirmed fetal compromise | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add a definition of confirmed fetal compromise. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 010 | 020 | Do we have the evidence for 'offer' – the Big Baby study is awaited. Would consider be more reasonable based on the current evidence? | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 010 1.2.22 | 020 | Could NICE advice on a gestational age for IOL and the evidence base. At present the Big Baby trial is not reported so should we be careful in making the statement 'Offer' and instead use the word 'Consider offering' | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. The committee discussed whether it was possible to define the best time to induce labour in suspected fetal macrosomia but the evidence included induction at a range of gestational ages and it was not possible to identify the preferred gestational age. The committee also considered this would be an individualised decision based on the estimated size of the baby, the woman's clinical circumstances and her preferences. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 010 | 020 | change offer to consider given current evidence | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 012 | 021 - 022 | So what should we use then? | Thank you for your comment. In order to make the recommendation more helpful, we have used the same wording as that used for women who are giving birth to a live baby and who have had a previous caesarean birth, which suggests that methods used for induction will need to take into account the risk of uterine rupture, for example by using mechanical methods. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 012 | 021 | Difficult to rationalise this statement. It is less specific for women with scar and live baby and does not offer any suitable options for consideration. | Thank you for your comment. In order to make the recommendation more helpful, we have used the same wording as that used for women who are giving birth to a live baby and who have had a previous caesarean birth, which suggests that methods used for induction will need to take into account the risk of uterine rupture, for example by using mechanical methods. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 013 | 010 | Verbal consent? | Thank you for your comment. We have added that this is verbal consent. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 014 1.3.11 | | Here, mechanical methods for IOL are recommended only where pharmacological methods aren't deemed suitable, or the woman chooses mechanical over pharmacological. This is not our current Trust practice, as per the audit of local evidence of outcomes related to balloon IOL. There appears to be no link to explain the reason for this recommendation, or the evidence around it. | Thank you for your comment. We have amended the recommendations to ensure women are informed that the risks of hyper stimulation may be lower with mechanical methods of induction, and so if mechanical methods are preferred by women, there would be no limitation to using this method. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 016 | | Thank you for clarifying guidance on when to switch from AN to IP CTG interpretation | Thank you for your comment and for your support for this recommendation. |
| Chelsea & Westminster | Guideline | 017 | | Comment: there is no evidence I have seen to date that demonstrates that induced labour is more painful than | Thank you for your comment. The committee's experience was that induced labour was reported (by women who had |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|-----------------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hospitals NHS Foundation Trust | | 1.5.7 and 1.5.8 | | <p>spontaneous labour. This language appears insensitive to both sets of women that one type of labour is less or more painful than another and perpetuates a misconception.</p> <p>Suggested amendment: The arrangements for support and pain relief should be discussed with the woman balancing that every woman has a different perception and threshold for pain regardless of whether the labour is induced or spontaneous in onset.</p> | experienced both spontaneous and induced labour) as more painful, although we agree that individual perceptions of pain may differ. However, the committee amended the recommendation to state that induced labour may be more painful, instead of more likely. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 017 1.5.6 | | <p>there is no evidence I have seen to date that demonstrate s that induced labour is more painful than spontaneous labour. This language appears insensitive to both sets of women that one type of labour is less or more painful than another and perpetuates a misconception.</p> <p>Suggested amendment: Explain to women being offered induction of labour that they are able to have a range of pain relief during the process and this can be escalated according to their needs [2008]</p> | Thank you for your comment. The committee's experience was that induced labour was reported (by women who had experienced both spontaneous and induced labour) as more painful, although we agree that individual perceptions of pain may differ. However, the committee amended the recommendation to state that induced labour may be more painful, instead of more likely. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 017 | 009 - 010 | <p>Same comment as above (comment 2) in terms of ... induced labour "is likely" to be more painful ... Maybe better to write: Explain to women being offered induction of labour that some women may find induced labour more painful than spontaneous labour.</p> | Thank you for your comment. We have amended the recommendation to state that induced labour may be more painful than spontaneous labour. |
| Chelsea & Westminster Hospitals NHS Foundation Trust | Guideline | 020 | 005 | <p>Bishop score: include a table with the Bishop score in the appendix of the guideline</p> | Thank you for your comment. The guideline aims to provide advice and recommendations on areas of uncertainty in clinical practice, and not to replace a medical textbook or other resources, and so we have not included this in the guideline. |
| Chesterfield Royal Hospital NHS FT | Guideline | 004 | 006 | <p>1.1.1 Discuss preferences about mode of birth with women early on in their pregnancy. – what is meant by early in weeks?</p> | Thank you for your comment. We have not provided a specific time in pregnancy at which discussions about mode of birth should start as this may vary between women, but we have clarified that in most cases (if the woman wishes) this will be an ongoing conversation during pregnancy and not a one-off discussion. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Chesterfield Royal Hospital NHS FT | Guideline | 007 | 016 | 1.2.7 Offer women who decline induction of labour an opportunity to revisit their options with a healthcare professional at least once a week. – in my opinion it is less frequent time to discuss and needs to be clarified in detail. e.g. if declined at 41 weeks -weekly revisit of options may increase complications e.g. stillbirth | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again. |
| Chesterfield Royal Hospital NHS FT | Guideline | 009 | 001 | 1.2.14 Support the woman's decision if she chooses not to have induction of labour after 24 hours. Discuss the woman's care options from this point on with her. – needs to clarify in detail e.g. should be advised/discussed with immediate vs delayed IOL (with risks and benefits) to help to choose the right choice and then support. | Thank you for your comment. The management of PROM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline. However, this new recommendation was added to clarify that after 24 hours it would be an individual decision about how long the woman would like to wait for spontaneous labour. As no evidence review was carried out we have been unable to add details of the risks and benefits of different options. |
| Chesterfield Royal Hospital NHS FT | Guideline | 010 | 020 | 1.2.20 HSIB recommendation of baby estimated weight more than 4 KG, should be considered for IOL vs LSCS | Thank you for your comment. The evidence review conducted for this guideline compared induction of labour with expectant management, and the definition of fetal macrosomia used was therefore based on the evidence from these studies. We did not consider evidence compared to caesarean birth and so are unable to include details on weight cut-offs above which caesarean birth would be indicated. |
| Chesterfield Royal Hospital NHS FT | Guideline | 012 | 021 | 1.2.31 Be aware that both dinoprostone and misoprostol are contraindicated in women with a uterine scar. In my opinion "Beware" is a comment with uncertainty. As any prostaglandin preparation are not licensed to be used with previous scar, there should be an option to use any mechanical dilator | Thank you for your comment. In order to make the recommendation more helpful, we have used the same wording as that used for women who are giving birth to a live baby and who have had a previous caesarean birth, which suggests that methods used for induction will need to take into account the risk of uterine rupture, for example by using mechanical methods. |
| Chesterfield Royal Hospital NHS FT | Guideline | 013 | 010 | Obtain consent from the woman before carrying out membrane sweeping – needs to clarify that verbal consent and documented in notes. Written not needed. | Thank you for your comment. We have added that this is verbal consent. |
| Chesterfield Royal Hospital NHS FT | Guideline | 014 | 023 | For women with a Bishop score of 6 or less, consider a mechanical 23 method to induce labour (for example, a balloon catheter) | Thank you for your comment. The evidence base for this review was sub-grouped based on a Bishop score of 6 or less, or a Bishop score of more than 6, so it is not possible to change this to something less prescriptive. Based on |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>Is it possible to change from Bishop score to "Feel of the cervix"? scoring system is very much prescriptive.</p> <p>Other choices apart from Balloon catheter should be there e.g, cervical osmotic dilator in general. The role of "Cervical osmotic Dilator" should be recognised and mentioned</p> | <p>stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour.</p> |
| City, University of London | Guideline | 004 | 008 | <p>I am pleased to see that the committee have included a comprehensive set of recommendations to give women more information about the risks of induction of labour. I would like to see more information on the specific impacts of the use of synthetic oxytocin – especially it's effect on labour contractions, but also that it prevents the body from using its own oxytocin to help manage some challenging aspects of labour (particularly pain). Synthetic oxytocin does not produce the same calming, mind-altering effects as natural oxytocin.</p> | <p>Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data the effect of oxytocin. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth.</p> |
| City, University of London | Guideline | 006 | 003 | <p>This recommendation does not include any recognition that length of pregnancy might normally vary between individual women; that for some women pregnancy may last beyond 42 weeks and this does not mean that it is 'prolonged'.</p> | <p>Thank you for your comment. To aid discussion about the normal length of pregnancy we have added information into the guideline about the percentages of labour which start spontaneously at each week of gestation. Furthermore, the committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the birth of preterm babies.</p> |
| City, University of London | Guideline | 006 | 010 | <p>I am concerned about the quality of evidence presented to support this recommendation. It is a significant change in guidance that will limit many women's choices for their own births – including place of birth. It will deny them many of the other benefits of birth in midwifery-led units, including improved safety for those with straightforward pregnancies (Birthplace 2011). The evidence seems predominantly low quality and does not justify the enormous 'on the ground' change that this represents.</p> | <p>Thank you for your comment. The methodological limitations of the included trials were reflected in the evidence report and taken into consideration by the committee when interpreting the evidence. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| City, University of London | Guideline | 006 | 020 | <p>(1st response) I am concerned that the evidence behind this recommendation is not robust enough – the literature review supplied does not adequately answer whether IOL reduces the risk of maternal morbidity and mortality and perinatal morbidity and mortality for this select group of women.</p> <p>(2nd response) I am concerned this recommendation has been included based on very little evidence beyond the knowledge and expertise of the committee despite the potential for serious unintended consequences.</p> <ol style="list-style-type: none"> 1. There is concern over the potential for stigmatisation of these groups of women, in that they will be considered not fit enough to carry a pregnancy to term, based on their weight, age, race, ethnic background or fertility. There is no evidence that this will have any impact on poor outcomes. In fact, induction of labour is an intervention that is associated with significant risk itself. In addition, women who identify (or who are identified by others) as coming from Black, Asian and ethnic minority backgrounds will routinely be presented with different options for care than other women. 2. Categorising all people from Black, Asian and ethnic minority backgrounds as 'high risk' is particularly troubling. Given the absence of evidence for this the recommendation risks introducing a form of racial bias into routine maternity care. We also have recognised a discrepancy as to whether the committee is defining Black, Asian and ethnic minority women as a "high risk group". While guidance document states they are "at a higher risk of complications associated with prolonged pregnancy", Evidence Review C labels Black, Asian and ethnic minority women as a "higher risk group" (Evidence review C – Timing, Page 19, Line 46). There is concern | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>that this recommendation is an example of 'race-based medicine', or "the system by which research characterising race as an essential, biological variable, translates into clinical practice, leading to inequitable care" (https://doi.org/10.1016/S0140-6736(20)32076-6). If Black, Asian and ethnic minority women are being regarded, as appears to be the case, as a high-risk group based on their skin colour, this implies that race is a biological variable that impacts women's pregnancy outcomes and can thus be controlled for via induction of labour. This reiterates the racist idea that Black, Asian and ethnic minority people are somehow biologically different from and inferior to white people, and I am concerned Rec 1.2.4 implies this. There is a history of discriminatory and racist treatment of Black, Asian and ethnic minority women in maternity, which has contributed to inequitable care and poorer outcomes. The recommendation renders race and ethnicity the problem, rather than racism and discrimination, despite the recognition from the RCOG, RCM, researchers, advocacy groups, and service users themselves that these are impacting women's care. The oversight in acknowledging this when citing outcomes among Black, Asian and ethnic minority women, as well as the treatment of these women as one group, shows that the committee has failed to consider the optics of this guideline.</p> <p>I recognise the desire to improve outcomes for these groups of women; however I would like to add reflection on this recommendation on the committee's part. I recommend that the committee reflect on why they find it appropriate to induce low-risk Black, Asian and ethnic minority women but not low-risk white women based on so little evidence, and</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>why they felt they had the power to regulate certain women's bodies but not others</p> <p>(3rd response) Whilst the poor outcomes for women from a minority ethnic background, higher BMI and older women is well recorded, I am appalled that the suggestion that universal induction of labour will improve outcomes. The systematic, institutional racism experienced by women of colour in the NHS should not ever be blamed on them. NICE can not blame women's bodies for the discrimination they experience that contributes to their poor outcomes. By attempting the 'fix' the problem by 'fixing' women's bodies, we will be ignoring any other causes for differences in outcomes for these groups of people. If the committee can't find the evidence for why these outcomes occur then they should commit to finding out.</p> <p>Most women in the world are women of colour. The committee cannot suggest that most of the world's women are incapable of safely birthing their own babies at term? The difference in the experience of British Black and Asian women is the racism they experience within our society and the overspill of this into the maternity care system. The impacts of institutional racism have been well documented and the committee should look outside of the clinical evidence to social sciences for more evidence on this.</p> <p>Furthermore, the impact of universal induction of labour for these women would result in:</p> <ul style="list-style-type: none"> - Many babies born prematurely and the long term implications for this (even in late premature births); - Women denied the chance to attempt a physiological labour; - The psychological consequences of feeling like your body is inherently faulty and incapable of birthing, before it has even been given the chance to try; | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>- Denying women in the additional safety of out of labour ward birth for straightforward pregnancies.</p> <p>This recommendation has implications not only for the induction of labour, but also for how the maternity services is publicly seen to view women and their bodies in future guidance. NICE should not be setting a precedent for racist, stigmatising guidance that presents women's bodies as inherently faulty and incapable because they happen to be Brown, larger or older. It also suggests the NHS would rather turn a blind eye to uncovering the real reasons for the discrepancies in outcomes for these groups of women.</p> <p>The committee itself describes the lack of evidence behind their own recommendation. Including such a guideline based on no evidence would discredit the entire NICE guidance development process. As a researcher, I am horrified that guidance affecting such a huge proportion of the population might even be put forward with no evidence-base.</p> <p>(4th response) – I would like to add to the points above that NICE guidelines not only have an effect on practice in the UK, but are used by countries around the world as the basis of their local guidelines, including some with majority BAME populations. What will happen when 99% of a population is advised to be induced early?</p> <p>That this is being recommended based on such low-level evidence, without any investigation into (a) the experience of women being induced, (b) evidence of long term adverse outcomes for mothers and babies which has begun to emerge (c) a credible economic evaluation of such a wholesale increase in the medicalisation of birth or (d) an equality impact assessment, is shocking and irresponsible.</p> <p>NICE should define (and justify) what they mean by 'Black and Minority Ethnic' – what about women from Eastern</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>Europe, Latin America and the Middle East? What about travellers who are known to have some of the worst outcomes but who are mostly ethnically 'White'? The difference in adverse maternal and neonatal outcomes varies enormously between groups, depending on the issue (one of the few to look at this is Puthussery et al. Ethnic variations in risk of preterm birth in an ethnically dense socially disadvantaged area in the UK: a retrospective cross-sectional study. <i>BMJ Open</i>. 2019;9(3):e023570). PHE' recommendations from 2020: Maternity high impact area 6 Reducing the inequality of outcomes for women from Black Asian and Minority Ethnic BAME communities and their babies.pdf did not find evidence that earlier induction would address disparities in outcomes based on ethnicity – instead it pointed to the value of high-quality care (i.e. Continuity of Care), multi-disciplinary working and social support. We need more research into exactly which groups are affected, in what way, and why, before we can theorise what interventions may reduce such disparities. The 2020 MBRRACE report pointed to 'a constellation of biases' being closely associated with poor outcomes. Will NICE's guideline be, in itself, construed as part of the bias which disadvantages already marginalised groups?</p> | |
| City, University of London | Guideline | 006 | 023 | <p>The Government's Women and Equalities Committee have recently published a report on the government's obesity strategy, stating that the measurement "BMI" should no longer be used in healthcare settings – a health at every size approach should be adopted instead. Identifying and categorising risk based on a woman's BMI should therefore not be in use in this guideline</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |
| City, University of London | Guideline | 006 | 023 | <p>Identifying a woman's race/ethnicity as a risk factor for poorer outcomes suggests that these women struggle to achieve the same outcomes as white women due to their biology, when rather evidence suggests that these women suffer poorer outcomes due to a constellation of bias and systemic racism. BME women experience better outcomes</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------|-----------|---------|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | with healthcare professionals they have relational continuity with and when they experience equity in healthcare provision, not when they are given higher rates of intervention | |
| City, University of London | Guideline | 007 | 006 | Please clarify when twice weekly monitoring should take place – this guideline suggests that fetal monitoring should take place from the point of declining induction – for some women this will be at 39 weeks. But the accompanying evidence documents suggests that fetal monitoring should take place from 42 weeks. This will be challenging in practice in places with high ethnic diversity e.g. London because this guideline suggests that women should come in for twice weekly monitoring if induction is declined. 68% of births happen at 39 weeks and beyond – a substantial proportion of these women will have a BMI >30, BME women and women over 35 – where will these women go to have their twice weekly monitoring in units that are already struggling with acuity and resources? | Thank you for your comment. Other recommendations (for example 1.2.2 and 1.2.4) have been amended so it is unlikely that the cohort of women being offered and declining induction will change significantly. This recommendation has also been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The options to do CTG and amniotic pool depth are only provided as suggestions, carried over from the previous version of the guideline, and have been in place since 2008, so it is unlikely these recommendations will have an impact on resources. |
| Cook Medical | General | | | Our concern is that the reduced risk of uterine hyperstimulation associated with mechanical methods is not discussed with women as part of this conversation. It is Cook Medical's opinion that all patients should be provided with uterine hyperstimulation risk information for all three of the recommended methods so that they can make the most informed decision with their practitioner. For a woman to fully comprehend and choose a suitable method, she must first understand the important aspects of security for both, mechanical and pharmaceutical options. Therefore, we suggest that the reduced risk of uterine hyperstimulation with mechanical induction methods be described in 1.3.7. | Thank you for your comment. We have amended this recommendation to make it a wider discussion about the risks and benefits of different methods of induction, and included that the risks of hyperstimulation are lower with mechanical methods. |
| Cook Medical | Guideline | 013 | 022, 023 | Section 1.3.7 states, "Discuss with women the risks of pharmacological methods to induce labour". | Thank you for your comment, although it appears just to replicate the recommendation. However, we have now amended this recommendation to include other methods of induction. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------|-------------------|-----------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cook Medical | Guideline | 014 | 023 - 028 | In the Draft Guidelines, Section 1.3.11 states “For women with a Bishop score of 6 or less, consider a mechanical method to induce labour (for example, a balloon catheter) if: <ul style="list-style-type: none"> • pharmacological methods are not suitable (for example, in women with a higher risk of hyperstimulation or those who have had a previous caesarean birth) or • the woman chooses to use a mechanical method.” | Thank you for your comment. |
| Cook Medical | Evidence Review B | 022 – 023 | 014, 015 006, 007 | In fact, Tables 6 and 7 in Evidence Review B shows that “Double Balloon or Cook’s Catheter” with a probability of 34% of being the best treatment of all interventions for hyperstimulation with fetal heart rate changes, and along with nitric oxide donor, were similarly effective and rank highly at minimising the risk of hyperstimulation. | Thank you for your comment. The committee acknowledged that double balloon or Cook catheters were effective and appeared to rank highly at minimising the risk of hyperstimulation with fetal heart rate changes. These interventions were also shown to have considerable efficacy at promoting vaginal birth within 24 hours, no significant effect on the need for caesarean or instrumental birth, no significant effect on NICU admission or epidural use. However, the committee decided to prioritise vaginal dinoprostone because it was more effective at promoting vaginal birth within 24 hours for women with a Bishop score of 6 or less, without significantly increasing the risk of adverse outcomes for the woman or her baby. |
| Cook Medical | Evidence Review B | 076 | 001 - 004 | Evidence Review B, page 76, lines 1-4 state “The committee discussed the main aim of induction of labour – to promote vaginal birth as safely as possible – and the committee therefore focused primarily on the outcome of no vaginal birth within 24 hours, but also balanced this with the evidence for hyperstimulation as this is one of the main concerns when inducing labour.” | Thank you for your comment. On the basis of that rationale, the committee agreed to recommend vaginal dinoprostone because it was more effective at promoting vaginal birth within 24 hours for women with a Bishop score of 6 or less, without significantly increasing the risk of adverse outcomes for the woman or her baby. |
| Cook Medical | Evidence Review B | 077 | 004 - 006 | The committee also states in Evidence Review B, page 77, line 4-6 “that hyperstimulation may be increased with vaginal dinoprostone (PGE2) preparations, as compared to placebo – this increase was significant for the vaginal gel and normal and slow release pessaries.” | Thank you for your comment. The committee acknowledged this and made a recommendation regarding the need to discuss the risks of pharmacological methods, including the fact that dinoprostone preparations can cause hyperstimulation. |
| Cook Medical | Evidence Review B | 078 | 005 - 013 | Additionally, the committee stated in Evidence Review B, page 78, lines 5-13 that they considered single balloon catheter and double balloon catheters to have the lowest chance of causing hyperstimulation and should therefore be considered safe and effective. | Thank you for your comment. The committee acknowledged that double balloon or Cook catheters were effective and appeared to rank highly at minimising the risk of hyperstimulation with fetal heart rate changes. These interventions were also shown to have considerable |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | efficacy at promoting vaginal birth within 24 hours, no significant effect on the need for caesarean or instrumental birth, no significant effect on NICU admission or epidural use. However, the committee decided to prioritise dinoprostone as vaginal tablet, vaginal gel or controlled-release vaginal delivery system or low dose (25 micrograms) oral misoprostol tablets dinoprostone because these were more effective at promoting vaginal birth within 24 hours for women with a Bishop score of 6 or less, without significantly increasing the risk of adverse outcomes for the woman or her baby. |
| Doula UK | Guideline | General | General | Many women and birthing people report that the offer of induction is presented to them as a demand, and that they are unaware that they can decline this recommendation. Those who try to decline induction report being coerced into accepting it. Any guideline on induction should very clearly reiterate that women and birthing people must be given the option to decline induction, and give guidance to clinicians in how to make a clear recommendation without coercing the woman or birthing person. Simply saying that <i>'A woman's individual needs and preferences should always be taken into account.'</i> is not sufficient. | Thank you for your comment. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline. |
| Doula UK | Guideline | General | General | Has the impact on the number of people needing induction of labour has per this guideline been assessed in terms of percentages and numbers? Given the high rate of each of the "at risk" categories suggested in the guideline who should be offered induction at 39 weeks pregnancy, it seems that almost no-one will be given the chance to have their labour start spontaneously? | Thank you for your comment. As a result of stakeholder feedback the guideline no longer recommends that induction of labour be considered at 39+0 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications. The amended recommendations on timing of induction make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Doula UK | Guideline | General | General | <p>We have already seen an increase in induction rates on a national and local level prior to this new recommendation. In cases where induction is necessary and an informed choice, the process does not happen independently of other maternity services. As a membership organisation and in our unique role, we see the impact that this has. Inductions occurs within a system whereby once the birthing person agrees to the procedure, the process starts on a prenatal ward – often where partners are unable to attend until the birthing person is considered to be in active labour.</p> <p>The sheer volume of inductions carried out currently mean that the process can be stalled, held up and delayed due to a number of factors outside of the birthing person's control. Staffing levels, available midwives, those labouring spontaneously or whose induction methods are successful all creating a very challenging delay and impact to others. If induction is going to become such a common recommendation, then the huge challenges that so often contribute to poor postnatal mental health and birth trauma must be addressed.</p> <p>Before the introduction of yet more inductions, consideration should be given to create wards that specifically cater for those who are being recommended induction, separate from wards for those that labour spontaneously, or those with antenatal complications. We must also address the fact that very few birthing people are given the opportunity to make an informed decision around the reasons why they are being offered induction, with many service users feeling as though they have no choice, or feel coerced by health care providers talking about risk of stillbirth without contextualisation. The evidence supporting induction is rarely balanced with evidence around the risk and chance of episiotomy, instrumental birth or caesarean birth, and in this</p> | <p>Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>context these recommendations are concerning.</p> <p>We also should look at any available evidence that exists in relation to perinatal mental health, postnatal depression and PTSD related to the way that birthing people give birth to their babies. As doulas, we often see the trauma related to mode of delivery and are often employed by multiparous women, with previous trauma due to induction.</p> | |
| Doula UK | Guideline | 001 | 006 | <p>There is evidence that medical staff and guidelines referring to pregnant trans men and non-binary people 'women' harms them (Greenfield and Darwin, 2021). Whilst it is probably intended to make the guideline inclusive, it has actually become a form of iatrogenic harm in itself. Also, as no data is captured that specifies the gender of the parent, it cannot be assumed that induction should be recommended at the same times and rates for pregnant non-binary people and trans men. The harm to mental health of a prolonged hospital stay is unknown. The difference that 'top surgery' makes to BMI is unknown. Whether testosterone usage has an effect on rates of uterine rupture is unknown. Without this medical evidence, how can the guideline be safely applied to this cohort?</p> | <p>Thank you for your comment. To ensure consistency between NICE guidelines the NICE editorial team have developed a more inclusive description and rationale for the use of the terminology relating to the intended population for maternity and obstetric guidelines, and this is included in the introductory information at the beginning of the guideline. Part of this rationale is, as you have stated, that the evidence for the recommendations is based on data from studies on women, and while the committee have extrapolated this evidence to other groups of pregnant people, you are correct that there was no evidence on which to base this assumption and further research is needed.</p> |
| Doula UK | Guideline | 004 | 001 | <p>This wording implies that if an induction is recommended, a woman or pregnant person does not have the right to decline it. It also sounds as though carers may consent to medical treatment against a pregnant woman or birthing person's wishes.</p> | <p>Thank you for your comment. We have removed this text referring to carers so it is consistent with standard NICE text at the beginning of other guidelines and makes it clear who should be involved in discussions and making informed decisions about care.</p> |
| Doula UK | Guideline | 004 | 008 | <p>There is no mention of possible increase in caesarean births. The result of the uterus contracting too strongly (fetal distress, subsequent emergency caesarean birth, and risk of intrauterine death) should be spelled out as a risk here.</p> | <p>Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update and so we are unable to provide data on caesarean birth as you suggest. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Doula UK | Guideline | 005 | 001 | <p>Add the risk of uterine rupture and damage to perinatal mental health here. Also add the findings from Dahlen et al. (2021) about the negative sequelae for woman/person and the baby:</p> <p>'Primiparous women with IOL versus spontaneous onset differed significantly for: spontaneous vaginal birth (42.7% vs 62.3%), instrumental birth (28.0% vs 23.9%), intrapartum caesarean section (29.3% vs 13.8%), epidural (71.0% vs 41.3%), episiotomy (41.2% vs 30.5%) and postpartum haemorrhage (2.4% vs 1.5%)'.</p> <p>'Following induction, incidences of neonatal birth trauma, resuscitation and respiratory disorders were higher, as were admissions to hospital for infections (ear, nose, throat, respiratory and sepsis) up to 16 years' (Dahlen et al., 2021).</p> | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on these outcomes. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Doula UK | Guideline | 005 | 003 | There does not appear to be any research to back up the reasons for induction. If the ARRIVE trial is being used, the conclusion was insufficient evidence. The science is flawed and should not be used as a basis for increased induction. | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. In addition, the committee has updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. |
| Doula UK | Guideline | 006 | 012 | What is the evidence to back up the claims of risks associated with pregnancy continuing beyond 41+0. There is NO scientific evidence to support that the placenta stops | Thank you for your comment. The review carried out for this part of the guideline update did identify that some risks increase with increasing gestational age, although we did not suggest this was due to a failing placenta. However, |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | working after 41 weeks. This is based on opinion only, and therefore should not a valid reason. | based on stakeholder feedback, we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| Doula UK | Guideline | 006 | 012 | Given Dahlen et al's evidence that many of these risks are associated with induction, rather than prolonged pregnancy, this evidence needs to be reviewed again. Whilst the correlations are clear, it is unclear whether the intervention of the induction or the length of pregnancy is the causal factor. | Thank you for your comment. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. |
| Doula UK | Guideline | 006 | 023 | <p>BMI is a very rough tool. Women and birthing people may decline to be weighed, or scales may not be available. Weight is then either given as an estimate, or guessed by the midwife. From our Facebook group we know that women decline being weighed to avoid the pressure and coercion that already exists.</p> <p>It is also worth noting the criticisms of BMI as a tool that does not take into account different norms within those of different ethnicities, and putting this together with the following point.</p> <p>If people are weighed, they are weighed at booking (by which point they could be nearly into the second trimester), which will mean their BMI is recorded as higher than it is.</p> <p>The majority of women with a BMI over 30 will have an uncomplicated birth, so why would we want to recommend</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>that we decrease their chance of an uncomplicated birth by increasing the induction rate amongst these women?</p> <p>So far, there is an absence of induction outcome research that examines differential outcomes (including physical health and mental health) based on BMI. This research would surely be necessary before such a recommendation was made?</p> | |
| Doula UK | Guideline | 006 | 024 | <p>The reason for the higher maternal mortality rate amongst Black and Asian women is structural racism. There is no biological difference that would account for these differences, and they still exist when socio-economic factors are taken into account. This is highlighted in the parliamentary report, which has unhelpfully been released on the same day as the IOL guideline consultation is closing (https://publications.parliament.uk/pa/cm5802/cmselect/cmhealth/19/1902.htm). Professor Knight states that there are no clinical differences in the reasons that Black and Asian women die in the perinatal period. Instead the three most frequent themes relating to the care disparities are that Black women are “not like me”, complexity of needs, and racist microaggressions. The main solution proposed by this report is continuity of carer (with the option to change carer for the pregnant person), something which has repeatedly been shown to have benefits in maternal and infant mortality and morbidity for all birthing people.</p> <p>Black women are already at a greater risk of birth trauma (Kendall-Tackett, 2014). Experiencing birth as a traumatic event has significant long term negative sequelae, including postnatal depression, postnatal anxiety, PTSD, secondary tokophobia, relationship breakdown and impaired bonds with infants (Greenfield, Jomeen and Glover, 2016). Induction is a risk factor for experiencing birth as a traumatic event</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>(Greenfield, Jomeen and Glover, 2016).</p> <p>So far, there is an absence of induction outcome research that examines differential outcomes (including physical health and mental health) based on ethnicity. This research would surely be necessary before such a recommendation was made? The parliamentary report cited earlier reflects on the lack of Black and Brown women's voices in co-creating such research. We would also respectfully point out the lack of Black and Brown women and other birthing people's voices in co-creating this guideline.</p> <p>Black and Brown women have been clear in recent days that this guideline pathologises their bodies, causing further damage to their mental health. The mental health of mothers is not an add-on to obstetric care. Suicide is a leading cause of maternal mortality, and iatrogenic harm to mental health must be recognised.</p> <p>The solution to the higher rates of maternal mortality amongst Black and Asian women should be to change the structures that mean that they have worse outcomes. It should not be to put the onus on these women by asking them to be induced early (and take on the risks that come with it). We are clear that any guideline which pathologises Black and Brown bodies should not be taken forward.</p> | |
| Doula UK | Guideline | 006 | 024 | 'Assisted conception' would include most pregnant lesbians, and pregnant bisexual/pansexual/Queer women in a same-sex relationship. There is no evidence that using donor sperm at home, or having IUI in a clinical setting increase any risks. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Doula UK | Guideline | 007 | 007 - 012 | Agree – monitoring gives only a snapshot of that moment in time. Therefore, why are we offering it? What purpose does it have? If carried out, monitoring at this stage should | Thank you for your comment. This recommendation has been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | explicitly exclude estimates of the baby's size, due to the unreliability of said measurements. | limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The monitoring suggested was carried over from the previous version of the guideline, and looking at the different types of monitoring that could be offered was not within the scope of this update so we are unable to make recommendations on other types of monitoring. |
| Doula UK | Guideline | 007 | 006 | We do not have the resources to provide this. | Thank you for your comment. Other recommendations (for example 1.2.2 and 1.2.4) have been amended so it is unlikely that the cohort of women being offered and declining induction will change significantly. This recommendation has also been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The options to do CTG and amniotic pool depth are only provided as suggestions, carried over from the previous version of the guideline, and have been in place since 2008, so it is unlikely these recommendations will have an impact on resources. |
| Doula UK | Guideline | 007 | 013 | We do not have the resources to provide this. | Thank you for your comment. Other recommendations (for example 1.2.2 and 1.2.4) have been amended so it is unlikely that the cohort of women being offered and declining induction will change significantly. This recommendation has also been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The options to do CTG and amniotic pool depth are only provided as suggestions, carried over from the previous version of the guideline, and have been in place since 2008, so it is unlikely these recommendations will have an impact on resources. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-------------------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Doula UK | Guideline | 007 | 016 | This will result in women and birthing people experiencing more coercion. | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again. |
| Doula UK | Evidence review D | 008 | 006 | The only study that examined maternal satisfaction was a study where 16,427 women declined to participate (Grobman et al., 2018). The volume of women who declined participation perhaps gives an indication that the majority of people do not want to be induced early (see comment 1 above)? This needs factoring into the recommendation of when to offer induction. | Thank you for your comment. The committee acknowledged the paucity of evidence for the outcome maternal satisfaction in this review, and they agreed that women's choice is key for providing optimal care in maternity services. Based on stakeholder feedback, the recommendations have been amended to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. The committee considered the proportion of women who declined to participate in the trial within normal parameters and noted that this may have been related to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal. |
| Doula UK | Guideline | 008 | 006 | This displays a misunderstanding, or could lead to a misinterpretation about what 'shared decision making' means. | Thank you for your comment. The NICE definition of shared decision-making is a collaborative process, making sure the person understands the risks and benefits through discussion and we think this applies to decisions about maternity choices, although the final decision is ultimately the woman's. We have reviewed the use of the terminology 'shared decision-making' throughout the guideline and have amended it in a number of places. However, there are some circumstances where there may be factors that relate to the decision that are within the remit of the healthcare professional too - such as their professional responsibility to act in the woman's best interests, and in this example to determine if suitable neonatal facilities are available. In this case we think the decision would therefore be shared, and so have not amended it in this recommendation. |
| Doula UK | Guideline | 008 | 022 | This implies that women must have an induction within 24 hours. If a woman declines an induction, will expectant | Thank you for your comment. The course of action after 24 hours of expectant management is provided in the next |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | management no longer be offered? Why would care be withdrawn if she declines induction? | recommendation, and at this point induction will be offered. As with all healthcare decisions it is the woman's choice whether or not to take up that offer. There is no suggestion that care will be withdrawn. |
| Doula UK | Guideline | 009 | 001 | Says support the woman's decision if she chooses not to have induction after 24 hours but the offer at page 8 line 19 onwards doesn't include this as part of the offer | Thank you for your comment. The recommendations offer expectant management up to 24 hours, and then after 24 hours offer induction if labour has not started naturally. This would be the recommended course of action to reduce the risk of infection to the baby. However, as with all other interventions that are offered, women can decline this offer and choose to wait longer, and the recommendation you are commenting on suggests the course of action to be taken in this instance. |
| Doula UK | Guideline | 011 | 003 | Is it ethical that NICE support recruitment to clinical trials in their recommendation? | Thank you for your comment. This group was highlighted for inclusion in clinical trials as the committee were aware of an ongoing clinical trial (Big Baby) which will provide specific data on the role of induction in suspected fetal macrosomia. NICE is very keen to support and promote ongoing research which may address uncertainties in clinical practice due to a lack of evidence. |
| Doula UK | Guideline | 013 | General | I feel like there should be a "DO NOT DO" recommendation here - unsure of wording though | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps. However, we have amended the recommendations to emphasise that the option of membrane-sweeping should be discussed with women, and their consent obtained. |
| Doula UK | Guideline | 013 | General | there is no reference to women and birthing people who do not want VEs for whatever reason but particularly if there's a history of trauma. This whole section screams coercion and intervention train. | Thank you for your comment. We have amended the recommendations to emphasise that the option of membrane-sweeping should be discussed with women, and their consent obtained. |
| Doula UK | Guideline | 013 | 003 | Explain to women: <ul style="list-style-type: none"> • that a membrane sweep IS a method of induction • what a membrane sweep is and how it is performed | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, including any |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-------------------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <ul style="list-style-type: none"> that discomfort & vaginal bleeding are possible and infection more likely, all of which can reduce choices as labour progresses. | risk of infection. However, we have now amended the recommendations to reflect that it may be considered a method to induce labour. |
| Doula UK | Guideline | 013 | 004 | Add that a membrane sweep increases the chances of infection | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, including the risk of infection. |
| Doula UK | Guideline | 013 | 010 | Although the wording says "obtain consent" this feels coercive - ENSURE consent is given before performing a membrane sweep might be more appropriate? | Thank you for your comment. We have reworded this recommendation to ensure there is a discussion with women and that if they agree to membrane-sweeping, consent is obtained. |
| Doula UK | Guideline | 013 | 012 | delete "formal" replace with "pharmacological or mechanical" | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps. However, we have now amended the recommendations on membrane-sweeping to reflect that it may be considered a method to induce labour, have clarified that it should be offered at antenatal appointments after 39 weeks, and expanded the recommendation on discussing it with women and obtaining their consent. |
| Doula UK | Guideline | 013 | 016 | seems unnecessary and excessive given the risks of discomfort, vaginal bleeding and infection. | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, the likelihood of success, optimal timing or frequency. However, we have amended this recommendation to emphasise that additional membrane sweeping should only be considered after a discussion with the woman. |
| Doula UK | Evidence review D | 017 | 033 | As no evidence was available it feels that this has therefore been ignored. Induction increases the risks of an instrumental birth, episiotomies, and 3 rd and 4 th degree tears. | Thank you for your comment. We are unclear to which section of the guideline your comment makes reference to, but we think it may be relevant for the section on |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|-------------------|---------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | latrogenic perineal trauma is an issue for women and birthing people that can be life changing. It should not be dismissed in this way. This is just as important as considering the reduction in risk of stillbirth/neonatal death through induction. | suspected fetal macrosomia. The recommendations have been reworded to clarify that options for birth are expectant management, induction of labour or caesarean birth. In addition we have included more information on the risk of shoulder dystocia and 3rd and 4th degree tears to aid understanding. |
| Doula UK | Evidence review C | 019 | 011 | <p>"The committee 9 also noted a possible increase in the need for assisted vaginal birth...this difference was not deemed clinically important."</p> <p>This is important and should have more weight in what we recommend with regards to when to offer induction. Instrumental births are often what people wish to avoid, with many birth plans stating that women would rather have a caesarean birth than an instrumental birth to avoid higher risks of 3rd and 4th degree tears or episiotomies..</p> | <p>Thank you for your comment. Based on stakeholder feedback, a possible increase in assisted vaginal birth has now been removed.</p> <p>'Clinically important' in this context refers to the fact that the intervention did not have an important effect on the outcome (assisted vaginal birth, in this case), not that the committee did not think that the outcome was important for decision-making. We have now included the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding of the evidence reviewed. The supporting information explains how this data was derived and how to interpret it.</p> |
| Doula UK | Guideline | 024 | Whole page | <p>The evidence cited does suggest that there are increased risks of adverse outcomes for these groups, but it does not suggest that induction will reduce these risks. That leap appears to have been made by Committee members based on professional experience. Whilst valuable, professional experience is no substitute for evidence in the making of NICE Guidelines.</p> <p>We should also be concerned about the impact of long-term outcomes which are poorer after induction of labour. Both the drugs and mechanical methods used in induction and the interventions that may result can have unwanted and potentially harmful consequences. These may be justified where induction will benefit an individual. But when induction is a routine recommendation and information on long-term outcomes is not being offered or considered, we are denying women and families the right to make informed decisions.</p> | <p>Thank you for your comment. The recommendations for women who may be at higher risk of stillbirth have been amended and revised substantially, and so we have updated this rationale section to reflect these changes to the recommendations.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | This recommendation is based not on evidence and research but NICE panel members are basing some sweeping statements about these groups of women being at high risk purely on their "knowledge and experience." No evidence is given to justify offering induction of labour to these women at 39 weeks. | |
| East Lancashire Hospitals NHS Trust | Guideline | General | General | <p>Here at East Lancashire Hospitals NHS Trust (ELHT), we have noticed a gap in these guidelines in relation to including the opportunity for antenatal hand expressing during the IOL period and associated potential outcomes on breastfeeding. Reasons for induction include maternal conditions such as diabetes which will impact on neonatal euglycaemia, growth restriction and pre eclamptic medication which may also impact a baby's ability to remain euglycaemic. The opportunity to support early feeding via colostrum harvesting, and thus a potential reduction in neonatal intervention, in conjunction with the known health outcomes of breastfeeding, demonstrate why we believe this practice should be a recommendation within the NICE IOL guideline.</p> <p>During the period 1st January to 31st March 2020 our Trust evaluated the outcomes for those mothers who were supported to harvest colostrum during this induction of labour time period. Overall, 211 women were admitted for IOL and gave birth to 213 live infants – according to our IT Athena system</p> <p>The Baby Friendly Team champion (BFTc) recorded antenatal colostrum harvesting by 47 IOL women, between 31st Dec 2019-27th Mar 2020, who gave birth to a live infant between 1st Jan-31st Mar 2020 at ELHT.</p> <p>Note: The BFTc also recorded additional colostrum harvesting by 10 women admitted for caesarean section (C/S)</p> | Thank you for your comment and for sharing your local data on colostrum harvesting and its impact on breastfeeding rates. The impact of induction on breastfeeding rates or the use of colostrum harvesting were not included in the scope of this guideline update but we will pass this information to the NICE surveillance team who are responsible for ensuring that guidelines are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response | | | | | | | | | | | | | | |
|----------------------------------------------------------------------|----------------------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|------------------|-----------|-----------------------------|----------|-----------------------------|----------|-------------------------------|-----------|-----------------------|----------|-----------------------------------|---------|--|
| | | | | <p>Infant feeding outcomes for each group of women are included in the table below (Jan-Mar 2020):</p> <table border="1"> <thead> <tr> <th>Infant feeding outcomes of:</th> <th>IOL mothers – K2: 21</th> </tr> </thead> <tbody> <tr> <td>Breastmilk <48h:</td> <td>67% (141)</td> </tr> <tr> <td>Exclusive brf at discharge:</td> <td>34% (72)</td> </tr> <tr> <td>Mixed feeding at discharge:</td> <td>22% (46)</td> </tr> <tr> <td>Some breastmilk at discharge:</td> <td>60% (126)</td> </tr> <tr> <td>Formula at discharge:</td> <td>38% (81)</td> </tr> <tr> <td>Missing discharge feeding method:</td> <td>2% (4*)</td> </tr> </tbody> </table> <p>A positive correlation can be seen for those mothers who were supported to harvest colostrum before birth in these groups had increased breastfeeding rates when compared to those that did not and also when compared to the whole population, and had higher rates of breastfeeding at discharge home. We felt this would be important and an excellent opportunity to include this in the NICE IOL guidelines</p> <p>Evaluation Summary:</p> <ul style="list-style-type: none"> Those mothers who had support to harvest colostrum whilst being induced (compared to all mothers and also compared to other mothers being induced without intervention) had: <ul style="list-style-type: none"> Higher breastfeeding initiation rates Higher rates of exclusive breastfeeding at discharge (less supplementation) <p>Higher rates of any breastmilk feeding at discharge</p> | Infant feeding outcomes of: | IOL mothers – K2: 21 | Breastmilk <48h: | 67% (141) | Exclusive brf at discharge: | 34% (72) | Mixed feeding at discharge: | 22% (46) | Some breastmilk at discharge: | 60% (126) | Formula at discharge: | 38% (81) | Missing discharge feeding method: | 2% (4*) | |
| Infant feeding outcomes of: | IOL mothers – K2: 21 | | | | | | | | | | | | | | | | | | |
| Breastmilk <48h: | 67% (141) | | | | | | | | | | | | | | | | | | |
| Exclusive brf at discharge: | 34% (72) | | | | | | | | | | | | | | | | | | |
| Mixed feeding at discharge: | 22% (46) | | | | | | | | | | | | | | | | | | |
| Some breastmilk at discharge: | 60% (126) | | | | | | | | | | | | | | | | | | |
| Formula at discharge: | 38% (81) | | | | | | | | | | | | | | | | | | |
| Missing discharge feeding method: | 2% (4*) | | | | | | | | | | | | | | | | | | |
| Greater Manchester and Eastern Cheshire Maternity Voices Partnership | General | | | <p>We are writing to you as a group of Maternity Voices Partnership Chairs and former Chairs from the Greater Manchester and East Cheshire Local Maternity System. We have a deep concern about the proposed amendments to the NICE guidelines on Inducing Labour.</p> | <p>Thank you for your comment. Based on stakeholder feedback we have made several amendments to the guideline. We will address your specific points in turn.</p> <p>1. The committee included 2 lay members with lived experience of induction of labour and wider experience of representing people using maternity services. The</p> | | | | | | | | | | | | | | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>We outline below the areas of particular concern and we urge NICE to reconsider the draft version in light of these concerns, those of other organisations such as AIMS and Birthrights, and those submitted by individuals.</p> <p>1. Nothing about us, without us! Although the committee for the draft guidelines include lay voices, they are detrimentally missing the voices of those with lived experience of being offered inductions of labour and are not reflective of the environment which exists within maternity services. For such an important document that will have a wide-reaching impact we suggest that a steering group of people with lived experience of the maternity service and collaboration with MVPs across the country to ensure that the guidelines are fit for purpose.</p> <p>2. The evidence base for the Inducing Labour guidelines are too narrow and do not reflect where there is controversy over flawed studies or low grade evidence. What's more, an upfront exploration around the long-term outcomes, negative consequences and iatrogenic harm of induction are not referenced. As the draft guidelines currently stand, the 'business as usual' approach to inductions will mean that women and their families will be denied the right to make informed choices.</p> <p>3. The suggested changes to offer induction in later pregnancy as routine, ignores qualitative and quantitative data around the inaccuracy of 'due' dates. As Sara Wickham states in her analysis: 'the offer of an earlier induction will mean more babies will be born before they are ready. These babies will be at risk of long term health issues as a result.'</p> <p>4. We also call for more research into the NICE guidance for women of Black, Asian and minority ethnic backgrounds, so that the guidance reflects the urgent need to challenge health inequalities for women in these groups, rather than inadvertently maintaining the dangerous status quo. This is reflected in the Parliamentary report into the safety of maternity services in England and to which</p> | <p>consultation process is the additional method we use to obtain input into the guideline from a wide range of stakeholders and individuals, and to ensure that the guideline is fit for purpose. This guideline received over 3000 comments in this way, and each one was read and considered by the committee in order to amend and improve the guideline.</p> <p>2. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction.</p> <p>3. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the birth of preterm babies.</p> <p>4. We have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report.</p> <p>5. To ensure consistency between NICE guidelines the NICE editorial team have developed a more inclusive description and rationale for the use of the terminology relating to the intended population for maternity and obstetric guidelines.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|-----------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>recommendations in the NICE draft guidelines should refer to.</p> <p>5. We believe that as a respected, national organisation NICE has an obligation to use inclusive language to protect marginalised groups of people. Using reductive language for “simplicity” is actively harmful. The implication of these amends to the guidelines will be profound for women and their families. It is imperative that NICE resist the temptation to rush these new amends through, and instead include people with lived experience and MVPs across the country to help shape and finalise these guidelines so that they are clinically robust, based on extensive and rigorous research (quantitative and qualitative) and so that the outcome of care is reflects the national conversation and need for person-centred care and informed decision making.</p> <p>We understand this letter is outwith the format requested but we urge you to consider all the feedback you're receiving.</p> | |
| Healthcare Safety Investigation Branch | Guideline | General | | <p>HSIB investigations have observed that IOL may be delayed (both the initiation of IOL, and during the process of IOL) due to workload, capacity, and acuity circumstances, and that this may contribute to a poor outcome for a mother or baby. HSIB anticipates this guidance will result in an increase in the number of women requiring IOL. HSIB considers services require additional guidance to support managing this demand, and auditable standards for IOL.</p> | <p>Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications.</p> |
| Healthcare Safety Investigation Branch | Guideline | 013 - 014 | 018 | <p>The heading of this section is pharmacological and mechanical methods, and the text does not include guidance on mechanical cervical ripening.</p> | <p>Thank you for your comment. This section contains recommendations on use of mechanical methods such as balloon catheters and so we have not changed the title of the section.</p> |
| Healthcare Safety Investigation Branch | Guideline | 013 - 014 | 018 | <p>HSIB investigations have found varying practices used for mechanical induction relating to the length of time devices are left in situ and use of subsequent IOL methods. Clarity here is required to support clinicians planning IOL.</p> | <p>Thank you for your comment. This update of the guideline did not include a review to determine how long balloon catheters should be left in place. However, NICE have developed Interventional Procedure Guidance (IPG) on double balloon catheters for induction (IPG528, 2015)</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | which recommends their use, says they should be left in place for up to 12 hours. |
| Healthcare Safety Investigation Branch | Guideline | 006 | 012 - 019 | It would be useful to support this by quantifying 'increased likelihood' of these events to support a mother to make an informed choice. | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| Healthcare Safety Investigation Branch | Guideline | 006 | 010 | HSIB considers being more specific about the maximum duration of pregnancy advised would support clinicians and remove ambiguity. | Thank you for your comment. The evidence review for the timing of induction showed that some risks increased with longer pregnancies but it was not possible to determine a maximum duration of pregnancy, and trying to specify this would not reflect an individualised approach to healthcare or allow women a choice. |
| Healthcare Safety Investigation Branch | Guideline | 006 | 021 | Language suggestion: replace risk with chance | Thank you for your comment. The term risk is mainly used as a synonym for 'harm' in this guideline, as in the term 'risks and benefits', and is also used to imply the probability of a negative outcome, whereas chance could mean a negative or positive outcome. We have therefore not changed 'risk' to 'chance'. |
| Healthcare Safety Investigation Branch | Guideline | 006 | 026 | Language suggestion: replace risk with chance | Thank you for your comment. The term risk is mainly used as a synonym for 'harm' in this guideline, as in the term 'risks and benefits', and is also used to imply the probability of a negative outcome, whereas chance could mean a negative or positive outcome. We have therefore not changed 'risk' to 'chance'. |
| Healthcare Safety Investigation Branch | Guideline | 007 | 016 | HSIB investigations have found that senior clinical oversight supports informed decision making in this circumstance, and that clear detailed documentation and accessible supporting information is often missing. | Thank you for your comment. The committee agreed that it would not be possible to specify that this discussion should have senior clinical oversight, as that not may be possible in all circumstances. The recommendations on decision-making have been amended to state that a woman's decision on induction must be recorded. |
| Healthcare Safety Investigation Branch | Guideline | 008 | 019 - 029 | Section 1.2.13 may not be required as information already presented in section 1.2.12 | Thank you for your comment. The second recommendation clarifies what is advised after 24 hours of expectant management so we have left this recommendation in place. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Healthcare Safety Investigation Branch | Guideline | 008 | 006 - 012 | HSIB considers a mother makes the decision, it is not a shared decision. Suggest instead: when supporting informed decision making, take into consideration the following... | Thank you for your comment. The NICE definition of shared decision-making is a collaborative process, making sure the person understands the risks and benefits through discussion and we think this applies to decisions about maternity choices, although the final decision is ultimately the woman's. We have reviewed the use of the terminology 'shared decision-making' throughout the guideline and have amended it in a number of places. However, there are some circumstances where there may be factors that relate to the decision that are within the remit of the healthcare professional too - such as their professional responsibility to act in the woman's best interests, and in this example to determine if suitable neonatal facilities are available. In this case we think the decision would therefore be shared, and so have not amended it in this recommendation. |
| Healthcare Safety Investigation Branch | Guideline | 009 | 013 - 014 | HSIB considers reducing the risk of uterine rupture will always be beneficial; wording this more clearly will support service providers developing business plans and local guidance | Thank you for your comment and support of this recommendation. |
| Healthcare Safety Investigation Branch | Guideline | 009 | 017 - 024 | HSIB investigations have identified that a detailed plan for cervical ripening, ARM and augmentation agreed with a woman and clearly documented and communicated to the multi-disciplinary team, supports IOL in women planning a VBAC | Thank you for your comment. It was not within the scope of this guideline update to update the recommendations on induction after previous caesarean birth so we have not examined the evidence for the most effective method of induction, but hope that the HSIB investigation findings which appear to relate to good clinical practice will be widely promulgated. |
| Healthcare Safety Investigation Branch | Guideline | 009 | 004 - 007 | Increased clarity is required on offering immediate IOL for women who have previous GBS and have decided to have IAP in this labour rather than screening for GBS at 35-37 weeks [as per RCOG GTG] | Thank you for your comment. This guideline focuses on induction of labour to reduce the risk of neonatal infection with ruptured membranes, but advice on the use of intrapartum antibiotic prophylaxis during labour would still apply and is not covered in this guideline, but is covered in the NICE guideline on neonatal infection (NG195) and we have added a link to this from the recommendation. |
| Healthcare Safety Investigation Branch | Guideline | 009 | 001 - 003 | Use of "the woman" when the rest of the guideline refers to "a woman" | Thank you for your comment. We have used a mixture of singular and plural forms throughout the guideline, depending what makes best sense in each context. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Healthcare Safety Investigation Branch | Guideline | 009 | 019 - 020 | The choice of expectant management is also required | Thank you for your comment. The stem of this recommendation was 'When birth is indicated... ' so this takes into account that a decision has been made that the birth needs to be expedited. To clarify this we have now changed the wording in the recommendation to 'If birth needs to be expedited...' |
| Healthcare Safety Investigation Branch | Guideline | 009 | 010 | Should be increased likelihood of CS not increased risk of | Thank you for your comment. We have used the word risk here to be consistent with the remainder of the guideline which uses 'risk' instead of 'chance' or likelihood'. |
| Healthcare Safety Investigation Branch | Guideline | 009 | 017 | Language suggestion: If birth is indicated | Thank you for your comment. We have changed this to birth. |
| Healthcare Safety Investigation Branch | Guideline | 009 | 022 | Language suggestion: "entitled to" feels inflammatory; could say: advise women they may decline | Thank you for your comment. We have changed this to 'can choose not to...' |
| Healthcare Safety Investigation Branch | Guideline | 010 | 017 - 018 | Fetal compromise – the means of assessing fetal compromise requires clarity: is this by CTG analysis, or by the use of Doppler studies? | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add a definition of confirmed fetal compromise. |
| Healthcare Safety Investigation Branch | Guideline | 010 | 007 | A breech presentation | Thank you for your comment. We have amended the title of this section to 'position' to ensure continuity of terminology |
| Healthcare Safety Investigation Branch | Guideline | 010 | 008 | In breech presentations | Thank you for your comment. We have amended the title of this section to 'position' to ensure continuity of terminology |
| Healthcare Safety Investigation Branch | Guideline | 010 | 009 | Language suggestion: birth is indicated | Thank you for your comment. We have changed 'delivery' to 'birth'. |
| Healthcare Safety Investigation Branch | Guideline | 010 | 018 | As advising not undertake IOL in the presence of fetal compromise, it would be more appropriate to recommend CS rather than offering it. | Thank you for your comment. 'Offer' is the usual NICE terminology for a strong recommendation, as women can be offered Caesarean birth but they do not have to accept this offer, and may decline. |
| Healthcare Safety Investigation Branch | Guideline | 010 | 020 | Do we have the evidence for 'offer' – the Big Baby study is awaited. Would 'consider' be more reasonable based on the current evidence? | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. |
| Healthcare Safety Investigation Branch | Guideline | 012 | 021 - 022 | The dose of mifepristone differs to the recommendations in existing guidance (gtg_55.pdf (rcog.org.uk)) and the BNF. Higher doses for certain conditions may be indicated. | Thank you for your comment. The recommendation this comment refers to does not contain a dose of mifepristone, but we think this comment relates to an earlier recommendation. The dose of mifepristone of 200 mg (followed by a prostaglandin) is based on the summary of product characteristics (SPC) for mifepristone and is in-line with the doses in the RCOG guideline. The higher dose (600 mg) can be used alone, if a prostaglandin or oxytocin cannot be used, but the committee agreed that this method was less effective. The RCOG green top guideline on stillbirth is currently being revised. |
| Healthcare Safety Investigation Branch | Guideline | 012 | 019 | More clarity on the means of monitoring contractions will support staff; is a tocograph indicated in the presence of fetal death or is manual assessment adequate? | Thank you for your comment. A manual method of monitoring of uterine contractions would be adequate if this is possible, and this has been added to the recommendation. |
| Healthcare Safety Investigation Branch | Guideline | 013 | 003 - 009 | Has evidence supporting a possible increased risk of infection associated with membrane sweeping been considered? | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps. |
| Healthcare Safety Investigation Branch | Guideline | 013 | 003 | Explain to women: add "before any vaginal examination is commenced". | Thank you for your comment. Adding this phrase would imply that membrane sweeps would only be discussed immediately prior to a vaginal examination, and it may be appropriate to have this discussion with women at any time in their pregnancy, so we have not made this addition. |
| Healthcare Safety Investigation Branch | Guideline | 013 | 010 | Can this be amended to clarify that verbal consent is sufficient? | Thank you for your comment. We have added that this is verbal consent. |
| Healthcare Safety Investigation Branch | Guideline | 014 | 025 | Is the guidance saying that pharmacological methods for IOL should not be used in women with a previous CS? | Thank you for your comment. This recommendation is stating that pharmacological methods may be less suitable after caesarean birth, due to the risk of uterine rupture. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Healthcare Safety Investigation Branch | Guideline | 016 | 008 - 015 | HSIB investigations have observed situations when IOL has been carried and then breech presentation identified in labour. Has consideration been made of including scanning for presentation either routinely or if there is any doubt about presentation? | Thank you for your comment. The recommendations on assessment before induction have been amended to include that an ultrasound scan should be carried if there are concerns about the position of the baby, such as a breech presentation. |
| Healthcare Safety Investigation Branch | Guideline | 016 | 019 - 021 | Thank you for clarifying guidance on when to switch from AN to IP CTG interpretation. Have NICE considered the potential that using intrapartum criteria before established labour (in presence of uterine activity without cervical dilatation) may lead to non-recognition of compromise in some babies by undergrading of the CTG. | Thank you for your comment and for your support for this recommendation. No review of CTG interpretation was undertaken as part of this update, but we will pass on your comments to the team who are updating CTG interpretation as part of the Intrapartum care guideline update. |
| Healthcare Safety Investigation Branch | Guideline | 017 | 006 | HSIB investigations have observed cases where the transition to active labour has been missed with intrapartum fetal monitoring not being commenced in a timely manner. Supporting clinicians to consider assessment to identify the onset of established labour in presence of women reporting pain is required. | Thank you for your comment. The recommendation your comment relates to is a link to the NICE guideline on intrapartum care, which is also currently being updated, so we will pass your comment to the team who are updating that guideline. |
| Healthcare Safety Investigation Branch | Guideline | 018 | 013 | HSIB investigations have observed differing practices around the recognition of hyperstimulation and the administration of tocolysis; further clarity about when to administer tocolysis would support a consistent approach. | Thank you for your comment. Tocolysis for hyperstimulation was not included in the scope of this update, and therefore the committee were unable to make any more detailed recommendations in this guideline. However, as you have identified this as an area of uncertainty we will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Healthcare Safety Investigation Branch | Guideline | 018 | 014 | HSIB investigations have observed cases where multiple methods of IOL have been used consecutively. It would be useful for NICE to identify some parameters around what constitutes an unsuccessful induction, and how many consecutive attempts are reasonable | Thank you for your comment. Unsuccessful induction was not included in the scope of this update, and therefore the committee were unable to make any more detailed recommendations in this guideline. However, as you have identified this as an area of uncertainty we will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Healthcare Safety Investigation Branch | Guideline | 019 | 014 | Clearer wording suggested: review USS for placental position. | Thank you for your comment. We have added that scans should be used to check for a low-lying placenta, as you suggest. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|----------------------------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Healthwatch Milton Keynes | Equality Impact Assessment | General | General | The Equality Impact Assessment does not acknowledge the gender diversity of women and birthing people, nor acknowledges that the Inducing Labour guideline chooses to refer to birthing people of all genders as 'women' and how this may impact on the care of gender diverse birthing people. | Thank you for your comment. To ensure consistency between NICE guidelines the NICE editorial team have developed a more inclusive description and rationale for the use of the terminology relating to the intended population for maternity and obstetric guidelines. The detail of this wording has now been included in the EIA form. |
| Healthwatch Milton Keynes | Equality Impact Assessment | 001 | General | 3.2: The use of the term 'choices should be respected' sits out of alignment with the draft guidance aims to reduce paternalistic language. Suggest that 'choices should be supported'. | Thank you for your comment. The committee agreed to use the terminology, 'choices should be respected', as at times they may differ from the healthcare professional's view. |
| Healthwatch Milton Keynes | Guideline | 001 | General | Whilst acknowledging in the 'This guideline covers' statement, the gender diversity of people who give birth, taking the position to refer to all birthing people as 'woman' or 'women' is disrespectful for birthing people. There is no evidence of consultation with birthing people of diverse genders evidenced to establish preferences. It is the consideration of Healthwatch Milton Keynes that referring to 'women and birthing people' would not make the text of the guidance onerous and recommends a review of this position by the committee. | Thank you for your comment. To ensure consistency between NICE guidelines the NICE editorial team have developed a more inclusive description and rationale for the use of the terminology relating to the intended population for maternity and obstetric guidelines, guidelines, and this is included in the introductory information at the beginning of the guideline. |
| Healthwatch Milton Keynes | Equality Impact Assessment | 002 | General | 3.4: By recommending that women and birthing people from Black, Asian or minority ethnic backgrounds may benefit from induction earlier than women with uncomplicated pregnancies who did not fall into these groups the Equality Impact Assessment fails to recognise the additional challenges women or birthing people from Black, Asian or minority ethnic groups may have with being fully supported to making informed decisions about accessing services and having supported access to home birthing options. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. We have therefore amended section 4 of the EIA form to represent the changes to the recommendations. |
| Healthwatch Milton Keynes | Guideline | 006 | 023 - 025 | The draft guidance seeks to distinguish Black, Asian or ethnic minority women and birthing people with uncomplicated singleton pregnancies as requiring different treatment options from white British women and birthing people based on insufficient evidence of increased positive outcomes. This | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|-----------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>difference in treatment of pregnancies based on ethnicity will advance inequalities of treatment of care.</p> <p>There is insufficient consideration/ reference to the increase in post-natal care requirements for individuals birthing through induction treatment including post-birth perineal health, incontinence care, breastfeeding uptake and support.</p> <p>With Primary Care services under considerable pressure following the Covid-19 pandemic such guidance where implemented may increase pressure on GP referrals. The increase in induction treatments alone would be costly to the NHS as a system, based on insufficient evidence of positive outcomes.</p> <p>There is great potential that as a result of this guidance, that women and birthing people from Black, Asian and other minority ethnic groups will suffer increased health inequalities and Healthwatch Milton Keynes recommend that further research be conducted, as the guidance highlights, prior to recommending a specific change in treatment pathways aimed at non-white women and birthing people.</p> | <p>There is already a research recommendation in the guideline to support further research in this area.</p> |
| Healthwatch Sheffield | Guideline | 004 - 005 | General | <p>1.1 Information and decision making</p> <p>We welcome the recommendations which refer to having discussions with women about the reasons why induction is being offered and the potential consequences in terms of their birth options and experience of giving birth. However, we feel that healthcare professionals should also stress to women that having an induction is their decision, particularly in light of the power imbalance within the healthcare professional- patient relationship.</p> | <p>Thank you for your comment. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline.</p> |
| Healthwatch Sheffield | Guideline | 004 | 006 | <p>Recommendation 1.1.1 – We feel that 'mode' may not be an appropriate word to use as the meaning in this context may not be clear to some pregnant women, their families and carers.</p> | <p>Thank you for your comment. We think the term 'mode of birth' is used widely and understood, and often used in discussions relating to 'mode and place of birth' so we have not changed this recommendation.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Healthwatch Sheffield | Guideline | 006 | 020 - 024 | <p>Recommendation 1.2.4 - We are disappointed that induction of labour from 39+0 weeks is to be considered for women with black, Asian or minority ethnic background who are otherwise having uncomplicated singleton pregnancies, without any consideration of the complex multi-factorial context which underpins the increased risk of complications associated with continued pregnancy for these women.</p> <p>We believe that further research into the root causes of the higher risk of complications experienced by women from black, Asian and ethnic minority backgrounds would enrich healthcare professionals' understanding and create opportunities for preventative measures to be designed and implemented, thus generating the potential for better outcomes and experiences for these women, and diminishing the need to offer them induction at 39+0 weeks. The Public Health England Report 'Maternity High Impact Area 6: Reducing the inequality of outcomes for women from Black, Asian and Minority Ethnic communities and their babies' (2020) highlights the multi-factorial context of the issue of increased risks and poorer outcomes.</p> <p>We would prefer to see reference to specific ethnicities rather than the blanket term 'black, Asian and minority ethnic background' being used in future research and guidance as this would allow for a more nuanced understanding for healthcare professionals and the women themselves.</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Healthwatch Sheffield | Guideline | 006 | 020 -024 | <p>Recommendation 1.2.4 - Women with black, Asian and minority ethnic backgrounds may speak English as a second language so may need extra time at an appointments with an interpreter to enable them to fully understand any discussions around induction of labour. Healthcare professionals may consider actively checking that patients who speak English as a second language have understood the information given to them, their options and that it is their decision.</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------|-----------|-----------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Healthwatch Sheffield | Guideline | 007 | 002 | There may be difficulties accessing medical records to indicate the previous obstetric history of some migrant women, for example those who have recently arrived in England. In such cases, consider giving women, their families and carers time with a health care professional to give their account of their obstetric history. | Thank you for your comment. We think this is a general point which could apply to any woman whose obstetric history is not recorded in NHS notes (for whatever reason) and we have therefore flagged this in the Equality Impact Assessment for this guideline, instead of amending this specific recommendation. |
| Healthwatch Sheffield | Guideline | 004 – 005 | General | 1.1 Information and decision making There is a lack of reference to the timing of information giving. We believe that women could benefit if healthcare professionals had some specific guidance around this. | Thank you for your comment. We have not provided a specific time in pregnancy at which discussions about mode of birth should start as this may vary between women, but we have clarified that in most cases (if the woman wishes) this will be an ongoing conversation during pregnancy and not a one-off discussion. |
| Healthwatch Sheffield | Guideline | 004 – 005 | General | 1.2 1.1 Information and decision making We would like to see some reference to providing a mixture of oral and written information to inform decision making, as we know this can be helpful to people when making decisions about their care. Similarly, we would recommend including explicit reference to ensuring that an individual's communication needs are satisfied during discussions with professionals and that information is given in formats appropriate to their needs. Although these issues are covered within the NICE guideline on patient experience in adult NHS services, we feel that including it within this guideline could increase the likelihood of it being implemented in practice and highlights its importance. | Thank you for your comment. We have added the example of written information leaflets to the recommendation on information. In order to keep the guidelines to a manageable length we have not repeated information which is in the NICE guideline on patient experience in adult NHS services. |
| Homerton University NHS Foundation Trust | Guideline | 006 | 012 | Rec 1.2.3 – women may not like to have an IOL offered to them at 41 weeks especially if they were intending to have their baby in a midwifery led setting. | Thank you for your comment. The recommendations have been revised to emphasise that the option of an induction after 41 weeks should be discussed with women, in conjunction the risks of a prolonged pregnancy and the impact induction will have on their birth experience (which will include their place of birth) |
| Homerton University NHS Foundation Trust | Guideline | 006 | 020 | Rec 1.2.4 - Although the source for this recommendation is from the MBRRACE report. We suggest more research is needed to ascertain the optimal timing of delivery for women | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>from BAME. Moreover, there could be a reluctance to accept IOL in this group of women without sound knowledge or research or worse, a feeling of being coerced into a delivery because they are deemed unsuitable to deliver beyond their due date.</p> <p>It is of vital importance to continue work on addressing the racial disparities in maternity which have led to this recommendation. It is of equal importance to include women from BAME group, for example, a focus group where their views and concerns can be heard or consulted on this decision of IOL at 39 weeks.</p> | <p>with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. The committee includes service users or lay people and people from a non-white background who are involved throughout the development process. The consultation process has taken into account the views of a large number of stakeholders and several hundred individuals, many of whom were service users or experts by experience, and a large number of whom have identified themselves as non-white.</p> |
| Homerton University NHS Foundation Trust | Guideline | 007 | 006 | <p>Rec 2.2.6 – As per comment 1 – if more women choose to decline an IOL at 41 weeks the recommendation to undertake twice weekly CTG for women refusing to have IOL is going to add to the workload of maternity services who may not have the capacity to undertake this recommendation.</p> | <p>Thank you for your comment. This recommendation has been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not. Suggestions of what monitoring could be offered is provided but there is no evidence to confirm that monitoring can improve outcomes. This recommendation has been in place since 2008 and we do not therefore think there will be an additional impact on the workload of maternity services.</p> |
| Homerton University NHS Foundation Trust | Guideline | 012 | 012 | <p>Rec 1.2.31 – misoprostol is contraindicated in women with a uterine scar (in context of IOL for intrauterine fetal death). The guideline does not make a recommendation about any regimen for women in this category.= what measures should be used</p> | <p>Thank you for your comment. In order to make the recommendation more helpful, we have used the same wording as that used for women who are giving birth to a live baby and who have had a previous caesarean birth, which suggests that methods used for induction will need to take into account the risk of uterine rupture, for example by using mechanical methods.</p> |
| Homerton University NHS Foundation Trust | Guideline | 012 | 021 | <p>Rec - 1.2.31 - Consider using mifepristone for women with IUD with two previous caesarean section in late preterm and term pregnancies. Women should be counselled on risks and benefits of a vaginal birth and that it could take more than two days. Her preferences should be factored into all management plans including different IOL methods. Consideration should be given to using misoprostol, gemeprost, foley catheter in inducing these women with</p> | <p>Thank you for your comment. No evidence for the safety or efficacy of mifepristone was identified in women with a previous caesarean birth, and the committee were concerned that it may lead to a very prolonged induction process, which may be distressing for women, therefore mifepristone was not recommended as a possible treatment option for women with intrauterine fetal death and a previous caesarean birth. However, in order to make</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | appropriate rest time between each method. Counselling should include the risk of uterine rupture. | the recommendation more helpful, we have used the same wording as that used for women who are giving birth to a live baby and who have had a previous caesarean birth, which suggests that methods used for induction will need to take into account the risk of uterine rupture, for example by using mechanical methods. |
| Hywel Dda University Health Board | General | General | General | <p>It is clear that some groups of women/babies have a slightly higher chance of stillbirth compared to other groups. The absolute risk may not be that high and we often have no trial evidence to show whether or not induction of labour would make a difference. The NICE panel members are basing some sweeping statements about these groups of women being at high risk purely on their "knowledge and experience." No evidence is given to justify offering induction of labour to these women at 39 weeks. NICE has rules as to what constitutes robust evidence but it is sometimes difficult to see how these rules are being applied in this particular draft guideline.</p> <p>Also of concern is the recommendation that induction of labour should be considered at 39 weeks for women "with a black, Asian or minority ethnic family background". There is no evidence that this is beneficial and, while it is vital that we look at how we can improve the inequalities faced by marginalised women situation, increased intervention may not be the answer. There is, again, no evidence of benefit, and many people have concerns that this reflects a belief that these women's bodies are less capable, rather than addressing systemic racism and other inequalities.</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and so earlier induction is no longer recommended in these groups of women. |
| Hywel Dda University Health Board | General | General | General | <p>Many women are dissatisfied with induction and for some women induction of labour can lead to trauma and mental health problems. Others have questions that remain unanswered or did not feel that they were given appropriate information upon which they could make the decision that was right for them.</p> <ol style="list-style-type: none"> 1. Research on what women want has been carried out. But none of this work has been taken into | Thank you for your comment. It was not within the scope of this update to carry out a qualitative review of women's experiences. However, the committee have updated the recommendations on information and decision-making to include the factors that women should take into consideration when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that it is the woman's |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>account by those developing the draft NICE guideline on inducing labour.</p> <p>The rationale for induction of labour is based on the "knowledge and expertise of the panel" rather than qualitative evidence which explores the impact that induction of labour can have on women and birthing people.</p> | <p>choice, and that her decision should be respected. This is based on the committee's expertise but the committee included 2 lay members with lived experience of induction of labour and experience of representing the views of maternity service users.</p> |
| Hywel Dda University Health Board | General | General | General | <p>The reference frame is too narrow:</p> <p>One of the concerns about this guidance is that the included evidence is very restricted. There is no discussion about long-term outcomes, negative consequences of induction or women's views. Instead, the questions considered by NICE are mainly limited to the immediate intrapartum period. This isn't helpful or ethical, because induction has long-term implications for women, babies and families.</p> <ol style="list-style-type: none"> 1. There is concern that long-term outcomes are poorer after induction of labour. Both the drugs and mechanical methods used in induction and the interventions that may result can have unwanted and potentially harmful consequences. These may be justified where induction will benefit an individual. But when induction is a routine recommendation and information on long-term outcomes is not being offered or considered, we are denying women and families the right to make informed decisions. 2. A paper from The Millenium Cohort Study showed that UK children born at earlier gestational ages are more likely to have special education needs at age 11 compared with those born in week 40, reaching a peak of 27.4% in children born very preterm. An increased risk of SEN exists even for children born at early term gestations and even when the birth was of spontaneous onset. | <p>Thank you for your comment. The committee discussed the fact that there were a large number of outcomes which could be considered for this review, and agreed to prioritise 7 for women and babies as they believed these were the most direct indicators of safety for timing of induction of labour. Longer term outcomes were not included as the committee believed these would be reported sparsely, however they prioritised neonatal morbidity (meconium aspiration/HIE), as this has potentially long term implications for the baby. To encourage future studies to assess longer term outcomes, the committee have amended the research recommendation to include these.</p> <p>Induction of labour is not recommended routinely. As reflected in the recommendations, women with uncomplicated pregnancies should be given every opportunity to go into spontaneous labour. In addition, based on stakeholder feedback, the recommendations have been amended to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected.</p> <p>We have checked the suggested references individually and these are not within the scope of this update. The Millenium cohort study (Alterman 2021) is a longitudinal study which assessed the association between gestational age at birth and special education needs later in life. Is not eligible as is it not a RCT, did not compare different</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | 3. And recent research by Dahlen et al (2021) showed that induction of labour leads to more intervention and more adverse maternal, neonatal and child outcomes. This study also showed that, although the induction rate has tripled in some groups of women in the past 16 years, there has been no reduction in stillbirth. | timings of induction and is a single-arm study. Dahlen 2021 is not eligible for inclusion because it did not compare different timings of induction and it is not a RCT. For further details regarding inclusion and exclusion criteria of studies, please see the review protocol in appendix A of evidence report C. |
| Hywel Dda University Health Board | Guideline | General | General | The draft NICE guideline on inducing labour has been met the organsiation worry and concern in many quarters, for several reasons. One element can be seen in the removal of a key line from the 2008 guideline. "Women with uncomplicated pregnancies should be given every opportunity to go into spontaneous labour." In the draft 2021 guideline, NICE state that: "This recommendation has been deleted because the next recommendation states which women with uncomplicated pregnancies should be offered induction, and so the committee agreed this recommendation was unnecessary." In some cases, statements about "the evidence" are not supported with a reference. When one clicks the links in the document in an attempt to see the evidence used to support changes and recommendations, the recommendation turns out to be based on the "knowledge and experience" of the panel. Which is very different from robust evidence and somewhat presumptive to assume that the knowledge and experience of a panel of professionals would surpass good quality research and evidence, women should be aware of this when making informed choices. | Thank you for your comment. We will address your points in turn. 1. Based on stakeholder feedback we have reinstated this recommendation into the guideline. 2. NICE guidelines are based on the committee's interpretation of the evidence and where there is a lack of evidence, the committee may decide to make or augment recommendations based on their knowledge and experience. |
| Hywel Dda University Health Board | Guideline | General | General | The ARRIVE Trial controversy The controversial ARRIVE trial is used as a key reference to underpin many of the changes in the draft guideline. Yet this trial has been criticised by many experts. It is described by NICE as "high quality evidence" and yet experts agree that there are numerous methodological issues with this study. | Thank you for your comment. The methodological limitations of the ARRIVE trial were reflected in the evidence report and taken into consideration by the committee when interpreting the evidence. One of the outcomes (maternal mortality/morbidity) was of high quality as one of the main limitations of this trial was lack of |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>More than 16,000 women declined to be in this study, which was about 73% of those asked. As a result, the women who were in the study may not be representative. The care that participants received was highly medicalised. The vast majority were cared for by a doctor, which does not happen in countries like the UK. The caesarean section rate was extraordinarily high given that the women in the study were "low risk." And the study showed no difference in mortality for babies.</p> <ol style="list-style-type: none"> 1. The study shows that perinatal deaths were 2 in the IOL group and 3 in the expectant management group and that this was not significantly different. So people who are saying that this study showed reduced risk of stillbirth as a result of induction of labour are incorrect 2. Perinatal death covers both stillbirth and neonatal death. It would be important to know when the 5 deaths occurred 3. Is there any way the deaths could be linked to the intervention, for example did the 2 baby's in the IOL group die as a result of a ruptured vasa praevia or cord prolapse? Did the 3 babies in the expectant management group die as a result of being in that group eg did their mothers present at 39 weeks and 2 days with altered fetal activity and there was a reluctance to induce because they were in the wrong arm of the trial? 4. 11 babies in the IOL group had "seizures" versus only 4 in the expectant group. What were the seizures from, and could these be linked in any way to the IOL? <p>The California Maternal Quality Care Collaborative (CMQCC) has published a commentary on the ARRIVE trial</p> | <p>blinding, but it was deemed unlikely to affect this outcome (mortality) due to its objective nature. The committee considered the proportion of women who declined to participate to be within normal parameters and considered this could be due to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal. We have now included the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding of the evidence reviewed. The supporting information explains how this data was derived, its limitations and how to interpret it. Your second point relates to induction in babies with suspected macrosomia. We recognise the evidence was not conclusive here and so have amended this recommendation to clarify that the choice of modes of birth should be discussed with the woman so that she can make an informed decision about mode of birth.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | questioning whether trial results can be generalized. The commentary points out that cesarean rates in low-risk 1st-time mothers undergoing induction in California's 240 hospitals averages 32% and ranges as high as 60%. CMQCC attributes the low rate in induced women in the ARRIVE trial to using a common definition of failed induction It's also important to consider the way in which evidence is generated and the belief systems of those who undertake and participate in such research. The percentage of macrosomic babies (≥ 4000 g) changes very little over the last few weeks of pregnancy. A study reported that the percentage of macrosomic babies went from 11% in week 38 to 14% in week 40—and this data comes from a population exclusively of high BMI women, who are more likely to have bigger babies than the population at large (Lee 2016). More importantly, the inability to birth larger babies largely originates in doctors' heads, not women's bodies. Every study that has ever looked at the issue has found that when doctors suspect the baby is going to be big, the odds of cesarean delivery go up markedly regardless of whether the baby is actually on the large side (Blackwell 2009; Levine 1992; Melamed 2010; Parry 2000; Peleg 2014; Sadeh-Mestechkin 2008; Scifres 2015; Weeks 1995; Weiner 2002). The reverse is also true: unsuspected big babies have much lower cesarean rates than babies correctly suspected. The fear that the baby will be too big for the woman to deliver becomes a self-fulfilling prophecy. It leads to inducing labor to prevent the baby growing even bigger, and induced labors are more likely to end in cesarean. It leads to more diagnoses of failure to progress (Blackwell 2009) and failed induction, especially in early labor, before this diagnosis can legitimately be made (Weeks 1995). And one which illustrates how vital it is not just to look at the results of research but at the wider context of research and practice. | |
| Hywel Dda University Health Board | Guideline | General | General | It is clear that some groups of women/babies have a slightly higher chance of stillbirth compared to other groups. The absolute risk may not be that high and we often have no trial | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>evidence to show whether or not induction of labour would make a difference. The NICE panel members are basing some sweeping statements about these groups of women being at high risk purely on their "knowledge and experience." No evidence is given to justify offering induction of labour to these women at 39 weeks. NICE has rules as to what constitutes robust evidence but it is sometimes difficult to see how these rules are being applied in this particular draft guideline.</p> <p>Also of concern is the recommendation that induction of labour should be considered at 39 weeks for women "with a black, Asian or minority ethnic family background". There is no evidence that this is beneficial and, while it is vital that we look at how we can improve the inequalities faced by marginalised women situation, increased intervention may not be the answer. There is, again, no evidence of benefit, and many people have concerns that this reflects a belief that these women's bodies are less capable, rather than addressing systemic racism and other inequalities.</p> | with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Hywel Dda University Health Board | Guideline | 005 | 011 | Should risks and benefits of NOT being induced not also be discussed in order to provide balanced counselling and to support women with their decision making | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on these outcomes. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Hywel Dda University Health Board | Guideline | 006 | 010 | This is against recent evidence by Dahlen et al (2021), which concluded that IOL in uncomplicated pregnancies 'increased rates of intrapartum interventions and adverse outcomes in the short term for mother and neonate, and of hospitalisation for infection in the longer term for children.' Additionally they concluded that they 'did not find any benefits of IOL for | Thank you for your comment. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>neonates, at any term gestation of labour onset'. The recommendations within this guideline directly contradict this 16-year population-based linked data study, which included 474652 births.</p> <p>It is vital that we understand and include the potential long term impact associated with induction of labour.</p> | to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. |
| Hywel Dda University Health Board | Guideline | 006 | 012 | <p>Figures need to be provided here to quantify these statements, and to balance them against the relative risks of these events should IOL be commenced.</p> <p>The data that is presented should be clear and objective, there is much discussion amongst clinicians that the data is coercive and undermines women and birth peoples abilities to make an informed choice about proceeding or declining induction of labour. Any data presented in graph / chart form should clearly reflect absolute versus relative risk to support informed decision making.</p> | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| Hywel Dda University Health Board | Guideline | 006 | 020 | <p>This is a very surprising addition. This would be a huge proportion of our women/birthing people having IOL, thus reducing their choice of place of birth and opportunity to be MLC in labour. This would result in a huge decrease in home and birth centre births, and a ridiculously unjustified increase in intervention. Furthermore this would likely increase the already high caesarean rate in the UK.</p> <p>Much of the evidence has been derived from the SWEPSIS which is a research study that has been well documented to have been discontinued due to safety concerns, however the authors themselves state that whilst acknowledging that the loss of any baby is one loss too many it is important to understand the reasons which contributed to the demise of the baby and whether it was exclusively linked to post maturity. The authors reported that one fetal loss had been associated with a cardiac anomaly and this should be made explicitly clear.</p> | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review choice of place of birth. However, based on stakeholder feedback, the recommendations have been amended to include the factors that should be taken into consideration by women when deciding whether or not to have an induction, which includes the fact that their choice of place of birth will be limited, as they may be recommended interventions (for example, oxytocin infusion, continuous fetal heart rate monitoring and epidurals) that are not available for home birth or in midwife-led units. In addition, we have also added an additional recommendation to |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. |
| Hywel Dda University Health Board | Guideline | 008 | 021 | Again this will massively increase intervention rates in women who may go on to birth spontaneously and without complications | Thank you for your comment. This recommendation has been in place since 2008 (the amendments made in 2021 were minor changes to the wording) and so is not likely to change current practice. |
| Hywel Dda University Health Board | Guideline | 009 | 017 | Please consider use of language; there is a huge drive to use empowering language such as 'birth' instead of 'deliver' | Thank you for your comment. We have changed this to birth. |
| Hywel Dda University Health Board | Guideline | 010 | 009 | Use of language (see above point) | Thank you for your comment. We have changed 'delivery' to 'birth'. |
| Hywel Dda University Health Board | Guideline | 013 | 014 | This is a huge intervention that evidence does not appear to support. Sweeps at 40 weeks in nulliparous women are rarely performed successfully so doing them earlier will only make this worse, putting women through additional invasive interventions. | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, or the likelihood of success. However, the recommendations have now been clarified to state that membrane sweeps should be discussed after 39 weeks (as opposed to 'from 39 weeks') so sweeps will happen from week 40 onwards. |
| Hywel Dda University Health Board | Guideline | 013 | 016 | Please consider including guidance on how often sweeps are to be performed, the interval between them and how many sweeps can be performed in routine cases. | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, the likelihood of success, optimal timing or frequency. However, we have amended this recommendation to emphasise that additional membrane sweeping should only be considered after a discussion with the woman. |
| Independent Midwives UK | Guideline | General | General | Areas highlighted in grey have been amended without reviewing the research. | Thank you for your comment. You are correct that an updated evidence review has not been conducted for sections of the guideline that have been shaded in grey, but we have made changes that could affect the intent without reviewing the evidence, in order to ensure the guideline was up to date. The reasons for the changes are provided in a supplement. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Independent Midwives UK | Guideline | 006 | 010 | 1.2.1.1 Changes in guidance such as the deletion of the advice that women with an uncomplicated pregnancy should be given every opportunity to go into spontaneous labour, have been made by the committee without reference to the evidence. The draft refers to the knowledge and experience of the panel. This is not robust evidence, this is low quality opinion. | Thank you for your comment. This recommendation has been replaced back into the guideline. |
| Independent Midwives UK | Guideline | 006 | 010 | 1.2.1.2 Normal full term pregnancy is described as 37 – 42 weeks. By recommending induction at 41 weeks the committee is effectively changing the accepted world wide definition of normal pregnancy length. | Thank you for your comment. The recommendations for induction at 41 weeks were based on evidence that certain risks may increase after this time, even though this may still be considered within the range of a normal term. However, based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| Independent Midwives UK | Guideline | 006 | 020 | 1.2.4 Offering induction at 39 weeks to people from black, Asian or minority ethnic backgrounds, is not supported by evidence and fails to address the reasons why pregnant people from these groups are more likely to suffer from adverse outcomes. Rather than ending their pregnancies early, with the associated risks of induction, work needs to be done on addressing the inequalities these groups face in accessing the healthcare system. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Independent Midwives UK | Guideline | 010 | 020 | 1.2.10.1 'The Big Baby Clinical Trial' has not published any conclusive evidence yet as to whether people with suspected fetal macrosomia would benefit from induction of labour as opposed to waiting for spontaneous labour. It is acknowledged that induction of labour is a risk factor for shoulder dystocia, so until the trial is concluded it is not appropriate to change NICE guidance. | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Independent Midwives UK | Guideline | 013 | 014 | 1.3.1.2 We refute the need to offer membrane sweeping as a routine procedure at 39 weeks. The evidence to support this and the efficacy of membrane sweeping and evidence around this procedure is weak. It can initiate a prolonged latent phase of pre-labour which will disadvantage the person who it is performed on. | Thank you for your comment. The recommendations have now been clarified to state that membrane sweeps should be discussed after 39 weeks (as opposed to 'from 39 weeks') so sweeps will happen from week 40 onwards. |
| King's College Hospital Maternity Voices Partnership | Guideline | 006 | 020 | <ul style="list-style-type: none"> Nothing about us, without us! The draft guidelines do not include or reflect the 'woman's voice'. This is not a co-produced document. We urge NICE to set up a steering group of women with lived experience of the maternity service and to collaborate with MVPs across the country to ensure that the guidelines are fit for purpose. Incidentally, co-production alongside people with lived experience should be a hygiene factor for NICE guidelines across the board The evidence base for the Inducing Labour guidelines are too narrow. What's more, an upfront exploration around the long-term outcomes and negative consequences of induction are not referenced. There are risks to all decisions and the risks surrounding an increase in induction rates need to be addressed. As the draft guidelines currently stand, the 'business as usual' approach to inductions will mean that women and their families will be denied the right to make informed choices. The suggested changes to offer induction in later pregnancy as routine, ignores qualitative and quantitative data around the inaccuracy of 'due' dates. As Sara Wickham states in her analysis: 'the offer of an earlier induction will mean more babies will be born before they are ready. These babies will be at risk of long term health issues as a result.' | <p>Thank you for your comment. The committee included 2 lay members with lived experience of induction of labour and wider experience of representing people using maternity services. The consultation process is an additional method we use to obtain input into the guideline from a wide range of stakeholders and individuals, and to ensure that the guideline is fit for purpose. This guideline received over 3000 comments in this way, and each one was read and considered by the committee in order to amend and improve the guideline.</p> <p>It was not within the scope of this update to carry out a review of the risks and benefits of induction of labour compared to expectant management. However, the committee have updated the recommendations on information and decision-making to include the factors that women should take into consideration when deciding whether or not to have an induction. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion of the risks and benefits with the woman so she can make an informed decision. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the birth of preterm babies. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. However, the committee agree</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-------------------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <ul style="list-style-type: none"> We also call for more research into the NICE guidance for women of black and minority ethnic backgrounds, so that the guidance reflects the urgent need to challenge health inequalities for women in these groups, rather than inadvertently maintaining the dangerous status quo. | that there is a need for further research into the optimal timing of induction for all women and have made 2 research recommendations. |
| King's College London | Guideline | 006 | 024 | There is nothing inherently different about women who describe themselves as being Black, Asian or from a minoritized community compared to White women. The worse outcomes are due to complex factors including socio-economic status, education, culture and racism (whether this is from the wider community or health professionals). There is no biological reason – race is a social construct. Induction has risks – as we all know. We should be trying to change the structures that mean that these women are having worse outcomes, rather than putting the onus on these women and asking them to be induced early (and take on the risks that come with it). | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| King's College London | Guideline | 007 | 007 - 012 | Agree – monitoring gives only a snapshot of that moment in time. Therefore, why are we offering it? What purpose does it have? Should we consider offering an alternative with better predictive ability e.g. fetal growth scan and dopplers? | Thank you for your comment. This recommendation has been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The monitoring suggested was carried over from the previous version of the guideline, and looking at the different types of monitoring that could be offered was not within the scope of this update so we are unable to make recommendations on other types of monitoring. |
| King's College London | Evidence review D | 008 | 006 | The only study that examined maternal satisfaction was a study where 16,427 women declined to participate (Grobman et al., 2018). The volume of women who declined participation perhaps gives an indication that the majority women do not want to be induced early? This needs factoring in to the recommendation of when to induce. | Thank you for your comment. The committee acknowledged the paucity of evidence for the outcome maternal satisfaction in this review, and they agreed that women's choice is key for providing optimal care in maternity services. Based on stakeholder feedback, the recommendations have been amended to include the factors that should be taken into consideration by women |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. The committee considered the proportion of women who declined to participate in the trial within normal parameters and noted that this may have been related to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal. |
| King's College London | Guideline | 010 | 005 | <p>Suggest the section on 'Breech Presentation' is re-written to reflect the ethos of informed choice and discussion, in a similar manner to the section on 'Previous caesarean birth.' Otherwise, the service is inequitable. A guideline on IOL with breech presentation is only applicable to women who have chosen to plan a vaginal breech birth. The guideline should reflect and respect this, using neutral, non-judgemental language.</p> <p>For example:</p> <p>1.2.19 Advise women with a baby in the breech position, who have chosen to plan a vaginal breech birth, that:</p> <ul style="list-style-type: none"> • induction of labour could lead to an increased risk of emergency caesarean birth, compared to spontaneous breech labour • induction of labour could lead to an increased risk of neonatal intensive care unit admission for the baby, compared to spontaneous breech labour • the methods used for induction of labour will be guided by the need to reduce these risks. See the recommendations on Methods for inducing labour. <p>1.2.22 If delivery is indicated, offer women who have a baby in the breech position a choice of:</p> <ul style="list-style-type: none"> • an attempt at external cephalic version, immediately followed by induction of labour if successful | <p>Thank you for your comment. Induction of labour with breech presentation was not included in the scope of this guideline update and so we have not been able to add more detail about the risks and benefits of induction, compared to a spontaneous labour and so we have not made the changes you suggest to these recommendations.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <ul style="list-style-type: none"> • caesarean birth or • induction of labour in breech presentation <p>Take into account the woman's circumstances and preferences. Advise women that they are entitled to decline the offer of treatment such as external cephalic version, induction of labour or caesarean birth, even when it MAY benefit their or their baby's health.</p> <p>Current wording is:</p> <p>Breech presentation</p> <p>1.2.19 Induction of labour is not generally recommended if a woman's baby is in the breech position. [2008, amended 2021]</p> <p>1.2.20 Consider induction of labour for babies in the breech position if:</p> <ul style="list-style-type: none"> • delivery is indicated and • external cephalic version is unsuccessful, declined or contraindicated and • the woman chooses not to have an elective caesarean birth. <p>Discuss the possible risks associated with induction with the woman. [2008, amended 2021]</p> | |
| King's College London | Guideline | 010 | 006 | <p>1.2.19 Induction of labour is not generally recommended if a woman's baby is in the breech position. [2008, amended 2021]</p> <p>Cannot locate evidence for this recommendation in evidence review. This statement is vague. Not generally recommended by who? Why? Induction of labour for breech presentation is common outside of the UK.</p> | Thank you for your comment. Induction of labour with breech presentation was not included in the scope of this guideline update and so there is no direct link to the evidence for these recommendations. However, the evidence is available on the NICE website as part of the 2008 guideline evidence. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| King's College London | Guideline | 010 | 014 | Discuss the possible risks of induction with the woman. Also vague. What are the risks? A systematic review has been done, so women can be offered evidence-based information rather than general reluctance. https://www.ejog.org/article/S0301-2115(17)30578-X/fulltext In any discussion of intervention, also appropriate to discuss potential benefits. | Thank you for your comment and for supplying details of this paper. Induction of labour for babies in the breech position was not included in the scope of this update, but we will forward this information to the NICE surveillance team who ensure guidelines are up to date. |
| King's College London | Guideline | 010 | 017 | How is 'confirmed fetal compromise' defined – does this include abnormal fetal Dopplers? | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add a definition of confirmed fetal compromise. |
| King's College London | Guideline | 010 | 020 | When should induction of labour be offered to women with suspected fetal macrosomia? I can see that this is defined lower down, but may be useful to refer to this in the text. | Thank you for your comment. Terms are defined in the guideline by hyperlinking them to the 'terms used' section as it would make the guideline unwieldy to include all the definitions as part of the recommendations. |
| King's College London | Guideline | 011 | 003 - 004 | Why are only the women with suspected macrosomia being supported for recruitment into clinical trials? There are many other indications explored on which the evidence base requires improvement. | Thank you for your comment. This group was highlighted for inclusion in clinical trials as the committee were aware of an ongoing clinical trial (Big Baby) which will provide specific data on the role of induction in suspected fetal macrosomia. |
| King's College London | Guideline | 015 | 005 - 019 | Are we really expected to discuss with the woman all of the pharmacological options which we cannot offer her for induction of labour? | Thank you for your comment. We have amended this recommendation to state that it is for information only, and that these methods of induction do not all need to be discussed with women. |
| King's College London | Guideline | 016 | 014 | Can we not confirm absence of contractions by asking the woman? We often see Braxton Hicks tightening on the CTG monitor which are mild but look the same as contractions do. These are normal in third trimester and are surely not a contra-indication to commencing induction. | Thank you for your comment. The committee have amended the wording of this recommendation to state that it is the absence of significant uterine contractions (not Braxton-Hicks) that must be confirmed before commencing induction of labour. |
| King's College London | Guideline | 016 | 023 | How frequently should intermittent monitoring be offered to a woman being induced but contracting irregularly? Is this the same frequency as for a woman in established labour? Intermittent monitoring for established contractions is already covered in 1.5.5. | Thank you for your comment. The committee agreed that it would not be possible to specify how often intermittent monitoring should take place if contractions were irregular, as this would depend on the clinical situation and would need to be an individualised decision. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------------------------------------------|-------------------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| King's College London | Guideline | 019 | 009 | Is this realistic, including acceptable to the woman? Induction may take 24-48 hours (particularly if using PGE2 slow-release pessary), can we realistically expect the woman to stay on CTG for the whole duration. Can we consider offering this to start only after contractions have commenced? | Thank you for your comment. We have amended the recommendation to state that continuous cardiotocography would only be required after the membranes had ruptured if the presenting part was not stable, so this is not likely to be the case for all women or for the whole duration of labour. The recommendations on monitoring suggest that unless there are clear indications for cardiotocography, intermittent auscultation may be used during induction. |
| King's College London | Evidence review C | 020 | 034 - 045 | Linked to comment 3 above. Why are we offering this if it has the ability to offer women a false sense of security? Telling women this does not rule out or prevent adverse effects and only provides a snapshot at the same time as offering this monitoring appears to give mixed messages to women | Thank you for your comment. This recommendation has been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The monitoring suggested was carried over from the previous version of the guideline, and looking at the different types of monitoring that could be offered was not within the scope of this update so we are unable to make recommendations on other types of monitoring. |
| King's College London - Maternal Health Systems and Implementation Research Group | Guideline | 006 | 024 | There is nothing inherently different about women who describe themselves as being Black, Asian or from a minoritized community compared to White women. The worse outcomes are due to complex factors including socio-economic status, education, culture and racism (whether this is from the wider community or health professionals). There is no biological reason – race is a social construct. Induction has risks – as we all know. We should be trying to change the structures that mean that these women are having worse outcomes, rather than putting the onus on these women and asking them to be induced early (and take on the risks that come with it). | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| King's College London - Maternal Health Systems and Implementation Research Group | Guideline | 007 | 007 - 012 | Agree – monitoring gives only a snapshot of that moment in time. Therefore, why are we offering it? What purpose does it have? Should we consider offering an alternative with better predictive ability e.g. fetal growth scan and dopplers? | Thank you for your comment. This recommendation has been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------------------------------------------|-------------------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | monitoring suggested was carried over from the previous version of the guideline, and looking at the different types of monitoring that could be offered was not within the scope of this update so we are unable to make recommendations on other types of monitoring. |
| King's College London - Maternal Health Systems and Implementation Research Group | Evidence Review D | 008 | 006 | The only study that examined maternal satisfaction was a study where 16,427 women declined to participate (Grobman et al., 2018). The volume of women who declined participation perhaps gives an indication that the majority women do not want to be induced early? This needs factoring in to the recommendation of when to induce. | Thank you for your comment. The committee acknowledged the paucity of evidence for the outcome maternal satisfaction in this review, and they agreed that women's choice is key for providing optimal care in maternity services. Based on stakeholder feedback, the recommendations have been amended to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. The committee considered the proportion of women who declined to participate in the trial within normal parameters and noted that this may have been related to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal. |
| King's College London - Maternal Health Systems and Implementation Research Group | Guideline | 010 | 005 | Suggest the section on 'Breech Presentation' is re-written to reflect the ethos of informed choice and discussion, in a similar manner to the section on 'Previous caesarean birth.' Otherwise, the service is inequitable. A guideline on IOL with breech presentation is only applicable to women who have chosen to plan a vaginal breech birth. The guideline should reflect and respect this, using neutral, non-judgemental language. For example: 1.2.19 Advise women with a baby in the breech position, who have chosen to plan a vaginal breech birth, that: <ul style="list-style-type: none"> induction of labour could lead to an increased risk of emergency caesarean birth, compared to spontaneous breech labour | Thank you for your comment. Induction of labour with breech presentation was not included in the scope of this guideline update and so we have not been able to add more detail about the risks and benefits of induction, compared to a spontaneous labour and so we have not made the changes you suggest to these recommendations. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <ul style="list-style-type: none"> induction of labour could lead to an increased risk of neonatal intensive care unit admission for the baby, compared to spontaneous breech labour the methods used for induction of labour will be guided by the need to reduce these risks. See the recommendations on Methods for inducing labour. <p>1.2.23 If delivery is indicated, offer women who have a baby in the breech position a choice of:</p> <ul style="list-style-type: none"> an attempt at external cephalic version, immediately followed by induction of labour if successful caesarean birth or induction of labour in breech presentation <p>Take into account the woman's circumstances and preferences. Advise women that they are entitled to decline the offer of treatment such as external cephalic version, induction of labour or caesarean birth, even when it MAY benefit their or their baby's health.</p> <p>Current wording is:</p> <p>Breech presentation</p> <p>1.2.19 Induction of labour is not generally recommended if a woman's baby is in the breech position. [2008, amended 2021]</p> <p>1.2.20 Consider induction of labour for babies in the breech position if:</p> <ul style="list-style-type: none"> delivery is indicated and external cephalic version is unsuccessful, declined or contraindicated and the woman chooses not to have an elective caesarean birth. | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------------------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | Discuss the possible risks associated with induction with the woman. [2008, amended 2021] | |
| King's College London - Maternal Health Systems and Implementation Research Group | Guideline | 010 | 006 | 1.2.19 Induction of labour is not generally recommended if a woman's baby is in the breech position. [2008, amended 2021] Cannot locate evidence for this recommendation in evidence review. This statement is vague. Not generally recommended by who? Why? Induction of labour for breech presentation is common outside of the UK. | Thank you for your comment. Induction of labour with breech presentation was not included in the scope of this guideline update and so there is no direct link to the evidence for these recommendations. However, the evidence is available on the NICE website as part of the 2008 guideline evidence. |
| King's College London - Maternal Health Systems and Implementation Research Group | Guideline | 010 | 014 | Discuss the possible risks of induction with the woman. Also vague. What are the risks? A systematic review has been done, so women can be offered evidence-based information rather than general reluctance. https://www.ejog.org/article/S0301-2115(17)30578-X/fulltext In any discussion of intervention, also appropriate to discuss potential benefits. | Thank you for your comment and for supplying details of this paper. Induction of labour for babies in the breech position was not included in the scope of this update, but we will forward this information to the NICE surveillance team who ensure guidelines are up to date. |
| King's College London - Maternal Health Systems and Implementation Research Group | Guideline | 010 | 017 | How is 'confirmed fetal compromise' defined – does this include abnormal fetal Dopplers? | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add a definition of confirmed fetal compromise. |
| King's College London - Maternal Health Systems and Implementation Research Group | Guideline | 010 | 020 | When should induction of labour be offered to women with suspected fetal macrosomia? I can see that this is defined lower down, but may be useful to refer to this in the text. | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------------------------------------------|-----------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | The committee discussed whether it was possible to define the best time to induce labour in suspected fetal macrosomia but the evidence included induction at a range of gestational ages and it was not possible to identify the preferred gestational age. The committee also considered this would be an individualised decision based on the estimated size of the baby, the woman's clinical circumstances and her preferences. |
| King's College London - Maternal Health Systems and Implementation Research Group | Guideline | 011 | 003 - 004 | Why are only the women with suspected macrosomia being supported for recruitment into clinical trials? There are many other indications explored on which the evidence base requires improvement. | Thank you for your comment. This group was highlighted for inclusion in clinical trials as the committee were aware of an ongoing clinical trial (Big Baby) which will provide specific data on the role of induction in suspected fetal macrosomia. |
| King's College London - Maternal Health Systems and Implementation Research Group | Guideline | 015 | 005 - 019 | Are we really expected to discuss with the woman all of the pharmacological options which we cannot offer her for induction of labour? | Thank you for your comment. We have amended this recommendation to state that it is for information only, and that these methods of induction do not all need to be discussed with women. |
| King's College London - Maternal Health Systems and Implementation Research Group | Guideline | 016 | 014 | Can we not confirm absence of contractions by asking the woman? We often see Braxton Hicks tightening on the CTG monitor which are mild but look the same as contractions do. These are normal in third trimester and are surely not a contra-indication to commencing induction. | Thank you for your comment. The committee have amended the wording of this recommendation to state that it is the absence of significant uterine contractions (not Braxton-Hicks) that must be confirmed before commencing induction of labour. |
| King's College London - Maternal Health Systems and Implementation Research Group | Guideline | 016 | 023 | How frequently should intermittent monitoring be offered to a woman being induced but contracting irregularly? Is this the same frequency as for a woman in established labour? Intermittent monitoring for established contractions is already covered in 1.5.5. | Thank you for your comment. The committee agreed that it would not be possible to specify how often intermittent monitoring should take place if contractions were irregular, as this would depend on the clinical situation and would need to be an individualised decision. |
| King's College London - Maternal Health Systems and Implementation Research Group | Guideline | 019 | 009 | Is this realistic, including acceptable to the woman? Induction may take 24-48 hours (particularly if using PGE2 slow-release pessary), can we realistically expect the woman to stay on CTG for the whole duration. Can we consider offering this to start only after contractions have commenced? | Thank you for your comment. We have amended the recommendation to state that continuous cardiotocography would only be required after the membranes had ruptured if the presenting part was not stable, so this is not likely to be the case for all women or for the whole duration of labour. The recommendations on monitoring suggest that |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------------------------------------------|-------------------|---------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | unless there are clear indications for cardiotocography, intermittent auscultation may be used during induction. |
| King's College London - Maternal Health Systems and Implementation Research Group | Evidence Review C | 020 | 034 - 045 | Linked to comment 3 above. Why are we offering this if it has the ability to offer women a false sense of security? Telling women this does not rule out or prevent adverse effects and only provides a snapshot at the same time as offering this monitoring appears to give mixed messages to women | Thank you for your comment. This recommendation has been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The monitoring suggested was carried over from the previous version of the guideline, and looking at the different types of monitoring that could be offered was not within the scope of this update so we are unable to make recommendations on other types of monitoring. |
| Kings College Hospital | Guideline | 006 | 020 1.2.4 | <ol style="list-style-type: none"> Nothing about us, without us! The draft guidelines do not include or reflect the 'woman's voice'. This is not a co-produced document. We urge NICE to set up a steering group of women with lived experience of the maternity service and to collaborate with MVPs across the country to ensure that the guidelines are fit for purpose. Incidentally, co-production alongside people with lived experience should be a hygiene factor for NICE guidelines across the board. The evidence base for the <i>Inducing Labour</i> guidelines are too narrow. What's more, an upfront exploration around the long-term outcomes and negative consequences of induction are not referenced. There are risks to all decisions and the risks surrounding an increase in induction rates need to be addressed. As the draft guidelines currently stand, the 'business as usual' approach to inductions will mean that women and their | Thank you for your comment. The committee included 2 lay members with lived experience of induction of labour and wider experience of representing people using maternity services. The consultation process is the additional method we use to obtain input into the guideline from a wide range of stakeholders and individuals, and to ensure that the guideline is fit for purpose. This guideline received over 3000 comments in this way, and each one was read and considered by the committee in order to amend and improve the guideline. It was not within the scope of this update to carry out a review of the risks and benefits of induction of labour compared to expectant management. However, the committee have updated the recommendations on information and decision-making to include the factors that women should take into consideration when deciding whether or not to have an induction. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion of the risks and benefits with the woman so she can make an informed decision. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>families will be denied the right to make informed choices.</p> <p>3. The suggested changes to offer induction in later pregnancy as routine, ignores qualitative and quantitative data around the inaccuracy of 'due' dates. As Sara Wickham states in her analysis: 'the offer of an earlier induction will mean more babies will be born before they are ready. These babies will be at risk of long term health issues as a result.'</p> <p>4. We also call for more research into the NICE guidance for women of black and minority ethnic backgrounds, so that the guidance reflects the urgent need to challenge health inequalities for women in these groups, rather than inadvertently maintaining the dangerous status quo.</p> | <p>birth of preterm babies. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. However, the committee agree that there is a need for further research into the optimal timing of induction for all women and have made 2 research recommendations.</p> |
| Kingston University and St Georges, University of London | Guideline | 006 | 012 | <p>Section 1.2.3 recommends that clinicians should: Explain to women that the risks associated with a pregnancy continuing 13 beyond 41+0 weeks increase over time, and include: 14 • increased likelihood of caesarean birth 15 • increased likelihood of the baby needing admission to a neonatal 16 intensive care unit 17 • increased likelihood of stillbirth and neonatal death 18 • a possible increased likelihood of assisted vaginal birth (using forceps 19 or ventouse). [2021]</p> <p>This guidance needs to include the absolute risks, based on the evidence, as 'increased' does not provide enough contextual information to make an informed decision about this, given the likelihood of adverse outcomes identified by</p> | <p>Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | Dahlen et al in their large observational study https://bmjopen.bmj.com/content/11/6/e047040 | |
| Kingston University and St Georges, University of London | Guideline | 006 | 020 | Section 1.2.4 This section advises that clinicians should 'consider induction of labour from 39+0 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications associated with continued pregnancy (for example, BMI 30 kg/m ² 23 or above, age 35 years or above, with a black, Asian or minority ethnic family background, or after assisted conception). The inclusion of 'women with a black, Asian or Minority ethnic family background' appears to be present without any sort of underpinning evidence. Recent debates on increased maternal mortality and perinatal mortality associated with ethnicity is cited as a general rationale, but the debates on this topic show that these outcomes are linked to complex factors including health inequalities and failure to listen to women when they speak up about their concerns. Induction of labour is an intervention known to increase pain and discomfort and there is clear evidence that it is associated with higher birth interventions and adverse outcomes (https://bmjopen.bmj.com/content/11/6/e047040). The proposal to recommend IoL on the basis of skin colour or ethnic background disadvantages women of colour and should be abandoned. The call for evidence about the reasons for poor outcomes in women of colour and their babies is to be welcomed. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Lactation Consultants of Great Britain | Guideline | General | General | The whole document relies on accuracy of due dates – which cannot be determined to the nearest day – as natural pregnancy length varies. For a foetus that is longer than average at dating scan and a mother whose natural pregnancy length is 41+6 this could lead to errors of weeks, not just days in the accuracy of information and advice given, and significant possible negative consequences of | Thank you for your comment. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the birth of preterm babies. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | any interventions given, including (but not only) inappropriate pre-term artificial rupture of membranes. | |
| Lactation Consultants of Great Britain | Guideline | General | General | Whilst not all birthing parents are provided optimum, safe care without bias or risk it is impossible to determine that the factors highlighted in these recommendations are the root cause of poor outcomes when induction of labour is not provided before 42+0 weeks of pregnancy. | Thank you for your comment. We hope the revised version of this guideline with amendments based on stakeholder feedback will increase the proportion of people who receive optimum, safe care. |
| Lactation Consultants of Great Britain | Guideline | General | General | The benefits and risks of induction of labour indicated as evidence in this guideline do not consider longer term implications of such intervention; with increased awareness of the influence of labour and birth on the short and long term physical and mental wellbeing of the woman/birthing person and healthy development of their baby, these factors cannot be ignored. | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. We did not have any data on long-term outcomes and it was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. |
| Lactation Consultants of Great Britain | Guideline | General | General | The suggested changes to offer induction in later pregnancy as routine, ignores qualitative and quantitative data around the inaccuracy of 'due' dates. As Dr Sara Wickham (MW) states in her analysis: 'the offer of an earlier induction will mean more babies will be born before they are ready. These babies will be at risk of long term health issues as a result.' https://www.sarawickham.com/articles-2/nice-guideline-on-inducing-labour/ | Thank you for your comment. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the birth of preterm babies. |
| Lactation Consultants of Great Britain | Guideline | General | General | The change in guidance now does not support spontaneous labour; there is no discussion on the benefits to the dyad of allowing the human mammalian blueprint of birth to unfold, including the impact on establishing breastfeeding. Dr Sarah Buckley states that "the hormones that make[physiological] birth happen also prepare us for breastfeeding and mother- | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|----------------------------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | infant attachment". IOL results in hormonal gaps that impact establishing breastfeeding and the initiation into parenthood. Offering women having uncomplicated pregnancies IOL earlier will mean that more babies are born before they are ready. Late preterm and early term babies have been shown to need more support to establish feeding. These babies are likely to be placed on the postnatal ward with high staff to dyad ratios, impacting on the already stretched service's ability to support breastfeeding. | based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. |
| Lactation Consultants of Great Britain | Equality Impact Assessment | 003 | 3.4 | This rationale states that 'the preliminary recommendations do not make it more difficult in practice for a specific group to access services compared with other groups.' This does not take into consideration the fact that many of the groups stated in 3.2 already struggle to access services and appropriate care due to the lack of training on the stated different body types as examples. By over medicalisation of the care of black, Asian and ethnic minority peoples, there is a huge risk of further lack of access caused by fear and mistrust and concern that individuals are seen only by the colour of their skin and not as individuals with an individual care plan. There is a real risk of further refusal to engage with health care professionals, making access to care a real challenge. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. We have therefore amended section 4 of the EIA form to represent the changes to the recommendations. |
| Lactation Consultants of Great Britain | Guideline | 005 | 015 | 1.1.4 Women and birthing people need to know that their babies are more likely to experience feeding difficulties due to IOL. This compounds trauma when the birth and then the feeding experience they had planned for does not occur. An immature baby's suck response is typically weak, disorganised and immature; therefore, the baby's ability to obtain milk is compromised (Nyqvist, Acta Paediatrica, 2008). The baby may also have respiratory difficulties, injuries from instruments and/or birth insults from the more forceful labour. | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on feeding difficulties or respiratory problems. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth, and have included examples some of the problems babies may face due to an earlier birth. We have also passed on your suggestion to the NICE surveillance team |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | which monitors guidelines to ensure that they are up to date. |
| Lactation Consultants of Great Britain | Guideline | 005 | 015 | 1.1.4 All drugs administered to the mother/birthing parent for pain relief or other reasons during the period before birth will need to be metabolised by the baby's immature liver, leading to increased incidence of hyperbilirubinemia and jaundice (Gourley 2002). Jaundiced babies feed more poorly; and conversely, ineffective feeding can cause and exacerbate jaundice. | Thank you for your comment. The detailed recommendations on pain relief during labour are contained in the NICE guideline on Intrapartum care, and this is cross-referenced from the pain section of the Induction of labour guideline. |
| Lactation Consultants of Great Britain | Guideline | 005 | 015 | 1.1.4 Separation of the mother / birthing parent and their immature baby born by IOL is very common, even though separation is well known to provide further stresses to the fragile parent / infant /breastfeeding relationship even further (Nygqvist et al, Midwifery, 1997). | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on separation or breastfeeding. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth, and have included examples some of the problems babies may face due to an earlier birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Lactation Consultants of Great Britain | Guideline | 005 | 015 | 1.1.4 The increase in IOL over the past 20 years has seen babies born who are having feeding difficulties. Alison Hazelbaker who developed the Assessment Tool for Lingual Frenulum Function (ATLFF), a tool that allows for differential diagnosis when tongue tie is suspected, has demonstrated a link between IOL and what is being referred to as 'faux tongue ties'. Faux ties are a deformation of tissues and are defined by Hazelbaker as "any structural compromise due to forces that overwhelm adaptive mechanisms of the tissues [and] create tensional dynamics that mimic both anterior and posterior tongue tie." Babies born following IOL are more likely to experience structural compromise than babies born via spontaneous | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on feeding difficulties. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth, and have included examples some of the problems babies may face due to an earlier birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|-------------------------|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | physiological birth, and are thus more likely to have compromised feeding in this regard. | |
| Lactation Consultants of Great Britain | Guideline | 006 | 020 - 025 | <p>Those in the groups covered by this recommendation (BAME, BMI > 30, older than 35, and assisted conception) will be offered induction at 39 weeks, unlike other birthing parents who will be offered induction at 41 weeks, without evidence to support this difference in treatment other than currently differing outcomes – which may be correlation rather than causation.</p> <p>This is a contradictory statement without robust scientific evidence to prove otherwise – why would “otherwise uncomplicated singleton pregnancies” require intervention based on general factors such as 12BMI, age, conception method or ethnic background? The offer should only be made based on an individual's personal risks otherwise this is not personalised care.</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Lactation Consultants of Great Britain | Guideline | 006 and 024 - 025 | 023 - 024 022 - 002 | The knowledge of experts by experience, the women and birthing people of black, brown and Asian ethnicity who have successfully continued their pregnancy to natural term when safe and appropriate care is provided, should be used to develop any guidelines specific to them in reducing negative outcomes in pregnancy and birth, possibly outwith this guideline. | Thank you for your comment. The committee includes service users or lay people and people from a non-white background who are involved throughout the development process. The consultation process has taken into account the views of a large number of stakeholders and several hundred individuals, many of whom were service users or experts by experience, and a large number of whom have identified themselves as non-white. |
| Lactation Consultants of Great Britain | Guideline | 006 | 020 | Why is this not phrased “Consider offering induction of labour...” with clear information about the potential risks as well as the potential advantages | Thank you for your comment. 'Offer' is the wording used by NICE to reflect a recommendation based on strong evidence, and 'consider' is where there is more uncertainty. Based on stakeholder feedback we have amended the recommendations for earlier induction for certain groups of women and instead included information on increased risks from a national audit (MBRRACE). |
| Lactation Consultants of Great Britain | Guideline | 014 | 014 | <p>1.3.9 For women with a Bishop score of 6 or less, their baby is not ready to be born, so offering induction routinely when there is not a high chance of response to interventions made to induce labour (page 20, line 11) without clear individual</p> | Thank you for your comment. The evidence review carried out for methods of induction analysed the data by the sub-groups of women with a Bishop score of 6 or less and woman with a Bishop score greater than 6. The evidence showed that the recommended methods of induction |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | clinical indication could be said to be contradictory to the medical ethos, "First, do no harm". | (dinoprostone, misoprostol and mechanical methods) were all effective at leading to vaginal birth within 24 hours, and did not increase the rate of caesarean birth or instrumental birth compared to placebo, in women with a Bishop score of 6 or less. |
| Lactation Consultants of Great Britain | Context | 029 | | Here it is stated that women may not get the satisfaction from having the birth experience they wanted. There is no mention that the baby will not have this either. The impact of induction of labour (IOL) on the mother/infant dyad is well evidenced and has long term repercussions. "IOL Induction of labour) for non-medical reasons was associated with higher birth interventions, particularly in primiparous women, and more adverse maternal, neonatal and child outcomes for most variables assessed. The size of effect varied by parity and gestational age, making these important considerations when informing women about the risks and benefits of IOL" (Dahlen et al. 2021) | Thank you for your comment. We are aware that there are other consequences of induction that are not mentioned here, as this text is designed as a summary of the aim of the guideline. It was not within the scope of this guideline update to carry out an evidence review on the risks and benefits of induction of labour compared to expectant management, but the committee have expanded the section on information and decision-making to include other factors that should be considered when a woman is making a decision about mode of birth. |
| Lactation Consultants of Great Britain | Guideline | 030 | 003 | 1.2.1 This update suggests that 'uncomplicated singleton' pregnancies should be offered induction at 41 weeks. The exclusion of black, brown and Asian bodies from this guidance, with replaced recommendation of induction at 39 weeks for these peoples described, suggests that by definition those of a black, Asian or ethnic minority group are complicated pregnancies despite being otherwise uncomplicated. This is clear racial bias and therefore highly inappropriate. | Thank you for your comment. The recommendations for induction of labour for prolonged pregnancy in women who may at a higher risk of stillbirth have been revised and no longer include the recommendation to consider induction from 39 weeks. |
| Lewisham and Greenwich NHS Trust | Guideline | 004 | 019 | The language ' some ' forms of induction could be more specific. Should be clarified here which forms of induction may cause hyperstimulation. | Thank you for your comment. We have amended the recommendation to specify that this warning applies to pharmacological methods only. |
| Lewisham and Greenwich NHS Trust | Guideline | 006 | General | (1) A quick review showed that 78% of our patients would need an induction of labour according to these recommendation. Other London units might face similar issues. Have the authors of the guidelines considered the pressures and gaps that this would cause and how | Thank you for your comment. We will address your points in turn: 1. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>would they recommend to deal with those as it might cause legal issues?</p> <p>(2) In the ARRIVE study 16,000 women declined to be in this study, which was about 73% of those asked. As a result, the women who were in the study may not be representative. The care that participants received was highly medicalised. The vast majority were cared for by a doctor, which does not happen in countries like the UK. 4The caesarean section rate was extraordinarily high given that the women in the study were “low risk.” And the study showed no difference in mortality for babies.</p> <p>A recent study in to section rates of women with an induction of labour showed a marked increase in those undergoing IOL. 38% of women having an induction of labour at 41 weeks had caesarean section. (Levine et al. 2021). An increase in the caesarean section rate would lead to more women subsequently labouring with a scar on their uterus and the risk of scar dehiscence.</p> <p>Long inductions significantly impact on midwifery and obstetric workload which in turn impacts on the level of care that midwives and drs are able to provide for women.</p> <p>Many primiparous women experience attempted IOL lasting for days. There is significant psychological and emotional cost to this. Seijmonsbergen-Schermer et al (2019) has linked long term harm associated with routine induction.</p> | <p>variations in populations giving birth in the unit and this may have resource implications.</p> <p>2. The methodological limitations of the ARRIVE trial were reflected in the evidence report and taken into consideration by the committee when interpreting the evidence. The committee considered the proportion of women who declined to participate to be within normal parameters and considered this could be due to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal.</p> <p>3.The committee acknowledged that although all included studies were from high-income countries, these were conducted in a variety of settings (not just the United Kingdom) where healthcare is mainly accessible through private funding and where there are usually fewer midwives available to support women during birth, such as the US. However the committee agreed that the evidence was broadly applicable to the current UK context as it provided evidence from similar healthcare systems from high income countries.</p> <p>4. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have now included tables with the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding of the evidence reviewed. The supporting information explains how this data was derived, its limitations and how to interpret it.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>Research from Dahlen (2021) has shown that induction of labour leads to more intervention and more adverse maternal and neonatal outcomes.</p> <p>(3) To be able to counsel women about the benefits of a recommended intervention, we need to be able to quantify the increased absolute risk to them or their baby in simple terms. Women cannot make an informed decision without this. Much of the wording is very vague and as a practitioner I would struggle to give them a rationale for this recommendation.</p> | |
| Lewisham and Greenwich NHS Trust | Guideline | 006 | 010 | <p>1.2.2 I am concerned why we are recommending induction should be commenced at 41 weeks. I understand the biggest piece of research used was the SWEPSIS research that concluded better maternal and fetal outcomes with induction at 41- 41+2 to over 42 weeks. At present in the UK we are currently recommending inducing before 42 weeks and normally at 41+3. It is not possible to know the exact timing of when this risk increases and therefore it would be more truthful to tell women that we recommend inducing before 42 weeks as the perinatal mortality was higher and to therefore be induced by 41+4/5 to allow time for the induction to take place. By choosing 41 weeks and by saying to women that 41 weeks is the cut off we are not being truthful. At present we are discussing these risks for 42+ weeks and therefore recommending induction for all women 1 week earlier than the current recommendation.</p> | <p>Thank you for your comment. The previous NICE guideline advised induction between 41+0 and 42+0 weeks, so the revised recommendations that were consulted on advised 41+0 to 41+3, so only changed the induction window by a few days. However, based on stakeholder feedback, we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based.</p> |
| Lewisham and Greenwich NHS Trust | Guideline | 006 | 012 | <p>The language here is unspecific – what is the increased risk of each of these outcomes? How can we present this to people in a way that they understand the absolute risk of these things occurring?</p> | <p>Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Lewisham and Greenwich NHS Trust | Guideline | 006 | 020 | <p>(1) There is very poor quality evidence base on which to make these recommendations – it is stated that this is based on the committee's knowledge and experience and that adverse outcomes for people with these characteristics are backed up by national audit data. As a midwife I don't know how I could justify recommending induction of labour to people just based on their BMI, ethnicity, age and mode of conception without a stronger evidence base for each of these to back up the recommendation. More research needs to be done into why these people have a higher risk of adverse outcomes, including, importantly, looking into systematic racial prejudice within obstetric and maternity healthcare systems, before this becomes national guidance.</p> <p>(2) This recommendation will be challenging in practice because of the high number of our clients that will fit into this criteria. There is also no exact timing of this increased risk for this wide group of women and we need to ensure that we are not over medicalising a group of clients in order to put every risk factor for a pregnancy into this group. This statement suggests we are not going to give individualised care as we would normally review every client to see if they need an induction or caesarian but instead see them as statistics.</p> <p>(3) Considering offering IOL to BMI 30 at 39 weeks onwards will actually fill the antenatal ward completely.</p> <p>(4) We lack staff to carry out all these inductions- women are already left hanging around for days</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-------------------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | waiting for an ARM- we cannot cope with this increase. | |
| Lewisham and Greenwich NHS Trust | Evidence review C | 008 | 006 - 007 | <p>I note that there is minimal evidence about maternity quality of life and maternal satisfaction. Given the topic of this review and the implications of induction of labour on women's autonomy and mental health, I feel that it is not appropriate to limit the research evidence to randomised controlled trials. Evidence should be gathered from qualitative research into women's experiences.</p> <p>The majority of women attending our Birth Options Clinic seeking an elective Cesarean Section without medical indication or, alternatively, seeking birth in low-risk settings against medical advice, are doing so because of a previous traumatic induction of labour. Previous traumatic induction is also a common theme in our Listening Clinic, with women describing PTSD, depression and high levels of anxiety which they associate with their induction. If the number of inductions rises, this will have a big impact on both our clinics and on the future number of out of guidelines birth requests, including a measurable increase in EICS without medical indication. It seems unethical to me to publish guidelines which do not balance the impact of induction on women against what may (or may not) be marginal gains for babies.</p> <p>During the pandemic, when partners were not allowed to stay with women during the early stages of their induction, we found this was an additional incentive for women to decline induction and to seek either expectant management, out of hospital birth or EICS without medical indication.</p> | <p>Thank you for your comment. The committee acknowledged the paucity of evidence for the outcome maternal satisfaction in this review. However, this was still taken into consideration whenever reported and the committee included 2 lay members with lived experience of induction of labour and wider experience of representing people using maternity services. It was not within the scope of this update to review qualitative evidence on women's experiences but, based on stakeholder feedback, the recommendations have been amended to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected.</p> |
| Lewisham and Greenwich NHS Trust | Evidence review A | 008 | 001 | <p>Given that only one of the included studies gave a definition of shoulder dystocia, it is hard to understand justification of the proposed NICE guideline recommendation to offer induction of labour for fetal macrosomia. Shoulder dystocia seems to be the only adverse outcome of fetal macrosomia that the induction of labour is attempting to avoid.</p> | <p>Thank you for your comment. The committee acknowledged that the definition of shoulder dystocia provided by Boulvain 2015 ("interval of 60 seconds or more between the delivery of the head and body") was not routinely used, and it was uncertain how a more widely used definition, such as the one provided in the RCOG</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | green-top guideline no 42 (“vaginal cephalic delivery that requires additional obstetric manoeuvres to deliver the fetus after the head has delivered and gentle traction has failed”) could have affected the outcome. Nonetheless, the committee highlighted that in Boulvain 2015, it was described that “the estimated benefit did not change when the definition of the primary outcome (significant shoulder dystocia, delay of ≥60 seconds, fracture, brachial plexus injury, intracranial haemorrhage, death) excluded the interval of 60 seconds or more between the delivery of the head and body”, therefore the committee agreed that, based on this evidence, it was appropriate to offer women with suspected fetal macrosomia and without diabetes a choice of induction of labour or expectant management. In addition, the committee recognised that some women may wish to have a caesarean birth to avoid the possible risks of vaginal birth of a big baby, and so they added this as an option into the recommendation as well. |
| Lewisham and Greenwich NHS Trust | Guideline | 010 | 016 - 017 | This is not specific- what is the definition of fetal growth restriction with confirmed fetal compromise? Is it with abnormal dopplers- currently we would induce if there was raised umbilical artery PI, or is it just if absent/reversed end-diastolic flow? I think the definition needs to be clearer here. | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add a definition of confirmed fetal compromise. |
| Lewisham and Greenwich NHS Trust | Guideline | 013 | General | Why is there so much focus on membrane sweeps when there is evidence that it does not change the way women deliver or the perinatal outcome and the effect is low. (2020 Cochrane review) A randomized control trial showed that the difference between expectant management and membrane sweep was only 15% (zamzani 2014). 15.6% of unexpected term admissions in the UK are due to sepsis. We know that the cervix and the intact mucous plug are of importance and prevent ascending infection. Especially in the age of absence of GBS screening. Any disturbance (especially recurrent as recommended in the Guideline) can potentially increase the risk of infection. More data is recently emerging that infection in labour could be related to membrane sweeping. How can this be recommended as routine | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps. However, we have amended the recommendations to emphasise that the option of membrane-sweeping should be discussed with women, and their consent obtained. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-------------------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | practice if found not to be efficient, often painful and uncomfortable and potential harm cannot be excluded? It should come as can be offered shortly before induction or if declining induction after counselling. | |
| Lewisham and Greenwich NHS Trust | Guideline | 013 | 014 | Why 39 weeks? We see primips at 38 and 40 weeks and multips at 38 and 41 weeks, so the 39 week suggests we might change our current antenatal care pathway to offer this choice? | Thank you for your comment. The recommendations have now been clarified to state that membrane sweeps should be discussed after 39 weeks (as opposed to 'from 39 weeks') so there should be no need to change the current antenatal care pathway. |
| Lewisham and Greenwich NHS Trust | Guideline | 015 | 023 | Many units are now using Dilapan either as first line agent for IOL or as another option avoiding risk of hyperstimulation- the wording implies that we shouldn't be using this at all, yet evidence I have seen is that it is a safe alternative without risk of hyperstimulation. Can it be included as one of the mechanical methods? | Thank you for your comment. Based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour, so they have been removed from this list. |
| Lewisham and Greenwich NHS Trust | Evidence review C | 018 | 040 | Where have the committee gathered the information that 'more women with low risk pregnancies are requesting induction'? How does this sit with the low recruitment rate for the Grobman trial? (Only 27% of those screened as eligible consented to be part of the trial). | Thank you for your comment. As reflected in the discussion, this statement is based on the committee's experience and it provides the rationale as to why, according to the committee, it would be useful to review evidence on the optimal timing of induction. The committee acknowledged the proportion of women that declined to participate in the included trials, but considered it within normal parameters and noted that this may have been related to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal. |
| Lewisham and Greenwich NHS Trust | Evidence review C | 019 | 005 | I am concerned that the committee have made a decision about earlier induction of labour (39+0) being an optimal time for induction as it reduces the likelihood of caesarean section, when all of the studies they have included to make this recommendation have been graded as LOW or VERY LOW quality when looking at the outcome of 'mode of delivery'. Furthermore, based on my reading of the evidence tables, I don't understand how the committee have concluded that there is a reduced chance of caesarean section with induction of labour at 39+0 versus 40 to 42 weeks and 42 versus 43 weeks. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. In addition, we have now included the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding of the evidence reviewed. The supporting information explains how this data was derived and how to interpret it. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-------------------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Lewisham and Greenwich NHS Trust | Evidence review C | 019 | 014 | <p>The possible reduction in assisted vaginal delivery with induction at 39 weeks compared to at 40 to 42 weeks is based on one study (Grobman 2018). The committee should consider that this study was carried out in the United States of America which has a different system of obstetric and maternity care to what is available in the UK with the NHS. This is significant because the people in the 'expectant management group' will not have been getting the same midwifery-led care that people in the UK would be getting were they also not having an induction, which is important as we know that care-provider can have an impact on the outcome of someone's pregnancy and birth.</p> <p>The Cochrane review of Midwife-led continuity models of care compared with other models of care for women during pregnancy, birth and early parenting by Sandall et al (2016) found that midwife-led continuity models resulted in fewer instrumental births. I think the findings of the study by Grobman (2018) must be considered in light of the differences between US and UK models of obstetric and maternity care. UK maternity care already has the potential to offer midwifery-led continuity of care for instance – which could lead to the improved outcomes for pregnant people and their babies.</p> <p>Another reason to take into consideration the different type of care that people in the UK would have (ie. midwifery-led care) compared to obstetric care in the US is place of birth. The Birthplace Study in the UK found that:</p> <ul style="list-style-type: none"> For planned births in freestanding midwifery units and alongside midwifery there were no significant difference in adverse perinatal outcomes compared with planned birth in an obstetric unit. | <p>Thank you for your comment. The committee acknowledged that the included studies were conducted in a variety of settings (not just the United Kingdom) where healthcare is mainly accessible through private funding and where there are usually fewer midwives available to support women during birth, such as the US. However the committee noted that most studies were sufficiently powered to detect differences between groups and that these were conducted in high-income countries, therefore these were generalizable to the UK setting and the low-risk population of women relevant for this review. Studies eligible for inclusion compared 2 or more induction timing strategies, although those that compared expectant management to a specified time point at which induction then occurred were also included, therefore it is expected that both treatment arms received a similar level of care.. We have now included the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding of the evidence reviewed. The supporting information explains how this data was derived, its limitations and how to interpret it.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------|-------------------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <ul style="list-style-type: none"> Women who planned birth in a midwifery unit (AMU or FMU) had significantly fewer interventions, including substantially fewer intrapartum caesarean sections, and more 'normal births' than women who planned birth in an obstetric unit. <p>(Birthplace in England Collaborative Group, 2011)</p> <p>As the Grobman trial does not consider place of birth, it is hard to know what the outcome would have been for the people who underwent 'expectant management' if they could have laboured and birthed in a midwifery-led setting.</p> <p>Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study BMJ 2011; 343 :d7400 doi:10.1136/bmj.d7400</p> | |
| Lewisham and Greenwich NHS Trust | Evidence review C | 020 | 028 | <p>It is difficult to comment on each of the individual 'risk factors' listed here when they have been lumped together - BMI >30, Black and Asian ethnicity and minority ethnicity, age 35 and over and assisted conception. The committee notes however that induction of labour will impact on choice of place of birth. I wonder if the committee would consider evidence from the Birthplace Study which found that for singleton 'low risk' pregnancies, the risk of intrapartum intervention when people gave birth in an alongside midwifery unit, a standalone midwifery unit and at home, was less than for people who gave birth in an obstetric unit. When this study was analysed to explore how ethnicity impacted on people's risk of intervention in birth based on place of birth, 'findings did not suggest that the benefits of planned birth in a non-OU setting differed for white and non-white women' (Hollowell et al 2015, p.161).</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. It was not within the scope of this update to review choice of place of birth. However, based on stakeholder feedback, the recommendations have been amended to include the factors that should be taken into consideration by women when deciding whether or not to have an induction, which includes the fact that their choice of place of birth will be limited, as they may be recommended interventions (for example, oxytocin infusion, continuous fetal heart rate monitoring and epidurals) that are not available for home birth or in midwife-led units. In addition, we have also added an additional recommendation to emphasise that</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>Firstly, I wonder how might this influence the committee's understanding of Black, Asian and ethnic minority pregnant people as 'higher risk', particularly when place of birth is taken into account.</p> <p>I think it is important to consider more greatly the impact that induction of labour will have on choice of place of birth and the knock on effect this may have on interventions and outcomes in labour. If increased likelihood of adverse impact on Black, Asian and minority ethnic people is a concern, then perhaps more could be done to facilitate them birthing in alongside midwifery units, free-standing midwifery units or at home where there is lower risk of intervention.</p> <p>Hollowell, J., Rowe, R., Townend, J., Knight, M., Li, Y., Linsell, L., Redshaw, M., Brocklehurst, P., Macfarlane, A. J., Marlow, N., McCourt, C., Newburn, M., Sandall, J. and Silverton, L. (2015). The Birthplace in England national prospective cohort study: further analyses to enhance policy and service delivery decision-making for planned place of birth. Health Service and Delivery Research, 3(36), doi: 10.3310/hsdr03360</p> | <p>whether or not to have an induction is a woman's choice and that choice should be respected.</p> |
| Lewisham and Greenwich NHS Trust | Guideline | 025 | 004 | <p>There would be significant cost implications due to the increase in LSCS, long induction processes and longer hospital stays. There would be significant impact on an already stretched workforce.</p> <p>This would negatively impact on student midwives education in the practice area.</p> | <p>Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. It may be that the new recommendations will encourage some women to have an earlier induction than they would previously, but a substantial change in the number of induced labours is not anticipated with the revised recommendations.</p> |
| Manchester University Hospitals NHS Foundation Trust | Guideline | 006 | 012 | <p>Section 1.2.3.</p> <p>The guidelines use of evidence is selective at this point and does not include a recent large study https://bmjopen.bmj.com/content/11/6/e047040. Whilst the recommendation is supported by several studies the fact that there is contrasting evidence for some benefits and this</p> | <p>Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | should be added to the discussion that takes place with women. | the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. |
| Manchester University Hospitals NHS Foundation Trust | Guideline | 006 | 020 | Section 1.2.4 Whilst there is evidence that IOL from 39 weeks will reduce stillbirth in groups with very likely placental dysfunction such as preeclampsia and fetal growth restriction there is (to our knowledge) no evidence to suggest that this increased risk can be blanketly applied to patients from BAME backgrounds or women with a BMI over 30. The evidence presented seek to extrapolate data that IOL seems to reduce caesarean section as a whole in "low-risk" women. Therefore, there is a potential justification for discussing IOL with all women from 39 weeks, but not in that have been defined as high risk by retrospective observational data as there is no evidence that the intervention (induction) will have selective benefits over existing risk stratification. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Manchester University Hospitals NHS Foundation Trust | Guideline | 006 | 020 | Section 1.2.4 The use of BAME as a risk group is significantly flawed as demonstrated by the recent Government report of systemic racism in the UK as it does not capture the significant differences that exist between different racial groups. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Manchester University Hospitals NHS Foundation Trust | Guideline | 007 | 006 | Section 1.2.6 Although the addition of "might" has toned down this recommendation there is still no evidence to support the practice of 2x weekly CTG or that it does not provide false reassurance to this group of women. It should there not be included. | Thank you for your comment. This recommendation has been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find this reassuring. Suggestions of what monitoring could be offered is provided but there is no evidence to confirm that monitoring can improve outcomes |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manchester University Hospitals NHS Foundation Trust | Guideline | 009 | 009 | Section 1.2.16 The methods for use in previous CS cases does not have any recommendations and the link to "methods" does not aid this. It would be very useful if in a guideline assessing evidence some comment on the benefits/risks of different methods of induction in this group was provided. | Thank you for your comment. The recommendations relating to induction of labour in women who have had a previous caesarean birth were not included in the scope of this update and so there is no link through to evidence. However, the evidence upon which these recommendations are based, is available on the NICE website as part of the 2008 guideline. |
| MEDICEM Technology | Guideline | General | General | Dear NICE Surveillance programme project team, thank you for the decision to open Labour inducing guideline for the revision following Surveillance report 2017. | Thank you for your comment. |
| MEDICEM Technology | Guideline | General | General | Dear Committee Members, please find the following comments as a support for the clinical activities throughout the UK, corresponding to paradigm shift in labour inducing practice within recent years. We share the same aim – to reduce workload of staff, to provide better comfort to women who are experiencing their significant moments, and, last but not least, to save NHS' resources, eventually. | Thank you for your comment and for your support for this update. |
| MEDICEM Technology | Guideline | 009 | 014 | We would like to propose amending the line with further <u>details:</u> <u>reduce these risks, whilst providing women with a chance to experience vaginal birth. Use of synthetic osmotic dilators may be offered to women who have had a previous caesarean birth to allow cervical priming without uterine contractility.</u> Please, find evidence of this in J Maier, S Klauke, K Brandt et al., Zervixreifung nach Kaiserschnitt: Prospektive Multicenter „in-label use“ Analyse eines osmotischen Dilatators vs. „off-label use“ Prostaglandin PGE2, Z Geburtshilfe Neonatol 2020; 224(06): 395-396 DOI: https://doi.org/10.1055/s-0040-1709322 In short, authors present results for prospective cohort (DILAPAN-S) in-label use, n=104, compared to retrospective cohort (PGE2) off-label use, n=78. | Thank you for your comment. It was not within the scope of this guideline update to update the recommendations on induction after previous caesarean birth so we have not examined the evidence for the most effective method of induction. However, the recommendations on methods of induction for this group of women advise the use of mechanical methods, and this would include cervical osmotic dilators |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>In prospective cohort, 50% VBACs occurred (42% spontaneous, 8% ventouse) within 44.2 hrs (mean)/44.6 hrs (median), from that 21% within 24 hours.</p> <p>In retrospective cohort, 53% VBACs occurred (47% spontaneous, 5% ventouse) within 24 hrs (mean)/29.4 hrs (median), from that 42% within 24 hours.</p> <p>Further to note, providing women with 50% chance to give vaginal birth following previous caesarean section may positively impact willingness of women to conceive after previous unfavourable experience and to help them lessen their misgiving that subsequent delivery is likely to finish with the caesarean section too.</p> | |
| MEDICEM Technology | Guideline | 012 | 007 | <p>We would like to propose amending the line with further <u>details:</u> offer <u>synthetic osmotic dilators for 12 hours followed by vaginal misoprostol 400 mcg every 3 hours</u></p> <p>Please, find evidence of this in MG David, E Perdiolle-Galet, C Baumann et al., Efficiency of osmotic dilators for labour induction in case of intra-uterine fetal death, Oral poster at breakfast 8 – Obstetrics and induction reference: A2055CB Volume 234, E97-E98, March 01, 2019 DOI: https://doi.org/10.1016/j.ejogrb.2018.08.374</p> <p>In short, authors present sub-analysis (n=154) of records from a tertiary care unit between 2002 and 2016. Protocol itself can be found in their previous publication: DOI: https://doi.org/10.1016/j.ejogrb.2019.10.013</p> <p>There were two cohorts – misoprostol only (n=117) and misoprostol administration following the cervical priming with synthetic osmotic dilators (n=37). Authors observed significant reduction for induction-delivery time in cohort with synthetic osmotic dilators (473 mins vs. 316 mins, p = 0.029), significant reduction for induction-ARM time in cohort with synthetic osmotic dilators (312.2 mins vs. 163.8 mins, p = 0.021) as well as significant reduction of dose of</p> | <p>Thank you for your comment. It was not within the scope of this guideline update to review the methods for induction after intrauterine fetal death in a population of women with a non-scarred uterus so we have not been able to make this change.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | misoprostol in cohort with synthetic osmotic dilators (1080 mcg vs. 720 mcg, p = 0.013). | |
| MEDICEM Technology | Guideline | 012 | 018 | <p>We would like to propose amending the line with further <u>details</u>: caesarean birth chooses an induced labour, <u>offer synthetic osmotic dilators for 12 hours followed by vaginal misoprostol 200 mcg every 3 hours</u></p> <p>As authors stated in their C Bertholdt, MG David, P Gabriel et al., Effect of the addition of osmotic dilators to medical induction of labor abortion: A before-and-after study, Eur J Obstet Gynecol (2019) DOI: https://doi.org/10.1016/j.ejogrb.2019.10.013</p> <p>aforementioned protocol can be used in case of history of caesarean delivery.</p> | Thank you for your comment. In order to make the recommendation more helpful, we have used the same wording as that used for women who are giving birth to a live baby and who have had a previous caesarean birth, which suggests that methods used for induction will need to take into account the risk of uterine rupture, for example by using mechanical methods. The study you have referenced would not have been eligible for inclusion in this review as it relates to abortion, not intrauterine fetal death and only a proportion of women had had a previous caesarean birth. |
| MEDICEM Technology | Guideline | 013 | 020 | Please, kindly include Bishop score table which can be used as a reference. | Thank you for your comment. The guideline aims to provide advice and recommendations on areas of uncertainty in clinical practice, and not to replace a medical textbook or other resources, and so we have not included this in the guideline. |
| MEDICEM Technology | Guideline | 014 | 012 | <p>We would like to propose amending the line with further <u>details</u>: <u>misoprostol and Instructions for Use in case of synthetic osmotic dilators regarding</u></p> | Thank you for your comment. We assume healthcare professionals will always follow the manufacturers' guidance and added the recommendation relating to the prostaglandin preparations based on advice from the MHRA due to the risk of hyperstimulation. We have therefore not added this for osmotic cervical dilators too. |
| MEDICEM Technology | Guideline | 014 | 023 | <p>Please, kindly consider updating your recommendations in 1.3.11. We would like to propose following wording:</p> <p>For women with a Bishop score of 6 or less who would prefer undergoing induction of labour without hormonal methods or hormonal methods are not suitable for them, offer a mechanical method (for example, synthetic osmotic dilators or a balloon catheter) in women:</p> | <p>Thank you for your comment. The recommendation already includes the majority of the points you have included in your suggested wording, relating to a woman's choice or the avoidance of hyperstimulation. Mechanical methods of induction are recommended for outpatient induction, and this is covered in the separate section of the guideline. There was no evidence of improved pain, sleep or rest for mechanical methods so we are unable to include this in the recommendations.</p> <p>Thank you for also including information on a number of</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <ul style="list-style-type: none"> • who are eligible for 12-hour-long outpatient cervical priming • where the uterine hyperstimulation poses a risk to women and/or to their babies • who have had a previous caesarean birth or have scarred uterus • who prefer spending their cervical priming with unnecessary pains, getting proper rest before labour and sleeping well, or in women who would find hormonal methods internally uncomfortable, going against their internal beliefs or • the woman chooses to use a mechanical method <p>To clarify our position, please, find the rationale behind it summarised below.</p> <p>As NICE based their review questions on PICO framework for intervention reviews (Evidence review B – Methods), Table 1: Summary of the protocol (PICO table), component 'Outcomes' consists of:</p> <p><u>Critical outcomes</u> No vaginal birth within 24 hours Uterine hyperstimulation with fetal heart rate changes Caesarean birth</p> <p>This text was identified as confidential and has been removed</p> <p><u>Important outcomes</u> Serious neonatal morbidity or perinatal death Serious maternal morbidity or death Maternal satisfaction Instrumental birth NICU admission</p> | <p>studies relating to osmotic cervical dilators. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date. However, based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>Use of epidural</p> <p>We understand that results regarding critical outcome 'No vaginal birth within 24 hours' could have not been identified within published results in the DILAFOL trial (non-inferiority randomised controlled trial): AF Saad, J Villareal, J Eid, et al. A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial). Am J Obstet Gynecol. 2019 Mar;220(3):275.e1-275.e9. DOI: https://doi.org/10.1016/j.ajog.2019.01.008 ('FB' used for 'Foley catheter cohort', n=209; 'DS' for 'DILAPAN-S cohort', n=208; intent-to-treat analysis)</p> <p>Bearing this in mind, we are revealing unpublished results regarding the rate of vaginal delivery within</p> <p>24 hours following insertion of mechanical agents (56.0% in FB and 47.0% in DS), as well as the rate of vaginal delivery within</p> <p>36 hours following insertion of mechanical agents (70.3% in FB and 71.2% in DS).</p> <p>Critical outcome 'Uterine hyperstimulation with fetal heart rate changes', being represented by 'Tachysystole during cervical ripening interval' in the DILAFOL trial, there were <u>no</u> cases of such condition occurring either in FB or in DS there.</p> <p>Critical outcome 'Caesarean birth' occurred in 23.9% of cases in FB and in 18.8% of cases in DS.</p> <p>Important outcomes:</p> <p>Serious neonatal morbidity or perinatal death</p> <p>5 minute Apgar score <7 – 0.5% in FB vs 0.5% in DS</p> <p>Cord arterial pH <7.1 – 1.9% in FB vs 1.2% in DS</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>Perinatal deaths – there were <u>no</u> cases of such condition occurring either in FB or in DS there</p> <p>Serious maternal morbidity or death</p> <p>Uterine rupture – there were <u>no</u> cases of such condition occurring either in FB or in DS there</p> <p>Maternal deaths – there were <u>no</u> cases of such condition occurring either in FB or in DS there</p> <p>Maternal satisfaction</p> <p>Statistically significant findings were observed for following variables (women do prefer DILAPAN-S over Foley catheter, considering):</p> <p>During cervical ripening, were you able to perform your desired daily activities? (P=0.001)</p> <p>During cervical ripening, did you get to get some relaxing time? (P=0.001)</p> <p>During cervical ripening, were you able to get some sleep? (P=0.01)</p> <p>Instrumental birth</p> <p>Operative vaginal delivery – 2.9% in FB vs 4.8% in DS</p> <p>NICU admission</p> <p>High level of neonatal care – 7% in FB vs 5.6% in DS</p> <p>Use of epidural</p> <p>Regional anesthesia – 90.0% in FB vs 83.7% in DS (for context, the rate of 'Analgesia during cervical ripening' was 18.2% in FB vs 16.7% in DS)</p> <p><u>Conclusion:</u></p> <p>"Dilapan-S is not inferior to the Foley balloon for preinduction cervical ripening at term."</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>"Advantages of Dilapan-S over Foley include Food and Drug Administration approval, safe profile, no protrusion from the introitus, no need to keep under tension, and better patient satisfaction."</p> <p>The COMRED trial (non-inferiority randomised controlled trial):</p> <p>R Gavara et al. (2021) An RCT Comparing Cervical Ripening Efficacy of Dilapan-S to Oral Misoprostol for Labor Induction at Term. ACOG ePoster. Gavara R. 04/03/21; 318840; 2520</p> <p>This text was identified as confidential and has been removed</p> <p>('MP' used for 'oral misoprostol 25 mcg', n=152; 'DS' for 'DILAPAN-S', n=151; 'VD' for 'vaginal delivery')</p> <p>"In the intent-to-treat analysis, VD within 36 hours of initiation of study intervention was more common in DS versus MP (61.6% vs 59.2%), with an absolute difference with respect to the MP of 2.4% (95% CI. -8% to 13%) indicating non-inferiority for the pre-specified margin."</p> <p>"Uterine tachysystole with and without abnormal fetal heart changes was less frequent in the DS group (2.6% vs 7.2%; P=0.1) and (22.5% vs 47.4%; P=0.0001), respectively."</p> <p>"VD and Cesarean delivery rate were not different among groups."</p> <p>"Patients that received DS reported lower pain scores (P=0.02), less abdominal discomfort (P=0.03) and were able to sleep more (P=0.02) during cervical ripening."</p> <p>"Hospital stay was shorter in the DS group."</p> <p><u>Conclusion:</u></p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>“Dilapan-S is non-inferior to oral Misoprostol for pre-induction cervical ripening at term.”</p> <p>“Advantages of Dilapan-S over Misoprostol include better safety profile, FDA approval, better patient satisfaction and pain scores.”</p> <p>Further, we would like you to be updated on two ongoing randomised controlled trials with DILAPAN-S in the outpatient setting for labour induction:</p> <p>HEMOCARE - https://clinicaltrials.gov/ct2/show/NCT03665688 Randomised, prospective, multicentre, open label study comparing 12-hour-long outpatient cervical ripening with 12-hour-long inpatient cervical ripening. HEMOCARE is estimated to be completed within September 2021, with estimated enrolment of 376 participants.</p> <p>IND HOME - EudraCT Number: 2019-004697-25 Randomised, prospective, single centre, open label study with three arms:</p> <ul style="list-style-type: none"> • 12-hour-long outpatient induction with DILAPAN-S • 24-hour-long outpatient induction with DILAPAN-S • 24-hour-long outpatient induction with Propess <p>IND HOME is estimated to be completed in the Summer 2022, with estimated enrolment of 465 participants.</p> | |
| MEDICEM Technology | Guideline | 015 | 023 | <p>Instead of the term ‘osmotic cervical dilators’, please kindly use the term ‘natural laminaria tents’.</p> <p>Please, find evidence of this in T Druncky, M Reidingerova, M Plisova et al., Experimental comparison of properties of natural and synthetic osmotic dilators, Arch Gynecol Obstet. 2015 Aug;292(2):349-54 DOI: https://doi.org/10.1007/s00404-015-3623-3</p> <p>where authors present data on natural and synthetic osmotic dilators. As per authors’ findings, synthetic osmotic dilators</p> | <p>Thank you for your comment. The committee agreed that osmotic cervical dilators was the over-arching term that included all devices that worked by absorbing fluid and swelling in the cervix, and were also aware that there were both naturally-derived and synthetic products included in this category. Based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour, so they have been removed from this list.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | reach significantly larger diameter against applied force (on average, almost three times more compared to Laminaria), exhibit higher consistency – “The difference in variance between Laminaria and Dilapan-S was statistically significant (p < 0.01)” – and synthetic osmotic dilators are also more uniform in their shape than Laminaria. | |
| MEDICEM Technology | Guideline | 017 | 019 | <p>We would like to propose amending the line with further <u>details: preparations of mechanical methods (for example, synthetic osmotic dilators or a balloon catheter)</u></p> <p>Please, find evidence supporting the use of particular methods within covid times in terms of mechanical methods being broadly adopted by NHS Trusts for their outpatient programmes, in: M Harkness, C Yuill, H Cheyne et al. 2021, Induction of labour during the COVID-19 pandemic: a national survey of impact on practice in the UK, BMC Pregnancy and Childbirth (2021) 21:310 DOI: https://doi.org/10.1186/s12884-021-03781-x</p> <p>Amongst other findings of their survey, authors report 23% change in methods used for cervical ripening (“Switching to use of Dilapan-S as a method of cervical ripening was notable”), and that 28% of senior obstetricians and midwives stated that more women were returning home during cervical ripening, including quotations in Tab.6 Outcomes from free-text responses content analysis – changes to IOL practice:</p> <p><u>Changes to IOL methods and process:</u> “We brought forward the mechanical ripening and ALL women who had Dilapan were offered home. Dilapan introduced, expectation that women will go home during Dilapan ripening.”</p> <p>Increase OB presence:</p> | <p>Thank you for your comment and for the information about the use of Dilapan for outpatient induction. The recommendations already include the option to use mechanical methods of induction, but as the committee did not have any evidence at the time of the guideline development for Dilapan they were not able to add this specific preparation. However, we will pass the details of the ongoing trials you have highlighted to the NICE surveillance team who monitor guidelines to ensure that they are up to date.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>"Doctors still doing Dilapan. Midwives mostly doing prostaglandins. More obstetric involvement as Dilapan training not yet rolled out to midwives."</p> <p>As manufacturers of DILAPAN-S, we listen carefully & act accordingly as per clinicians' requests.</p> <p>Kindly be aware of the training portal on the RCOG webpage we are about to launch in the second half of 2021. Subsequently, there is a parallel training program dedicated to midwives to be founded in 2021 as well.</p> <p>Further, we would like you to be updated on two ongoing randomised controlled trials with DILAPAN-S in the outpatient setting for labour induction:</p> <p>HEMOCARE - https://clinicaltrials.gov/ct2/show/NCT03665688 Randomised, prospective, multicentre, open label study comparing 12-hour-long outpatient cervical ripening with 12-hour-long inpatient cervical ripening. HEMOCARE is estimated to be completed within September 2021, with estimated enrolment of 376 participants.</p> <p>IND HOME - EudraCT Number: 2019-004697-25 Randomised, prospective, single centre, open label study with three arms:</p> <ul style="list-style-type: none"> • 12-hour-long outpatient induction with DILAPAN-S • 24-hour-long outpatient induction with DILAPAN-S • 24-hour-long outpatient induction with Propess <p>IND HOME is estimated to be completed in the Summer 2022, with estimated enrolment of 465 participants.</p> | |
| MEDICEM Technology | Guideline | 018 | 010 | Please, kindly provide definition of the term 'uterine hyperstimulation' which might be used as a reference. | Thank you for your comment. We have included a definition of hyperstimulation in the 'terms used' section of the guideline. |
| MEDICEM Technology | Guideline | 020 | 003 | NICE glossary – please, kindly provide definitions for the terms: | Thank you for your comment. We have included a definition of an osmotic dilator as this is included in the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------|-----------|---------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | 'Synthetic osmotic dilators' and 'Natural laminaria tents' to be both clearly distinguished as non-interchangeable terms. | recommendations, but not laminaria tents as these are not recommended. |
| MEDICEM Technology | Guideline | 028 | 022 - 030 | <p>As manufacturers of the synthetic osmotic dilators DILAPAN-S, we have to express our concerns with wording used in this paragraph.</p> <p>We do not share NICE's opinion regarding "no evidence for the effectiveness of osmotic dilators at promoting vaginal birth within 24 hours" (evidence for this follows) as neither we share the opinion that osmotic cervical dilators, which do not pose a risk of uterine hyperstimulation within their course of action, comprise solely laminaria as only these have been mentioned within the paragraph.</p> <p>We do believe that NICE Committee will reconsider their recommendations within the published guideline. The current state of knowledge favours synthetic osmotic dilators to natural laminaria tents. Synthetic osmotic dilators consistently prove either their non-inferior position in clinical effectiveness and safety outcomes when being compared to hormonal agents in multiple randomised, controlled, prospective trials or even statistical significance in terms of maternal satisfaction, pain scores or uterine hyperstimulation.</p> <p>To clarify our position, please, find the rationale behind it summarised below.</p> <p>As the last literature search for evidence review B was updated in May 2020, we understand that the manuscript of 'A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial)' could had</p> | <p>Thank you for your comment. Based on stakeholder feedback, the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour. The DILAFOL trial was included in the evidence review but there was no data on vaginal birth in 24 hours. We are also aware that the COMRED and SOLVE trials have been completed but has not been fully published yet. Thank you for the information provided on the HOMECARE and IND HOME trials. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>been successfully identified in terms of synthetic osmotic dilators usage, with 419 participants enrolled. DOI: https://doi.org/10.1016/j.ajog.2019.01.008</p> <p>Since then, two randomised controlled trials comparing synthetic osmotic dilators with widely used hormonal agents in the field of labour induction have been completed.</p> <p>In April 2021, trial titled 'COMRED – Comparison of Misoprostol Ripening Efficacy With Dilapan-S', randomised, prospective, multicentre, open label study has been completed with 303 participants enrolled. https://clinicaltrials.gov/ct2/show/NCT03670836</p> <p>In March 2021, trial titled 'A Randomised Controlled Trial of a Synthetic Osmotic Cervical Dilator for Induction of Labour in Comparison to Dinoprostone Vaginal insErt: the SOLVE Trial', randomised, prospective, multicentre, open label study has been completed with 674 participants enrolled. https://clinicaltrials.gov/ct2/show/NCT03001661</p> <p>Bearing in mind the critical outcome of 'No vaginal birth in 24 hours', we are revealing unpublished results of the DILAFOL trial regarding the rate of vaginal delivery within</p> <p>24 hours following insertion of mechanical agents (56.0% in FB and 47.0% in DS), as well as the rate of vaginal delivery within</p> <p>36 hours following insertion of mechanical agents (70.3% in FB and 71.2% in DS).</p> <p>In the COMRED trial and the SOLVE trial, the rate of vaginal birth within 24 hours was established within Secondary outcomes too and can be found in the published manuscripts, or upon request.</p> <p>To provide Committee Members with further details in terms of ongoing randomised clinical trials with synthetic osmotic</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>dilators DILAPAN-S, there are two studies in the field of outpatient clinical setting for labour induction:</p> <p>HEMOCARE - https://clinicaltrials.gov/ct2/show/NCT03665688 Randomised, prospective, multicentre, open label study comparing 12-hour-long outpatient cervical ripening with 12-hour-long inpatient cervical ripening. HEMOCARE is estimated to be completed within September 2021, with estimated enrolment of 376 participants.</p> <p>IND HOME - EudraCT Number: 2019-004697-25 Randomised, prospective, single centre, open label study with three arms:</p> <ul style="list-style-type: none"> • 12-hour-long outpatient induction with DILAPAN-S • 24-hour-long outpatient induction with DILAPAN-S • 24-hour-long outpatient induction with Propess <p>IND HOME is estimated to be completed in the Summer 2022, with estimated enrolment of 465 participants.</p> | |
| Medicines and Healthcare products Regulatory Agency | Guideline | | | <p>Since we provided the advice, there have been some further updates to the Dinoprostone product information to strengthen the warnings around uterine hyperstimulation, uterine rupture and associated complications of foetal and neonatal death, and ensuring that use is restricted to qualified health care professionals and hospitals and clinics with specialised obstetric units with facilities for continuous monitoring and a strengthening of the warning regarding the maximum recommended dose/dosing interval.</p> | <p>Thank you for your comment. The committee considered this information may change the balance of concern relating to dinoprostone preparations and oral low dose misoprostol and, after re-reviewing the evidence for hyperstimulation, have included oral misoprostol as an alternative to dinoprostone. However, the warnings about hyperstimulation with both preparations remain, as well as the advice to follow the manufacturers' advice.</p> |
| Mid Cheshire Hospitals NHS Foundation Trust | Guideline | General | General | <p>Whilst the trust agrees with the evidence surrounding the reason to induce women earlier to reduce stillbirth and improve outcomes, these guidelines would have an immense physical and financial impact on the maternity unit. Following the introduction of the Saving Babies Lives Care Bundle the induction rate has steadily risen. It is currently stands at 38.15% (1201 out of 3118 deliveries) on a 12</p> | <p>Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction, and the recommendation to consider earlier induction in certain groups of high risk women has been removed. As a result of these amendments we anticipate a potentially much smaller impact on the number of women</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>month average for 2020/21. This increase has already put additional pressures on beds and staffing.</p> <p>Having identified the women who would fulfil the new criteria for induction of labour we have identified a further 452 women who would have required induction over the year. This does not include women with assisted conception as, in line with HFEA guidelines, this is not routinely recorded on the woman's electronic record.</p> <p>This would potentially equate to a 53% induction rate an increase of 14.85%.</p> <p>Women being induced require more midwifery care and a longer inpatient stay. This increase would mean a 14.85% increase in staffing to accommodate time spent with additional inpatient care plus an increase in medication, pain relief and potentially epidurals.</p> <p>In addition, women may also require an extra Community Midwife appointment for a sweep at 39 weeks.</p> <p>A standardised information leaflet is required so that all women receive balanced information to enable them to make an informed choice, outlining that this may also affect their chosen place of birth.</p> <p>To enable trusts to implement this guideline safely, adequate notice is required along with discussion with NHS England for funding for workforce and estate, as well as the increased medication and consumable costs.</p> | <p>being induced, although the committee recognised that there may be an increase in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit, and this may have resource implications</p> |
| Middlesex University | Guideline | 012 | 014 | <p>In the ARRIVE study 16,000 women declined to be in this study, which was about 73% of those asked. As a result, the women who were in the study may not be representative. The care that participants received was highly medicalised. The vast majority were cared for by a doctor, which does not happen in countries like the UK. The caesarean section rate was extraordinarily high given that the women in the study were "low risk." And the study showed no difference in mortality for babies.</p> | <p>Thank you for your comment. We will address your points in turn:</p> <ol style="list-style-type: none"> 1. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. 2. The methodological limitations of the ARRIVE trial were reflected in the evidence report and taken into consideration by the committee when interpreting the evidence. The committee considered the proportion of women who declined to participate to be within normal |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>A recent study in to section rates of women with an induction of labour showed a marked increase in those undergoing IOL. 38% of women having an induction of labour at 41 weeks had caesarean section. (Levine et al. 2021). An increase in the caesarean section rate would lead to more women subsequently labouring with a scar on their uterus and the risk of scar dihesence.</p> <p>Long inductions significantly impact on midwifery and obstetric workload which in turn impacts on the level of care that midwives and drs are able to provide for women.</p> <p>Many primiparous women experience attempted IOL lasting for days. There is significant psychological and emotional cost to this.</p> <p>Seijmonsbergen-Schermers et al (2019)has linked long term harm associated with routine induction.</p> <p>Research from Dahlen (2021) has shown that induction of labour leads to more intervention and more adverse maternal and neonatal outcomes.</p> | <p>parameters and considered this could be due to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal.</p> <p>3. The committee acknowledged that although all included studies were from high-income countries, these were conducted in a variety of settings (not just the United Kingdom) where healthcare is mainly accessible through private funding and where there are usually fewer midwives available to support women during birth, such as the US. This may have led to an increase in the proportion of women having a caesarean birth, and the committee agreed to explicitly address this point in Appendix A. However the committee agreed that the evidence was broadly applicable to the current UK context as it provided evidence from similar healthcare systems from high income countries.</p> <p>4. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have now included tables with the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding of the evidence reviewed. The supporting information explains how this data was derived, its limitations and how to interpret it.</p> |
| Middlesex University | Guideline | 025 | 004 | <p>There would be significant cost implications due to the increase in LSCS, long induction processes and longer hospital stays. There would be significant impact on an already stretched workforce.</p> <p>This would negatively impact on student midwives education in the practice area.</p> | <p>Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. It may be that the new recommendations will encourage some women to have an earlier induction than they would previously, but a substantial change in the number of induced labours is not anticipated with the revised recommendations.</p> |
| Midwifery Unit Network | Guideline | 006 | 1.12 | <p>A shift towards earlier inductions may lead to 15%-20% more inductions (Rydahl E et al 2019). This higher induction rate puts a strain on the maternity service and is likely to</p> | <p>Thank you for your comment. We will address each of your points in turn:</p> <p>1. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>result in longer periods of hospitalisation for women and their companions. In addition to this we know that IOL is more painful and require more resources in terms of midwifery, obstetric and anaesthetic staff to respond to this.</p> <p>WHO advised IOL is not recommended in women with an uncomplicated pregnancy of less than 41 weeks and this does not highlight any differences in ethnicity, societal or economic significance.</p> <p>It appears that NICE is basing the change of advice on one study which is Middleton P, Shepherd E, Morris J, Crowther CA, Gomersall JC. Cochrane Database Syst Rev. 2020 Jul 15;7(7):CD004945. doi: 10.1002/14651858.CD004945.pub5. PMID: 32666584. Whilst this extensive study shows some benefits for neonatal outcomes there is limited focus on the woman and her physical and psychological wellbeing. There is also scant reference to the impact on maternity services and staffing requirements in this approach.</p> <p>To counter this study Dahlen et al (2021) published a 16 year population based study using linked data methods. Their findings were as below.</p> <p><i>IOL for non-medical reasons was associated with higher birth interventions, particularly in primiparous women, and more adverse maternal, neonatal and child outcomes for most variables assessed. The size of effect varied by parity and gestational age, making these important considerations when informing women about the risks and benefits of IOL.</i></p> <p>On this basis alone, offering IOL to women who reach 39 weeks without any indications to offer IOL based on one study appears to be rash and without consideration of what</p> | <p>pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have also removed the recommendation about earlier induction in some high risk groups of women. Based on these changes, and the fact that 98.9% of women who go into spontaneous labour will have done so by 42+0 weeks, the committee recognised that there may be an increase in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications.</p> <p>2. The recommendations on timing of induction are based on published randomised controlled trials (RCTs) that compared different induction of labour timing strategies. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected.</p> <p>The Cochrane review by Middleton 2020 compared induction of labour with spontaneous labour, therefore it was not eligible for inclusion in this systematic review. Dahlen 2021 is not eligible because it did not compare different induction strategies and it is not a RCT. Evidence report C includes full information on each primary study. For further details regarding inclusion and exclusion criteria of studies, please see the review protocol in appendix A of evidence report C.</p> <p>3. The recommendations on increased monitoring make it clear that this may not benefit the fetus or woman but some women may find this reassuring.</p> <p>4. The committee included 2 lay members with lived experience of induction of labour and wider experience of</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>women want. The physical and psychological benefits are not considered as an outcome and we know from RCM Covid examination of IOL that women were not happy with the services response (<i>Data based on rapid reviews by professorial advisory group (Cheyne, Page, Downe, Spiby, Renfrew, Sandall, Hunter, Lavender, Dykes) version 2: April 7th 2020</i>)</p> <p>Conclusion:</p> <p>MUNet are not confident that offering IOL at 41+ weeks is commensurate with women's views and the immediate and longer considerations of physical and psychological wellbeing.</p> <p>MUNet question the availability of NHS midwives and obstetricians to increase the amount of work to accommodate up to a 27% increase in workload for this group alone without the normal IOL that is generally advised for fetal or maternal issues.</p> <p>MUNet question the evidence given for offering increased surveillance if the woman declines IOL. There is weak evidence that this is of benefit to the fetus and to the woman. The clinician is put in a no win situation with this advice.</p> <p>MUNet are unhappy that maternity services have not been considered in this advice change. The time women will be inpatient in any unit will be increased, with greater risk of infections, greater risk of pain requirements, greater risk of failed IOL, increased risk of interventions before and during labour and finally being apart from her family due to restrictions on her normal support.</p> | <p>representing people using maternity services. The consultation process is the additional method we use to obtain input into the guideline from a wide range of stakeholders and individuals, and to ensure that the guideline is fit for purpose. This guideline received over 3000 comments in this way, and each one was read and considered by the committee in order to amend and improve the guideline.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Midwifery Unit Network | Guideline | 006 | 020 | <p>1.2.4</p> <p>1. BMI < 30 IOL of labour at 39 weeks gestation Induction of labour for obesity has many undesirable outcomes including;</p> <ul style="list-style-type: none"> • failure to proceed into labour due to uneffaced cervix • increased risk of multiple methods of IOL • increased risk of caesarean section • increased risk of haemorrhage • increased risk of infection perinatally • increased risk of longer hospital stay <p>Relph, S., Guo, Y., Harvey, A.L.J. <i>et al.</i> Characteristics associated with uncomplicated pregnancies in women with obesity: a population-based cohort study. <i>BMC Pregnancy Childbirth</i> 21, 182 (2021). https://doi.org/10.1186/s12884-021-03663-2</p> <p>MUNet would suggest that BMI without comorbidity should be treated the same as pregnancies that are uncomplicated by comorbidity.</p> <p>2. Age < 35 IOL of labour at 39 weeks gestation Induction of labour for age based on 35 years at end of pregnancy</p> <ul style="list-style-type: none"> • Age > 35 years is a confounding argument as many women start their pregnancies later in life compared to 2 decades ago. Many women have taken advice prior to pregnancy and are aware of preconceptual advice. It is also notable that women aged 35 years are very different in terms of health than women who are 45 years or more. • Is IOL still advised for a multiparous woman who has had previous healthy pregnancies before and this is the index pregnancy? This seems unnecessary and unwise given the lack of evidence for this specific point. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>MUNet would suggest that this is removed from the guidance and a personalised approach is taken to advise women on age-based data. This is surely what Montgomery would advise in these circumstances?</p> <p>3. Black Asian, Minority Ethnicity background IOL of labour at 39 weeks gestation</p> <p>From all the recommendations in the new NICE IOL guidance this is perhaps the most worrying for women and midwives.</p> <ul style="list-style-type: none"> Using race to target women in their pregnancies to counsel for IOL at 39 weeks sounds no less than inverse racism. There is no evidence to suggest that this action would save babies lives in this group, Given that there are other associated issue with IOL and increased risks in morbidity for all women are we not placing this group of women in a higher rate of morbidities if not mortalities given NPEU/MBBRACE evidence? This change runs the risk of alienating the very women that midwives find hardest to reach (this is based on evidence from midwifery case studies). Targeting women based upon their colour also is an unusual way of offering care, midwives particularly would be challenged to have positive dialogue with families if this were national guidance. We have searched for 'colour, ethnicity, IOL, outcomes) and cannot find a single study despite comprehensive searching among medical databases. | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <ul style="list-style-type: none"> Already in social media there is an outcry regarding this recommendation, and we would suggest that this will not diminish. <p>MUNet are categorical in its opinion of this recommendation and would ask the NICE IOL GDG to remove this recommendation.</p> | |
| Midwifery Unit Network | Guideline | 009 | 009 | 1.2.16 Advising women who have had a previous caesarean section that they should be offered IOL and or CS does not consider that they may wish to have the option of conservative management. (Montgomery ruling). If we are offering all options to women the conservative management and awaiting onset of natural labour should be included. | Thank you for your comment. We recognise that many women will wish to have a vaginal birth after a previous caesarean birth. However, the stem of this recommendation was 'If birth is indicated.....' so these recommendations would apply where a decision has been made that it is necessary to expedite birth. In order to clarify this, we have amended the wording to 'if birth needs to be expedited.' |
| Midwifery Unit Network | Guideline | 010 | 002 | 1.2.18 This is really ridiculous that we should be discussing maternal request IOL when many of the recommendations leave few women to include. | Thank you for your comment. There may be women who have no medical indication for induction but who wish to request this, and this recommendation provides advice for healthcare professionals in this scenario. |
| National Childbirth Trust | Guideline | General | | Many recommendations have been made on experience and expert knowledge rather than an evidence-based approach. It is essential that wherever this occurs it should be directly referenced in the guideline rather than in the evidence document. Parents are unlikely to read the evidence documents, and they should have available access to the level of confidence in the data informing the recommendations to make an informed decision. | Thank you for your comment. The recommendations relating to timing, macrosomia and methods of induction were all based on systematic reviews of the literature and the studies included in these reviews, the quality of the evidence and the findings of the systematic review are included in the evidence reviews which are referenced from the guideline and are available on the NICE website alongside the guideline for consultation. However, where there is a lack of evidence the committee do use informal consensus to make recommendations, and this is part of standard NICE methodology. This can be easily seen by clicking on the link to the rationale and impact box which follows each set of recommendations, but it would be too unwieldy to include this information in full alongside the recommendations. |
| National Childbirth Trust | Guideline | General | | Language is very important in making information accessible. We would ask that any instance of "delivery" be | Thank you for your comment. We have made the change to 'birth' in the 2 recommendations that still used the word |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | replaced with "birth", and language overall reviewed to remove unnecessarily complex language (for example, "prolonged" change to "longer pregnancy") | 'delivery'. We have changed the title of this section to 'Pregnancy lasting longer than 41 weeks'. |
| National Childbirth Trust | Guideline | General | | Informed decisions cannot be made without accurate and applicable information. It is our view that quantifiable information of actual risk/chance should be offered wherever possible. As the guideline is intended for parents use as well as clinicians, ensuring this information is accessible within the guideline is important to increase accessibility and reduce inequality of health information. | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update and so we are unable to provide data tables as you suggest. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also added in tables which provide risk data for earlier versus later induction which we hope will be helpful for discussions between healthcare professionals and women. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| National Childbirth Trust | Guideline | General | | The areas shaded in grey are not forming part of this consultation despite the original language being problematic and the updated versions continue to be problematic. For example: P9 Lines 21-24 Suggest modifying: "Advise women that they are entitled to decline the offer of treatment such as induction of labour or caesarean birth, even when it would benefit their or their baby's health." To say: "...even when it is considered that it would benefit them or their baby's health." | Thank you for your comment. You are correct that an updated evidence review has not been conducted for sections of the guideline that have been shaded in grey but that amendments have been made to the wording. We have further amended the wording of this recommendation to state that '...it may benefit their or their baby's health'. |
| National Childbirth Trust | Guideline | General | | Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why The introduction of vaginal sweeps from 37 weeks, induction from 41 weeks, and the offer of induction to all non-white women from 39 weeks gestation will impact the maternity services significantly. Workforce issues may make these | Thank you for your comment. We think that your concern that workforce issues may make the guidelines unimplementable are addressed with amendments made to the recommendations as a result of feedback from stakeholders. The guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction. The guideline no longer |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | guidelines unimplementable given the skilled care required to identify, monitor and support the significant number of women who would be considered for earlier induction on a routine basis. | <p>recommends an offer of induction of labour from 41+0 weeks or that it should be considered at 39+0 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications.</p> <p>Rather than a membrane sweep being offered to nulliparous women during the 40 and 41 week antenatal visits, the guideline now recommends a discussion with the women at antenatal visits after 39+0 weeks as to whether they would like a vaginal examination for membrane sweeping.</p> |
| National Childbirth Trust | Guideline | General | | <p>Would implementation of any of the draft recommendations have significant cost implications?</p> <p>The financial cost to the health service will also be significant not only in induction costs, but also in postnatal inpatient care (with increases in assisted births), community services and primary care with potential increases in infection and incontinence management due to increases in perineal trauma associated with increased instrumental births.</p> | <p>Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications.</p> |
| National Childbirth Trust | Guideline | General | | <p>What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)</p> <p>The guidelines presume a level of discussion and autonomy for women and birthing people that does not always exist in practice. The availability of quality information to all is poor and the guidelines could be made much more accessible to parents and clinicians by including the required information and an appropriate decision tool (or links to them) in the guidance. The use of online accessibility tools such as RECITE would increase accessibility for all parents.</p> | <p>Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update and so we are unable to provide data tables as you suggest. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date.</p> <p>All NICE web content is designed to be as accessible as possible, including for users who use screen-reading software.</p> |
| National Childbirth Trust | Guideline | General | | <p>The recommendations in this guideline were largely developed before the coronavirus pandemic. Please tell</p> | <p>Thank you for your comment and for letting us know about the changes to maternity care due to the Covid-19</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication.</p> <p>Antenatal education for parents has been restricted and is currently unavailable in many trusts due to Covid-19. How readily available the information is to make an informed choice about induction is difficult to say.</p> <p>Whilst trusts are starting to increase access for birth supporters to the maternity wards, many are still restricted. Throughout the pandemic women and birthing people have experienced induction of labour on maternity wards without their chosen support, describing distressing experiences. Increasing induction for well healthy women would increase the number of women experiencing this alone.</p> <p>The pandemic has exacerbated issues with shortages and burnout in the maternity workforce (evidenced in Health and Social Care Committee 'The safety of maternity services in England' report). Adequate staffing levels and skill mixes are essential to ensure the provision of safe care for the significant number of women who would be considered for earlier induction on a routine basis.</p> | <p>pandemic, and how this may impact on the recommendations on induction of labour.</p> |
| National Childbirth Trust | Guideline | 001 | 006 (In box) | <p>We feel it is inappropriate having acknowledged not all pregnant people identify as women, to then continue to name them as such throughout the guideline "For simplicity of language". We suggest continued acknowledgement of birthing people not identifying as women throughout the guideline, and engagement with LGBTQ+ communities to find acceptable identifying terms.</p> | <p>Thank you for your comment. To ensure consistency between NICE guidelines the NICE editorial team have developed a more inclusive description and rationale for the use of the terminology relating to the intended population for maternity and obstetric guidelines, guidelines, and this is included in the introductory information at the beginning of the guideline.</p> |
| National Childbirth Trust | Guideline | 004 | 001 | <p>The language used omits the right to information on which to base informed decisions about care which would support women and birthing people to access the information they require.</p> | <p>Thank you for your comment. We have removed the text referring to carers so it is consistent with standard NICE text at the beginning of other guidelines and makes it clear who should be involved in discussions and making informed decisions about care.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>“...carers have the right to be involved in planning and making decisions” is ambiguous as “carer” could be interpreted as either a medical practitioner or birth support/carer. Any birth support/carer should only have a right to be involved in planning and decision making with the consent of each individual woman or birthing person. The term “carer” should be defined more clearly and the requirement for consent from the woman or birthing person included in the text.</p> <p>“Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity) and safeguarding.” As this guideline purports to be for use by “pregnant women, their carers and families” it is important that the recommendations and their strength are clear. The availability of this information is limited as not contained within the direct link made, and only found through further searching of the indicated page. Perhaps a pop-up box could be included in the online format so that the meaning of recommendation wording is explained clearly.</p> | <p>The second set of wording you refer to is standard text used at the beginning of all NICE guidelines, and ensures that if, for example, legislation about consent changes, it can be updated on the NICE website and does not have to be updated in each individual guideline, so we have not changed this text.</p> |
| National Childbirth Trust | Guideline | 004 | 006 | <p>The requirement to discuss mode of birth early in pregnancy may not be appropriate for all women and birthing people who may be coming to terms with pregnancy and not ready to digest or consider the information. We suggest the information could be made available in multiple formats early on in pregnancy for parents to consider when ready and discuss at later appointments with their midwife.</p> | <p>Thank you for your comment. We have not provided a specific time in pregnancy at which discussions about mode of birth should start as this may vary between women, but we have clarified that in most cases (if the woman wishes) this will be an ongoing conversation during pregnancy and not a one-off discussion. We have added to the later recommendation about the provision of information that this should include written information.</p> |
| National Childbirth Trust | Guideline | 004 | 008 | <p>During the explanation of induction suggested, women should be made aware induction of labour (as with all care) is an offer and they are free to make a choice about how they wish to proceed with their care.</p> | <p>Thank you for your comment. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | have reiterated this message at several other points in the guideline. We have also included that this decision must be recorded in the woman's notes. |
| National Childbirth Trust | Guideline | 004 | 010 | Suggest adding "utilise a personalised care plan to discuss and record preferences for birth and consider how these could be best facilitated or adapted in all birthing environments" | Thank you for your comment. We have added that discussions about mode of birth and the woman's decision should be recorded in her notes. |
| National Childbirth Trust | Guideline | 004 | 015 | The limiting of birth pool use due to induction in this section is incongruous with the later inclusion of birth pools as a form of pain relief during induction. As different midwifery facilities impose different criteria for pool use arbitrarily, we suggest the limitation should perhaps not be included in the guideline and left to negotiated care between women, birthing people and their care providers. | Thank you for your comment. The use of a birthing pool may be limited, but may still be an option, so we have not amended these recommendations. |
| National Childbirth Trust | Guideline | 004 | 019 | "some methods of induction can cause the uterus to contract too frequently, called hyperstimulation." This information should be clear in which forms of induction it refers to and the consequences of hyperstimulation for women and birthing people. | Thank you for your comment. We have amended this sentence to make it clear that this just refers to pharmacological methods of induction. We have also reworded his sentence to make it clear what hyperstimulation is, and have also added a definition of hyperstimulation to the 'terms used' section and the separate glossary supplement. |
| National Childbirth Trust | Guideline | 005 | 001 | "...contractions can lead to changes in fetal heart rate and result in" Wherever information is offered suggesting increased risk this should be quantified for parents to make informed choices. We suggest offering tangible information in terms of x people in 100/1000 (for example) who would experience changes in foetal heart rates. Foetal wellbeing is ambiguous and should include information detailing in what way foetal wellbeing is compromised. | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on these outcomes. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| National Childbirth Trust | Guideline | 006 | 010 - 019 | The risks associated with continued pregnancy should be offered in quantifiable terms X in 100/1000 (for example). It is not acceptable or appropriate to expect parents to search repeatedly for information in multiple areas/sites as this both reduces the likelihood of accessing accurate information but | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>also increases the cost to those who rely on expensive Pay-as-you-go contracts, as these parents are more likely to be living in deprived circumstances. This adds a cost implication to their information access that increases inequality.</p> <p>Expectant management is not included in these options despite no optimal time for induction being established in the evidence. Since publication of the draft, further evidence (Bowe et al. 2021) could perhaps support identification of women and birthing people most likely to develop complications through placental cause. Could this be considered to support decision making?</p> | <p>absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. Thank you for informing us about the Bowe paper, which we have passed on to the NICE surveillance team who are responsible for ensuring that guidelines are up to date.</p> |
| National Childbirth Trust | Guideline | 006 | 010 | <p>The recommendation to induce labour at (or as close to) 41 weeks in well healthy women is primarily based on low quality evidence. The inclusion of Wennerholm 2019 is likely to overestimate the treatment effect as the study was discontinued before it had enough subjects to power the study and includes potentially inappropriate statistical analysis of the secondary outcome perinatal mortality (Timpka, 2019).</p> <p>No optimal time of induction has been ascertained through evidence-based appraisal.</p> <p>For well healthy women the meta-analysis indicates no effect on shoulder dystocia, perinatal death, brachial plexus injury, or caesarean birth, and favours expectant management for 3rd/4th degree tears.</p> | <p>Thank you for your comment. The recommendations for induction at 41 weeks were based on evidence that certain risks may increase after this time. However, based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based.</p> <p>The committee specifically discussed the quality of the evidence from the SWEPIs study (Wennerholm 2019). The strengths of this study include its large size and relevance to this question. However, the fact that the study was terminated early due to ethical concerns and never reached the sample size intended to power its primary endpoint was a limitation, which may have led to an overestimation of the treatment effect in the intervention group and decrease the precision of the results. These limitations were acknowledged by the committee and were reflected in the overall quality of the evidence of this study. The committee discussed the fact that as such a study was initiated and was terminated on the grounds of</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | perinatal mortality differences, it is unlikely that future research into this specific question will be conducted. Taking this into consideration the committee considered what recommendations could and should be made on the basis of this study, and agreed that the results should be considered with the results of the other studies reviewed. |
| National Childbirth Trust | Guideline | 006 | 020 | <p>Whatever the intention of this section, the recommendation of healthcare interventions based on ethnicity alone is a racist guideline presenting ethnicity alone as a risk factor. It does not account for the causality of higher stillbirth and mortality rates and disregards accounts of inequitable treatment leading to poorer outcomes. Implementing this recommendation in the absence of a holistic strategy to improve care and reduce disparity in outcomes for women and birthing people of colour risks further harm. We have seen no evidence presented in any of the supporting documents or wider research to substantiate this recommendation and it is confirmed in the evidence sections that there is no evidence to indicate an optimal induction date, or data comparison for women and birthing people of colour. The guideline will substantially increase inequity in maternity care, increase intervention and iatrogenic harm for women and birthing people of colour.</p> <p>We request the guidance for Black, Asian and Minority Ethnic women and people of colour with healthy uncomplicated pregnancies to consider induction of labour from 39+0 weeks be removed from this guideline.</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| National Childbirth Trust | Guideline | 006 | 020 | The recommendation for women with high BMI and women aged over 35 to consider induction from 39 weeks should be displayed with information for parents about the risk of complications vs the risk of expectant management. Without this information, expectant management does not seem to be offered as an option. | Thank you for your comment. We have replaced the recommendation on considering earlier induction for women who may be at a higher risk with information from the MBRRACE report, which provides absolute risks. |
| National Childbirth Trust | Guideline | 008 | 021 - 022 | Suggest including expectant management beyond 24 hours with quantifiable data increases in infection. | Thank you for your comment. The management of PROM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | new neonatal infection guideline, so we have not reviewed the data on the risks and benefits of induction of labour compared to expectant management in prelabour rupture of the membranes, or the risks of expectant management beyond 24 hours, and so have not been able to make the changes you suggest. |
| National Childbirth Trust | Guideline | 008 | 013 | Suggest adding "Discuss increased chances of infection (with quantifiable data) and offer...." | Thank you for your comment. This recommendation was taken from the NICE guideline on neonatal infection (NG195) and so, to ensure consistency between guidelines, it has not been possible to add in quantifiable data. |
| National Childbirth Trust | Guideline | 009 | 004 | Suggest adding "Discuss increased chances of infection (with quantifiable data) and offer...." | Thank you for your comment. This recommendation was taken from the NICE guideline on neonatal infection (NG195) and so, to ensure consistency between guidelines, it has not been possible to add in the additional information you suggest. |
| National Childbirth Trust | Guideline | 009 | 019 | Having informed women who have had a previous caesarean birth that induction of labour could lead to uterine rupture or emergency caesarean, it looks odd to now be recommending induction of labour without any qualification and it is unclear where the evidence is to support this recommendation. Suggest there is additional information added regarding the method of induction being proposed. | Thank you for your comment. We recognise that many women will wish to have a vaginal birth after a previous caesarean birth. However, the stem of this recommendation is 'If birth is indicated....' so these recommendations would apply where a decision has been made that it is necessary to expedite birth. In order to clarify this, we have amended the wording to 'if birth needs to be expedited.' Information about the methods of induction (for example, using mechanical methods) has been included in the previous recommendation. |
| National Childbirth Trust | Guideline | 010 | 019 | Suggest adding information regarding accuracy of diagnosis of foetal macrosomia without gestational diabetes, and quantifiable increases of outcomes. | Thank you for your comment. The committee recognise that diagnosis of fetal macrosomia can be difficult, but the recommendations on risk were based on randomised controlled trials where the methods of diagnosing suspected macrosomia would be the same in both arms, and so the identified risks will take into account any inaccuracy in diagnosis. We have added additional information into the recommendations to provide more detail on the magnitude of the risks. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| National Childbirth Trust | Guideline | 012 | 012 | Whenever "risk" or chances of action increasing it should include quantifiable data wherever possible. We suggest including the incidences of uterine rupture in these instances. | Thank you for your comment. We did not identify any evidence for this review and so were unable to provide any more detail on the rates of uterine rupture in this situation. |
| National Childbirth Trust | Guideline | 013 | 010 | Suggest including "Ensure consent is obtained and the woman or birthing person is aware they can request the procedure stop at any time before membrane sweeping. The procedure should cease as soon as the woman or birthing person requests. Their wishes should be respected should the procedure be declined." | Thank you for your comment. We have added additional recommendations to the section at the beginning of the guideline on information and decision-making on the right of women to decline or stop induction procedures, so we have not repeated this for every intervention. |
| National Childbirth Trust | Guideline | 013 | 019 | Suggest including "offer of a vaginal examination... and discuss options for an informed decision about methods of induction" | Thank you for your comment. This recommendation is about explaining to women the purpose of the vaginal examination and the Bishop score. We have amended the wording of this recommendation to explain to women that this will help guide the method of induction they will be offered first, and that consent should be obtained. The discussion about different methods of induction is covered in the next recommendation. |
| National Childbirth Trust | Guideline | 014 | 002 -003 | The risks of hyperstimulation for each medication should be made clear. | Thank you for your comment. There was evidence from the systematic review on the rates of hyperstimulation with dinoprostone and misoprostol so this has been added in a table. |
| National Childbirth Trust | Guideline | 014 | 007 | The methods to which this statement referred should be listed. | Thank you for your comment. We have added examples to this recommendation to provide further clarification. |
| National Childbirth Trust | Guideline | 014 | 009 | The implications of being unable to reverse hyperstimulation by misoprostol should be made clear and quantified if possible. | Thank you for your comment. There was no evidence available to allow the reversal of hyperstimulation to be quantified. This warning came from a Drug Safety Update relating to the Mysodelle vaginal insert (now discontinued) and the committee were asked by the MHRA to include this warning in the guideline. Drug Safety Update, 6 February 2018; Misoprostol vaginal delivery system (Mysodelle): reports of excessive uterine contractions (tachysystole) unresponsive to tocolytic treatment. https://www.gov.uk/drug-safety-update/misoprostol-vaginal-delivery-system-mysodelle-reports-of-excessive- |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|------------|---------|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | uterine-contractions-tachysystole-unresponsive-to-tocolytic-treatment |
| National Childbirth Trust | Guideline | 015 | 001 | Amniotomy and oxytocin infusion are separate procedures. Women and birthing people may wish to treat them as such, and their sequential use should be made clear as an option. | Thank you for your comment. This recommendation was based on evidence for the efficacy of amniotomy and oxytocin used together. However, the committee recognised that sequential use may be preferred by some women and so have added an additional recommendation to state this. |
| National Childbirth Trust | Evidence C | 018 | 011 - 023 | The inclusion of the Wennerholm 2019 study would surely reduce the quality/certainty of the evidence as the study was discontinued before it had enough subjects to power the study and includes potentially inappropriate statistical analysis of secondary outcome used to inform this guidance. (Timpka, 2019). The GRADE assessment of perinatal mortality would be expected to be downgraded for imprecision as there are just 11 events, hence the quality/certainty of the evidence would be expected to be lower. | Thank you for your comment. The committee discussed the quality of the evidence from the SWEPIs study (Wennerholm 2019). The strengths of this study include its large size and relevance to this question. However, the fact that the study was terminated early due to ethical concerns and never reached the sample size intended to power its primary endpoint was a limitation, which may have led to an overestimation of the treatment effect in the intervention group and decrease the precision of the results. These limitations were acknowledged by the committee and were reflected in the overall quality of the evidence of this study. The GRADE assessment of perinatal death for the comparison 41 versus 42 weeks has now been downgraded due to risk of bias. Imprecision is assessed by considering whether the width of the 95% CI of the effect estimate was relevant for decision making considering each outcome independently. In this case, the 95% CI did not cross minimally important thresholds, therefore the outcome was not downgraded due to imprecision. |
| National Childbirth Trust | Guideline | 020 | 003 - 004 | It would be helpful to ensure that the jargon buster has been used on the guideline to prevent parents having to go between sites. | Thank you for your comment. The wording in NICE guidelines is edited to ensure that as little jargon as possible is used. |
| National Childbirth Trust | Guideline | 075 | Figure 5 Perinatal death | ** Wennerholm 2019 terminated early due to significantly higher perinatal mortality in delayed induction group. We suggest it is important to add here that "...empirical evidence suggest that trials stopped early for benefit | Thank you for your comment. The committee specifically discussed the quality of the evidence from the SWEPIs study (Wennerholm 2019). The strengths of this study include its large size and relevance to this question. However, the fact that the study was terminated early due to ethical concerns and never reached the sample size |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------|----------------------------|---------|--------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <i>overestimate treatment effects.</i> " (Guyatt et al. 2011 ; Bassler, et al 2010) | intended to power its primary endpoint was a limitation, which may have led to an overestimation of the treatment effect in the intervention group and decrease the precision of the results. These limitations were acknowledged by the committee and were reflected in the overall quality of the evidence of this study. |
| National Childbirth Trust | Guideline | 083 | Table 24: Comparison 5: 41 versus 42 weeks | Perinatal death: The GDG needs to explain here why there is no downgrading for imprecision when there are just 11 events as this determines an overall quality/certainty rating as High. GRADE guidance recommends calculating the Optimal Information Size (OIS) – has this been done and reported? (Guyatt et al. 2011) | Thank you for your comment. The GRADE assessment of perinatal death for the comparison 41 versus 42 weeks has now been downgraded due to risk of bias. Imprecision is assessed by considering whether the width of the 95% CI of the effect estimate was relevant for decision making considering each outcome independently. In this case, the 95% CI did not cross minimally important thresholds, therefore the outcome was not downgraded due to imprecision. |
| NHS England & NHS Improvement | Equality Impact Assessment | General | General | The equality impact assessment has not recognised the impact of particular groups of women, namely women over 35, women with a high BMI and black and brown women of being singled out for different treatment on the back of evidence that these groups have worse outcomes in general but with no evidence that induction may improve these outcomes. The impact of this recommendation on the relationship between these groups and maternity services should be explicitly considered in the impact assessment, noting that if the guideline is followed, a disproportionate percentage of these women are likely to undergo an induction, potentially resulting in a worse birth experience in general (notwithstanding the fact that some women have a positive experience of induction). | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| NHS England & NHS Improvement | Evidence | | | Caveat by NHSEI: The below comments in yellow have not been subject to a systematic review of the evidence but reflect the collective opinions of the Maternity and Women's Health Team at NHSEI. We welcome new approaches to reducing stillbirth. The ARRIVE trial which seems to underpin much of the change in recommendations has limitations. There are well- | Thank you for your comment. The committee acknowledged that although all included studies were from high-income countries, these were conducted in a variety of settings (not just the United Kingdom) where healthcare is mainly accessible through private funding and where there are usually fewer midwives available to support women during birth, such as the US. However the committee agreed that the evidence was broadly |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------|-----------|-----------|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | documented concerns over methodology and how representative it is. For example, most of the care of the women (who were classified as low risk), was undertaken by doctors, which is not representative of care in the UK. Other concerns regarding the study point to the findings being misinterpreted; the misunderstanding being that the trial is demonstrating reduced risk of stillbirth when inducing at 39 weeks, but the study was only powered to look at the outcome of risk of caesarean section and not perinatal mortality. The study was not sufficiently powered to determine if perinatal mortality was significantly affected by induction at 39 weeks. | applicable to the current UK context as it provided evidence from similar healthcare systems from high income countries. We have now included the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding of the evidence reviewed. The supporting information explains how this data was derived, its limitations and how to interpret it. |
| NHS England & NHS Improvement | Guideline | 004 - 005 | 1.1.2 – 1.133 | Caveat by NHSEI: The below comments have not been subject to a systematic review of the evidence but reflect the collective opinions of the Maternity and Women's Health Team at NHSEI. We welcome the clear guidance here on the factors to be discussed. Women need to be given evidence based statistics about the likelihood of their baby dying or any other adverse outcome with and without induction. Best practice regarding tools to present evidence should be followed including current evidence about long term outcomes using best principles of risk communication. A woman's personalisation and choice will become very limited based on their birth options and anticipated birth experience. Therefore, we recommend this is clearly stated in order to properly inform women. This may significantly increase maternity inequalities based on access, experience, and outcomes. | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data necessary for a decision aid. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth, and have included examples some of the problems babies may face due to an earlier birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. We have also added further recommendations to emphasise that the decision to have an induction or not, rests with the woman and that decision must be respected, and we have taken inequalities into account and recommendations are written to reduce inequalities and to be woman-centred. |
| NHS England & NHS Improvement | Guideline | 006 | 012 - 019 | Caveat by NHSEI: The below comments in yellow have not been subject to a systematic review of the evidence but reflect the collective opinions of the Maternity and Women's Health Team at NHSEI. | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | We agree that women should be given information to inform them of the increased risks of stillbirth beyond 41 weeks. A balanced discussion, that includes risks of early induction and induction is required, and not limited as laid out in this draft guideline to the discussion when a woman requests induction. These must be put in context by providing evidence based statistics about the absolute risk of these outcomes with or without induction. This is a minimum requirement for women to make an informed decision. | evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. |
| NHS England & NHS Improvement | Guideline | 006 | 023 - 024 | Further clarity regarding why babies “with a black, Asian or minority ethnic family background” have been identified as an ‘at risk’ group would be helpful. MBRRACE-UK 2020 identifies the groups most at risk of perinatal mortality as Black and Asian babies (and babies born to mothers living in the most deprived areas); it’s not clear why all Black, Asian and minority ethnic babies are included in this section. Cabinet Office guidance recommends the use of the term ‘minority ethnic’ not ‘Black, Asian and minority ethnic’ and encourages specific ethnic groups to be used wherever possible. <i>Please also refer to the comment about line numbers 20-26 when considering this comment.</i> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. We will keep this use of terminology under review, but current NICE style is not to capitalise black or white. Please see the NICE style guide here: https://www.nice.org.uk/corporate/ecd1/chapter/talking-about-people-including-deaf-and-blind-age-faith-family-background-gender |
| NHS England & NHS Improvement | Guideline | 006 | 020 | 1.2.4 Whilst it asks for complications, preferences, and history to be considered, the guideline does not appear to take account of the causality of higher stillbirth rates and disregards accounts of inequitable treatment leading to poorer outcomes. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| NHS England & NHS Improvement | Guideline | 008 | 006 | The only study that examined maternal satisfaction was a study where 16,427 women declined to participate (Grobman et al., 2018). The volume of women who declined participation perhaps gives an indication that the majority women do not want to be induced early? More research is needed on this topic. | Thank you for your comment. The committee acknowledged the paucity of evidence for the outcome maternal satisfaction in this review, and they agreed that women’s choice is key for providing optimal care in maternity services. Based on stakeholder feedback, the recommendations have been amended to include the factors that should be taken into consideration by women |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. The committee considered the proportion of women who declined to participate in the trial within normal parameters and noted that this may have been related to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal. The committee decided not to prioritise a research recommendation in this area as considered that there is sufficient evidence to base their recommendations on and decided to prioritise other topics within the inducing labour area. |
| NHS England & NHS Improvement | Guideline | 010 | 017 | How is 'confirmed fetal compromise' defined – does this include abnormal fetal Dopplers? | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add a definition of confirmed fetal compromise. |
| NHS England & NHS Improvement | Guideline | 010 | 020 | When should induction of labour be offered to women with suspected fetal macrosomia? | Thank you for your comment. The committee discussed whether it was possible to define the best time to induce labour in suspected fetal macrosomia but the evidence included induction at a range of gestational ages and it was not possible to identify the preferred gestational age. The committee also considered this would be an individualised decision based on the estimated size of the baby, the woman's clinical circumstances and her preferences. |
| NHS England & NHS Improvement | Guideline | 011 | 003 -004 | All women should be invited to take part in clinical trials. | Thank you for your comment. This group was highlighted for inclusion in clinical trials as the committee were aware of an ongoing clinical trial (Big Baby) which will provide specific data on the role of induction in suspected fetal macrosomia. |
| NHS England & NHS Improvement | Guideline | 013 | 010 - 011 | Strongly welcome the explicit guidance to obtain consent for membrane sweeping as we are aware of a number of cases where explicit consent has not been obtained. | Thank you for your comment and support of this new recommendation on consent. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------|-----------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| NHS England & NHS Improvement | Guideline | 013 | 016 - 017 | This should read "Discuss offering". | Thank you for your comment. This recommendation has been revised to emphasise that it should be a discussion with the woman about additional sweeps. |
| NHS England & NHS Improvement | Guideline | 016 | 012 | The Bishop score involves a vaginal examination for which consent needs to be obtained. What guidance is available on whether it is safe to continue with an induction without this examination? | Thank you for your comment. This recommendation is about explaining to women the purpose of the vaginal examination and the Bishop score. We have amended the wording of this recommendation to explain to women that this will help guide the method of induction they will be offered first, and that consent should be obtained. The committee agreed that it would not be possible to safely carry out an induction of labour without doing a vaginal examination. |
| NHS England & NHS Improvement | Guideline | 016 | 023 | How frequently should intermittent monitoring be offered to a woman being induced but contracting irregularly? Intermittent monitoring for established contractions is already covered in 1.5.5. | Thank you for your comment. The committee agreed that it would not be possible to specify how often intermittent monitoring should take place if contractions were irregular, as this would depend on the clinical situation and would need to be an individualised decision. |
| NHS England & NHS Improvement | Guideline | 019 | 009 | Is this realistic, including being acceptable to the woman? Induction may take 24-48 hours. | Thank you for your comment. We have amended the recommendation to state that continuous cardiotocography would only be required after the membranes had ruptured if the presenting part was not stable, so this is not likely to be the case for all women or for the whole duration of labour. The recommendations on monitoring suggest that unless there are clear indications for cardiotocography, intermittent auscultation may be used during induction. |
| NHS England & NHS Improvement | Guideline | 024 | 025 | <p>Caveat by NHSEI: The below comments in yellow have not been subject to a systematic review of the evidence but reflect the collective opinions of the Maternity and Women's Health Team at NHSEI.</p> <p><i>The committee noted "that in their knowledge and experience, women from the Black, Asian and minority ethnic family background, women with 25 BMI of 30 kg/m2 or more, women aged 35 years or more, and women who had assisted conception were at a higher risk of adverse events in a pregnancy that was prolonged beyond term".</i></p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>However, the evidence review underpinning recommendations 1.1.1, 1.1.2, 1.1.5, 1.2.2 to 1.2.4, 1.2.7, 1.2.8 and research recommendations in the NICE guideline noted that "The committee noted that there was a lack of direct evidence available from this review, therefore they based the recommendation on women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications associated with continued pregnancy on their knowledge and experience".</p> <p>Furthermore in Appendix M – Post-hoc analyses Post-hoc analyses explored the relationships between BMI and age (as well as other subgroups, referenced in the discussion) and timing of induction. Few studies reported their population sub-grouped by these categories and no studies reported on ethnicity.</p> <p>Is this a strong enough evidence base to support this broad brush statement with wide implications and we agree with the research recommendation on Page 112 Appendix L – Research recommendations "At what gestational age should induction of labour be offered if spontaneous labour does not ensue? At what gestational age should induction of labour be offered in the subgroups of women who may be more likely to experience adverse outcomes if pregnancy continues?"</p> | |
| NHS England & NHS Improvement | Guideline | 025 | 003 - 005 | Based on your recommendations there is likely to be an increased number of women from the Black, Asian and minority ethnic family background, at higher BMI and over 35 who are induced. Therefore, we recommend that information should be tailored to women's obstetric & medical history rather than demographic risk factors. We are suggesting that you remove the timing because of bias, racism, and prejudice around women of this ethnic background. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| NHS England & NHS Improvement | Guideline | 025 | 005 | Currently, there appear to be issues with capacity and staffing within antenatal inpatient services to accommodate the long waiting list. Therefore, we think it would be helpful to | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | have more research conducted around independent predictive relationship between Black, Asian and minority ethnic women. We believe that 'ethnic' should be removed from the list of risk of induction of labour. | with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| NHS England and NHS Improvement | Guideline | 006 | 020 - 026 | <p>Caveat by NHSEI: The below comments in yellow have not been subject to a systematic review of the evidence but reflect the collective opinions of the Maternity and Women's Health Team at NHSEI.</p> <p>We have identified that there appears to be no evidence offered to substantiate this and it is also confirmed in the evidence section that there is no evidence to indicate an optimal induction date. Women with a higher BMI, in some ethnic minority groups and older than 35 may be more likely to have complications to occur, but decision making on induction should be based on current state of health not potential risks. We are concerned about the impact this could have on the trust black and brown women have in maternity services. We should be trying to change/mitigate the impact of structures that mean that these women are having worse outcomes, rather than putting the onus on these women and asking them to be induced early (and take on the risks that come with it).</p> <p>We are concerned that this would result in a large number of women being offered induction of labour at 39 weeks. Some providers have up to 40% of women from minority ethnic groups and in addition to that would be for example, women with raised BMI and older mothers, and that the capacity of units to offer this many inductions may be challenging.</p> <p>Induction is not without risk (Rydahl et al (2019) Routine induction in late-term pregnancies. BMJ Open 9:12) and there is evidence that this can have a negative impact on the newborn in terms of subsequent cognitive development (RCOG Each Baby Counts report). This should be included</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------|-------------------------------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | in the shared decision tool that needs to be developed to support this discussion. | |
| Norgine Pharmaceuticals Limited | Guideline / Evidence review B | 013 | 014 | <p>We agree that low dose oral misoprostol should be offered to women who would prefer an oral route for induction of labour, however, we also believe that the guidance should be extended to it being considered a first line option for induction of labour.</p> <p>The guidelines should be updated to acknowledge that the SPC for oral misoprostol 25µg does not allow for concurrent use with other labour induction agents or oxytocic drugs. This is an issue when oral misoprostol is used as a second line agent, depending on the elimination time for the first line agent.</p> <p>With regard to the positioning of oral misoprostol and vaginal dinoprostone in the draft guidance, in evidence review 2 for three of the six endpoints in the Bishops score≤6 oral misoprostol has a median rank higher than all forms of dinoprostone. This evidence would suggest that the benefits of low dose oral misoprostol relative to dinoprostone is equivocal.</p> <p>The final decision appears heavily weighted toward vaginal delivery within 24 hours. As noted in the 2016 review by Aliferovic this may be a controversial outcome. Other sources have commented on this outcome and further justification behind the use of this outcome in the NICE guidance would be welcomed.</p> <p>As noted above, the evidence base for informing a first line treatment decision is limited. There is a need for high quality UK based evidence around the use of low-dose oral misoprostol in the induction of labour and a definitive decision or recommendation on positioning should be based on this.</p> | <p>Thank you for your comment. The MHRA had advised the committee to include warnings about the use of misoprostol, based on previous warnings about the hyperstimulation seen with the vaginal insert, and the committee therefore included warnings about hyperstimulation, monitoring uterine activity and fetal condition, and a possible reduced response to tocolysis. The recommendations have now been amended to recommend low dose oral misoprostol as an alternative to dinoprostone (and not just when dinoprostone has failed to work) but the committee have continued to follow the MHRA advice to provide warnings about its use. The committee agreed that the main aim of induction of labour is to achieve a vaginal birth without adverse effects for the woman or her baby, therefore the outcomes relating to mode of birth (no vaginal birth within 24 hours and caesarean birth) were deemed critical. While the 24 hour limit may appear artificial, the committee agreed that this is a well-established outcome measure for assessing efficacy when inducing labour, and would provide a good indication of the relative efficacy of different methods. The committee focused primarily on the outcome of no vaginal birth within 24 hours, but also balanced this with the evidence for hyperstimulation as this is one of the main concerns when inducing labour. Much of the data for the other outcomes did not provide much clear evidence of benefit or harm on which the committee could base decisions. For example, there were few clear differences between placebo and any of the interventions for the outcomes of caesarean birth, instrumental birth, NICU admission, use of epidural, maternal mortality or serious morbidity, perinatal mortality, or maternal satisfaction (in either the whole population or the subgroups with higher or lower Bishop score). The committee decided not to prioritise a research recommendation in this area as considered that there is</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>The evidence base for this therapy area is evolving. As an example, there is an ongoing application submitted to the HTA/NIHR fora comparative study of Prostaglandin Pessary vs Oral Misoprostol for Induction of Labour at Term. This study evaluates whether low-dose oral misoprostol is non-inferior to vaginal dinoprostone for the induction of labour.</p> <p>We suggest a research question be included that allows for the guidance to be revisited when key clinical studies have completed.</p> | sufficient evidence to base their recommendations on and decided to prioritise other topics within the inducing labour area. |
| Norgine Pharmaceuticals Limited | Guideline | 014 | 011 | <p>Of the medicines linked to in the guidelines only ANGUSTA and Mysodelle are licensed for the induction of labour. The EMC listing for Mysodelle states that the manufacturer has discontinued this product.</p> <p>Of the remaining misoprostol products listed, none are available at the dosing recommended in section 1.3.10. The use of these unlicensed medicines at the dosing required often requires 'compounding'/splitting of tablets to be undertaken in order to achieve the desired dose. Whilst the evidence base for oral misoprostol is largely driven by studies that have used compounding, misoprostol products used in compounding to prepare formulations for induction of labour have been removed from the market in a number of European countries e.g. France and Germany.</p> <p>We suggest that the linked products be those that are licensed for the induction of labour.</p> | Thank you for your comment. The only misoprostol preparation now available in the UK and approved for use for the induction of labour is misoprostol 25 microgram oral tablets, and we have amended the link to refer to the SPC for this product. NICE guidelines do not include unlicensed products when an equivalent licensed product is available. You are correct that Mysodelle has been discontinued by the manufacturers. |
| Norgine Pharmaceuticals Limited | Guideline | 028 | 015 - 021 | <p>The MHRA guidance referred to relates to vaginal misoprostol insert, not to other uses of misoprostol in this population and this should be stated.</p> | Thank you for your comment. We have worked closely with the MHRA and followed their advice on the warnings relating to hyperstimulation with pharmacological methods of induction included in the guideline. We have now acknowledged in the rationale section that the previous MHRA warning related to the vaginal insert. |
| Norgine Pharmaceuticals Limited | Guideline | 028 | 015 | <p>We disagree with the decision to group all misoprostol preparations together, even with the caveat that the higher</p> | Thank you for your comment. The MHRA had advised the committee to include warnings about the use of misoprostol, based on previous warnings about the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------------|----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>risk of hyperstimulation is driven by increased doses and vaginal preparations.</p> <p>Evidence Review 2, table 9 ranks oral misoprostol <50mcg as having a higher probability of being the best treatment in relation to this outcome when considering pharmacological options only. This outcome is supported by a recently published meta-analysis that found oral misoprostol had a lower risk of hyperstimulation with or without FHR changes compared to vaginal misoprostol and vaginal dinoprostone (Kerr et al 2021)</p> <p>This section should be amended to:</p> <ul style="list-style-type: none"> Separate entirely misoprostol into the low dose oral formulation, for which there is lower risk of hyperstimulation (as detailed above), to vaginal formulations, for which there is higher risk of hyperstimulation <p>Make clear that vaginal misoprostol should not be offered routinely for induction of labour</p> | <p>hyperstimulation seen with the vaginal insert, and the committee therefore included warnings about hyperstimulation, monitoring uterine activity and fetal condition, and a possible reduced response to tocolysis. The recommendations have now been amended to recommend low dose oral misoprostol as an alternative to dinoprostone (and not just when dinoprostone has failed to work) but the committee have continued to follow the MHRA advice to provide warnings about its use.</p> |
| Nottingham University Hospitals NHS Trust | General | General | General | <p>Some interesting and helpful changes, with emphasis on giving information and offering choices (and allowing time for women to make the choices). Seems option of CS should now be one of the choices offered in most if not all scenarios. Discussions will need careful wording.</p> <p>Has anyone anywhere performed an analysis of the effect on induction rates if we start 'considering' IOL for all women > 35, or with IVF or with BMI > 30? Lack of evidence base to support this 'consideration'. Are all these women going to be consultant led so that a conversation can be had at 36 weeks about IOL at 39 weeks? I really don't know what 'consider' means.</p> <p>"As there was no evidence to identify the optimal timing of induction in these groups" - why have you excluded Walker et al from evidence around IOL at 39 for women aged ≥ 35</p> | <p>Thank you for your comment, and support of the guideline providing more choices, including caesarean birth where appropriate.. We will address your points in turn.</p> <ol style="list-style-type: none"> Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a potential impact of induction rates. Walker 2016 was excluded because women in the expectant management (control) group were offered induction at 41+0 to 42+0 weeks, but they could decline and continue with expectant monitoring and be managed according to local clinical practice. Studies that compared induction of labour against expectant management with insufficient information to determine the timing of eventual induction in the expectant management group were not included. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>years? https://www.nejm.org/doi/full/10.1056/NEJMoa1509117) Committee have misread Grobman https://www.nejm.org/doi/full/10.1056/NEJMoa1800566) as saying IOL doesn't improve feeling of control. The difference was 4 points on the agency scale and highly statistically significant. In favour of IOL. Who says that is "no clinically important difference?" They cite Grobman as showing that IOL reduces CS but they say that is "in favour" of induction. Surely we're long past saying low CS rate is good. Very disappointing to see laminaria and osmotic cervical dilators grouped together. Good evidence base for osmotic cervical dilators (COMRED study – non-inferiority RCT comparing Dilapan and misoprostol https://clinicaltrials.gov/ct2/show/NCT03670836) and SOLVE trial due to be published (RCT of Dilapan versus Proppess). We have heard of multiple units who have introduced Dilapan with excellent results (local data available). This part of the consultation must be revised. For suspected macrosomia, please add the gestational age at which we should offer women IOL. Strange that for suspected macrosomia they don't mention CS as option, whereas do for prolonged pregnancy and IUFD Very happy to see the offer of membrane sweeps from 39+0 weeks for all women, this is a very welcome recommendation.</p> <p>In prolonged pregnancy section, they talk about offering increased fetal monitoring in women who prefer to avoid IOL. Does this include the group where they advocate offering IOL from 39 weeks? I am assuming 'yes' In PPRM 34-37 weeks with GBS in current pregnancy, they say offer immediate birth. Would they not advocate steroids x2 doses before this (esp if needing CS)?</p> | <p>3. Based on your feedback, we have rectified the statement regarding quality of life for Grobman 2018 4. Based on stakeholder feedback the committee have reviewed the evidence for osmotic cervical dilators again and have now included them as option as a mechanical method of induction. 5. The committee discussed whether it was possible to define the best time to induce labour in suspected fetal macrosomia but the evidence included induction at a range of gestational ages and it was not possible to identify the preferred gestational age. The committee also considered this would be an individualised decision based on the estimated size of the baby, the woman's clinical circumstances and her preferences. 6. Thank you for your support of the recommendations on membrane-sweeping. These have now been amended to clarify that this should be discussed with the woman after 39 weeks. 7. As the recommendation on earlier induction for woman who may be at high risk has now been removed, your comment about monitoring after 39 weeks is no longer applicable. 8. Maternal corticosteroids are covered in the NICE guideline on preterm labour and birth, where there is a recommendation to consider them between 34+0 and 35+6 weeks of pregnancy. We have therefore included a cross-reference to this guideline. 9. We have not included oxytocin dosing regimens for induction of labour as this would be used in accordance with the manufacturers' recommendations.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------------------------------|-----------|---------|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | No oxytocin regimens are given, despite controversies over dosing and rate of increase etc | |
| Oxford University Hospitals NHS Foundation Trust | Guideline | 006 | 020 | <p>1.2.4 It should be noted here that adoption of section 1.2.4 which states '<i>consider induction of labour from 39+0 weeks in women with otherwise 20 uncomplicated singleton pregnancies who are at a higher risk of 21 complications associated with continued pregnancy (for example, BMI 22 30 kg/m2 or above, age 35 years or above, with a black, Asian or minority 23 ethnic family background, or after assisted conception)</i>' would in Oxford lead to a further near doubling of the induction rate and that in some maternity units would mean induction of labour in most women.</p> <p>NICE's stated role is 'to improve outcomes for people using the NHS...' By failing to prioritise the use of resources for those at most need, adherence to this guideline could achieve the opposite by adding burden to already hard pressed maternity services.</p> | Thank you for your comment. As a result of stakeholder feedback the guideline no longer recommends that induction of labour be considered at 39+0 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications. The amended recommendations on timing of induction make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| Oxford University Hospitals NHS Foundation Trust | Guideline | 010 | 020 & evidence review | <p>We request that the guideline recommendation 1.2.22 is withdrawn. This recommendation is made despite the committee's acknowledgement that there is a lack of evidence that it is beneficial: '<i>The committee considered that there was not strong clinical evidence to support induction of labour as preferable to expectant management in women with suspected fetal macrosomia.</i>'</p> <p>Despite this, our principal problem is with the implications for appropriate and equitable use of resource.</p> <p>Induction requires additional resource and midwifery numbers, acknowledged and factored into 'Birthright Plus' (https://www.birthrateplus.co.uk/) which is endorsed by NICE. This is almost dismissed in the discussion as the recommendations '<i>...represent common current practice. The committee considered that these recommendations would not lead to an increase in resource use as they reflect</i></p> | <p>Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence.</p> <p>As the recommendation states that a discussion should be held with the woman about the choice of mode of birth, we do not anticipate this recommendation having a great impact on workload or resource use.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p><i>standard practice for the majority of centres.</i> There is a crucial difference between the observation that maternity units do sometimes arrange induction for known/ suspected macrosomia, and the recommendation that they should. Most importantly, this recommendation will mean that not offering induction of labour for larger babies will be considered substandard practice.</p> <p>So why does this matter? It would mean a large increase in the number of inductions. Induction of labour is the principal mechanism by which maternity services try to prevent stillbirth. More induction means more use of more midwifery, medical and anaesthetic hours. Frequent, current shortages of these are consistent themes in published national audits and reviews of perinatal deaths eg MBRRACE (https://www.mbrace.ox.ac.uk). Induction usage is therefore best prioritised to those at most risk of serious adverse outcome, and the recommendation to offer induction of labour at 41+0 weeks is welcome in this regard. For suspected macrosomia, however, the 'offer' puts suspected macrosomic babies on an equal footing with those at far higher risk. And by adding to the workload of maternity units the policy potentially puts other pregnancies at increased risk.</p> <p>The effects of this on workload can be calculated. Using data from Oxford, the Birthrate Plus acuity tool can be used to calculate the additional midwifery requirement. The 'new policies' of induction at 41+0 for all and for suspected macrosomia (projected at 39 weeks), using a projected 80% 'acceptance rate' among women, would lead to an additional 750 inductions per year (approx. 2/ day) and would 'require' an additional 30 WTE midwives.</p> | |
| Oxford University Hospitals NHS Trust | Guideline | General | General | This guideline and the increase in cohort for IOL along with management of women who choose not to be induced has wide reaching ramifications for maternity services: | Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <ul style="list-style-type: none"> NHS providers constrained by estates – no capital monies being allocated for buildings which impacts on the provision of space and increased bed capacity associated with more women being IOL and declining IOL Midwifery staffing: Birthrate Plus acuity scoring system allocates women having IOL to Category III which has a ratio of midwife time of 1.2. This would therefore require on average 20% more midwifery hours per additional IOL. The RCM planning document "Working with Birthrate plus" uses an average 8 hour labour to calculate staffing shortfall. Using the RCM acuity prediction, an additional 1.6 midwifery hours would be required for each IOL. For OUHFT it will mean 5.15- 10.3 WTE equivalent in staff to deliver the requirements of this guideline Impact of delays as mentioned below | later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| Oxford University Hospitals NHS Trust | Guideline | General | General | <p>We are concerned that there is no evidence of an impact document undertaken on this IOL guideline along with the bigger picture implications associated with other NICE guidelines e.g offering CS increases CS rate In terms of the National picture, what does this mean for maternity services- capacity and demand? We feel this has the potential to put other women with higher relative risk at harm as maternity services wont be able to meet demands of these and other guidelines Evidence to support our concerns:</p> <ul style="list-style-type: none"> Based on paper accepted for publication by BMJ Open (<i>Delay in the induction of labour process: a retrospective cohort study and computer simulation of maternity workload – Robertson, Clacey, Reddy</i>) Booked inductions are significantly associated with delay in the IOL process and this delay is reported | Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>as a theme in adverse outcomes (Each Baby Counts reports) and poor patient experience</p> <ul style="list-style-type: none"> For each additional booked IOL per week, the number of women experiencing delay of more than 24 hours in transfer to Labour Ward after cervical priming increases by 1.3% | |
| Oxford University Hospitals NHS Trust | Guideline | 006 | 020 - 025 | <p>Rec 1.2.4 The inclusion criteria to consider IOL at 39 weeks if BAME, BMI>30, age>35 or IVF will add an additional 2281 IOL per year with a total including the above of 2281 IOL per year which will be 46.3% of our births</p> | <p>Thank you for your comment. As a result of stakeholder feedback the guideline no longer recommends that induction of labour be considered at 39+0 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications. The amended recommendations on timing of induction make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications.</p> |
| Oxford University Hospitals NHS Trust | Guideline | 006 | 010 - 011 | <p>Rec 1.2.2 – We are concerned that this recommendation will have challenging implications for us as a maternity service – especially the % of women that will require IOL and resources needed to meet this guideline At present our birth rate is around 7500births per year – including 1347 IOL; 17.8% births With adoption of offer IOL at 41+0 and LGA (>95th centile) at 39 weeks we will have an additional 882 IOL per year; 29.7% births</p> | <p>Thank you for your comment. As a result of stakeholder feedback the guideline no longer recommends induction from 41+0 weeks or that induction of labour be considered at 39+0 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications.</p> <p>We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications.</p> |
| Oxford University Hospitals NHS Trust | Guideline | 007 | 013 - 015 | <p>Rec 1.2.6 We are concerned that the recommendation has no ramifications for safety and has implications on workload as we have found that only 80% women will accept IOL and as the cohort will now be bigger, it will require an offer of</p> | <p>Thank you for your comment. Other recommendations (for example 1.2.2 and 1.2.4) have been amended so it is unlikely that the cohort of women being offered and declining induction will change significantly. This</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | more CTGs and requests for USS (that we don't currently offer) | recommendation has also been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The options to do CTG and amniotic pool depth are only provided as suggestions, carried over from the previous version of the guideline, and have been in place since 2008, so it is unlikely these recommendations will have an impact on resources. |
| Oxford University Hospitals NHS Trust | Guideline | 010 | | 1.2.22 We are concerned that there is no timing for IOL included in this recommendation and again the implications for workload and potential impact indirectly on pt safety need to be taken into consideration | <p>Thank you for your comment. The committee discussed whether it was possible to define the best time to induce labour in suspected fetal macrosomia but the evidence included induction at a range of gestational ages and it was not possible to identify the preferred gestational age. The committee also considered this would be an individualised decision based on the estimated size of the baby, the woman's clinical circumstances and her preferences.</p> <p>As the recommendation states that a discussion should be held with the woman about the choice of mode of birth, we do not anticipate this recommendation having a great impact on workload or patient safety.</p> |
| PANDAS Foundation | Guideline | General | | We are worried by the lack of links to any research that would inform if it were appropriate to offer induction. Instead there are comments such as "the committee were aware that", and lacked actual evidence. | Thank you for your comment. The recommendations relating to timing and methods of induction were based on systematic reviews of the literature and the studies included in these reviews, the quality of the evidence and the findings of the systematic review are included in the evidence reviews which are referenced from the guideline and are available on the NICE website alongside the guideline for consultation. |
| PANDAS Foundation | Guideline | General | | We are worried that the proposed guidelines suggest that birthing people are informed solely of increased "risks" without tailored discussions on WHY this maybe so. We are worried that without this, it's incredibly hard to make | Thank you for your comment. It was not within the scope of this update to carry out a review of induction of labour versus expectant management, and so we have not been able to provide detailed information on the risks and benefits of induction. However, the committee have |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | important decisions regarding ways to birth, and places all of the risk regarding this once again on the birthing person. | expanded the section on information and decision-making to include other factors that should be considered when a woman is making a decision about mode of birth. For the reviews on timing of induction and methods of induction, where information on risks or benefits was available we have tabulated this and included it in the guideline (or an appendix) to help with decision-making. |
| PANDAS Foundation | Guideline | General | | PANDAS is worried about the mental health implications of birthing people and their families due to this change. We know that this change has been proposed, in part, to address the Black Maternal Health disparity, but we have grave concerns that this will actually worsen those, especially in terms of mental health outcomes. We know that medicalised births are more likely to lead to trauma and PTSD, and steering birthing people away from births they may have wanted (home births, midwife centre led births etc) may well have an adverse effect. We also believe that this change in guidelines will actually further & broaden the disparity, which is surely the opposite in aim to the issues it's trying to address. We are also concerned that this change may bring about more cases of antenatal perinatal mental health issues due to the anxiety and stress that these guidelines may cause. | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. Based on stakeholder feedback we have also replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women with a higher BMI, who are older, who have had assisted conception or from certain ethnic family groups. |
| PANDAS Foundation | Guideline | 006 | 020 | Not having white skin is not a medical issue or reason for induction. We are concerned about the mental health implications of this for birthing people and their families. Pathologising black and brown bodies in this manner is not justified and we believe it will lead to further disparities. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Perinatal Institute | Algorithm | General | General | Regarding induction for suspected fetal growth restriction: The algorithm rightly includes an 'Avoid Induction' section in case of fetal growth restriction with confirmed fetal compromise. However it is missing a section in 'Induction may be offered' if there is suspected fetal growth restriction – on the basis of smallness for gestational age, serial growth assessment, or Doppler investigations. The indications are important for induction of labour and are variously elaborated | Thank you for your comment. The role of induction if there is fetal growth restriction was not included in the scope of this update and so we have not amended these recommendations. As the algorithm reflects the guideline recommendations we are therefore unable to amend the algorithm as you suggest. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------|-----------|------------|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | in the RCOG's SGA Green Top Guidelines, NHS England's 'Saving Babies' Lives Care Bundle / Element 2 Guidelines, and the Perinatal Institute's GAP (Growth Assessment Protocol) Care Pathway. | |
| Perinatal Institute | Guideline | 006 007 | 020 003 | The algorithm as well as the guideline rightly emphasise the importance of counselling women regarding risks and options, and to help them make informed choices. To address the dearth of information available for clinicians for counselling, we recently undertook a study of over 1 million NHS pregnancies to assess the <u>prospective risk of stillbirth according to fetal size at term</u> . The analysis detailed the increasing risk from 37 weeks in size centile categories 10<90, 3<10 and <3. Results are available as abstract https://obgyn.onlinelibrary.wiley.com/doi/full/10.1002/uog.22874 and an oral presentation at the 2021 RCOG World Congress Prospective Risk of Stillbirth.mp4 and have been submitted for publication. | Thank you for your comment and telling us about this work. We will pass this on to the NICE surveillance team who are responsible for ensuring guidelines are up to date. |
| Powys Teaching Health Board | General | | | A lot of very key parts of this document are shaded in grey and it is suggested that comments cannot be made on these | Thank you for your comment. You are correct that an updated evidence review has not been conducted for sections of the guideline that have been shaded in grey. This update was a partial update, and only sections of the guideline where new evidence had been identified were updated. |
| Powys Teaching Health Board | General | | | ARRIVE trial – the trial did not show a difference in the primary outcome of mortality/morbidity for the neonate, although it did show a reduction in the secondary outcome for caesarean section rates. The concern here is that IOL is being suggested as a safety issue for the fetus/baby suggesting should a woman decline IOL she could be putting her baby at risk when actually this is not the case based on the evidence. This was also conducted on low risk nulliparous women, but the findings are being generalised for all women. It is noted in the evidence review that the evidence around caesarean birth is of low quality. Furthermore the | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have now included tables with the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding of the evidence reviewed. The supporting information is split by parity and it explains how this data was derived, its limitations and how to interpret it. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------|----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | instrumental/operative birth showed no clinically important difference, but because it has neared statistical significance it is being used in favour of earlier IOL. | |
| Powys Teaching Health Board | General | | | Service implications where there are already frequent delays with women awaiting IOL – how to manage these expectations – IOL is seen as a need to deliver the baby and then delays lead to anxiety, some women could be waiting a long time for the IOL process start. Staff shortages can impact and there can be back-logs of women who are waiting for IOL – this is a significant concern. Hospitals already have capacity issues trying to find beds for current women having IOL without decreasing the gestation and increasing the demand. | Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| Powys Teaching Health Board | General | | | 2021 article - Intrapartum interventions and outcomes for women and children following induction of labour at term in uncomplicated pregnancies: a 16-year population-based linked data study BMJ Open – Dahlen et al Looked at IOL v's Spontaneous labour onset in uncomplicated term pregnancies with live births. Australian study but are comparable demographics. Just under 500,000 births. 15% had IOL for non-medical reasons. Primiparous women with IOL – more likely to have instrumental birth, IP caesarean section (29% for IOL versus 13.8% for spontaneous labour), more likely to have an epidural in labour, more likely to have an episiotomy and more likely to have a postpartum haemorrhage. The trend was similar for multiparous women except for caesarean section which was lower. Incidences of neonatal birth trauma, resuscitation and respiratory disorders were higher for the IOL group. Admissions for ear, nose and throat infections, respiratory infections and sepsis were also higher for the IOL group to age 16. Didn't include women over age 35 | Thank you for your comment. Dahlen 2021 is not eligible for inclusion because it is not an RCT and did not compare different timings of induction. For further details regarding inclusion and exclusion criteria, please see appendix A in evidence report C. |
| Powys Teaching Health Board | General | | | To support clinicians to have appropriate and meaningful discussion with families relating to the decision to continue with pregnancy versus having an IOL it would be helpful to | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------|----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | have the statistics for continuing pregnancy versus IOL in a comparison table to be able to compare the risks and benefits of each option. Neither appear without some risk and a comparison might help those discussions with women and their families for them to make an informed choice. | about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| Powys Teaching Health Board | General | | | Trauma related to IOL – we note there is no evidence that has been considered regarding maternal quality of life and just one on satisfaction/experience of care – this is a key element and not only for the mother but also the partner too. There is not a single mention of how the whole process of IOL, the long delays, failed IOL and ultimate C/S effects women psychologically. There are large numbers of birth trauma clinics commencing to pick up the pieces of long term psychological trauma. | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. We did not have any data on long-term outcomes and it was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. |
| Powys Teaching Health Board | General | | | Offer at least once a week review if declining IOL – This can have the effect of making the women feel coerced into having to agree to the IOL. | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again. |
| Powys Teaching Health Board | General | | | Twice weekly CTG and max amniotic pool depth – resources – do the current staff have the capacity for this? St George's Fetal Medicine unit have been performing scans at 41+3 for 20 years at their post dates clinics. The AFI fluid index is a much better tool to assess fetal wellbeing than CTGs at this gestation. | Thank you for your comment. The options to do CTG and amniotic pool depth are only provided as suggestions, carried over from the previous version of the guideline, and have been in place since 2008, so it is unlikely these recommendations will have an impact on resources. As they are only suggested monitoring tools, units would be able to carry on with monitoring tools they currently use. |
| Powys Teaching Health Board | General | | | Impact on future pregnancies if women are more likely to have intervention – more pregnancies becoming high risk – erosion of low-risk or midwifery-led care | Thank you for your comment. We recognise increased levels of intervention will impact on the number of women able to give birth in midwifery-led care in the current and possibly in future pregnancies. However, based on stakeholder feedback, we have amended the recommendations on timing of induction for prolonged |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | pregnancy to make the focus a discussion of the risks of later versus earlier induction with the woman (and we have included tabulated details of absolute risks), so she can make an informed decision. We have also replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report. We have therefore revised the likely impact on the NHS of the recommendations. |
| Powys Teaching Health Board | General | | | Guidance on how EDD is calculated – from dating scan, LMP, Naegele's rule should this be clarified in the guideline. | Thank you for your comment. The NHS uses the 12 week dating scan to determine the gestational age of the baby and hence its due date, so we have included this in the guideline. |
| Powys Teaching Health Board | General | | | With regards to the current Coronavirus pandemic. Reducing the gestation for routine IOL without scientific research reasons, will ensure that women are spending far more time within a hospital setting thereby increasing their risk of nosocomial transmission. Women are being kept in hospital for many days undergoing the IOL process without being able to have anyone there. There is very restrictive visiting. Partners are not allowed into hospitals until their partner is in established labour. | Thank you for your comment. The recommendations on information and decision-making include the fact that induction may lead to a longer length of stay. We are aware that visiting restrictions due to Covid-19 are now being eased in most hospitals. |
| Powys Teaching Health Board | General | | | Have you looked at the financial implications of increasing the IOL rate on length of stays for women, the level of staffing needed to be able to provide high quality safe effective care and the financial impact on the NHS? | Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| Powys Teaching Health Board | Guideline | General | General | We are concerned that there is no mention of the negative implication that can come from induction of labour and what the risks of this may be for woman and baby. | Thank you for your comment. It was not within the scope of this update to carry out a review of induction of labour versus expectant management, and so we have not been able to provide detailed information on the risks and benefits of induction. However, the committee have expanded the section on information and decision-making |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | to include other factors that should be considered when a woman is making a decision about mode of birth. |
| Powys Teaching Health Board | Guideline | | | <p>Is there evidence/data available on how long on average the IOL process takes based on gestation at onset of IOL? This is important information for families to understand.</p> <p>Earlier IOL increases the incidence of failed inductions thereby leading to an increase in the caesarean section rate. This further impacts on their next pregnancy and birth by increasing their risk factors and reduces their chances of having a vaginal birth.</p> | Thank you for your comment. It was not within the scope of this update to look for data on the length of induction based on different gestational ages and so we have not been able to include this information. Likewise, the committee had no evidence to show that earlier inductions were more likely to be unsuccessful or to an increased rate of caesarean birth. |
| Powys Teaching Health Board | Guideline | | | <p>Service impact of IOL at 41 weeks – 31% of our population labours at 41 weeks. This is within midwifery-led/home settings. <u>The impact this would have on midwifery - led services cannot be underestimated.</u></p> <p>Women labour in midwifery led settings up to 42 weeks. If they were all admitted for IOL after 41 weeks where is the capacity for this increased flow to OUs? This would increase the cascade of intervention that occurs with birth in an obstetric environment.</p> <p>Labour is a normal physiological process. Women have not yet lost the ability to go into spontaneous labour.</p> | Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| Powys Teaching Health Board | Guideline | | | <p>39/40 Membrane sweeping – the evidence within the document does not appear to suggest anything around timing of membrane sweeping – what frequency is being suggested. What about infection? What about the pain from the repeated vaginal procedure?</p> | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, or the frequency. However, the recommendations already highlight that the procedure may cause discomfort. |
| Powys Teaching Health Board | Guideline | | | <p>39/40 membrane sweeping and IOL – this gestation is not in line with the NICE schedule of antenatal care – is this being going to change?</p> | Thank you for your comment. We have clarified that membrane sweeps should be discussed after 39 weeks, so the timing of the sweep is not prescriptive. |
| Powys Teaching Health Board | Guideline | 006 | 012 | <p>1.2.3 - 41/40 GESTATION FOR ALL SINGLETON PREGNANCIES if this is being offered it would be helpful for the guideline to state the actual statistics for the increased likelihood for adverse outcomes should they continue with</p> | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | pregnancy until 42+0 weeks (which is stated as being the point up to at which the labour will normally start) | limitations of the evidence upon which these tables are based. |
| Powys Teaching Health Board | Guideline | 006 | 020 | This guideline is going to impact on a large number of women, especially with suggestion of IOL for women with BMI over 30 (almost 30% of our population in Powys), black, Asian or minority ethnic family background, assisted conception or women aged over 35 etc from 39 weeks gestation. These women are not being provided with an optimum chance of spontaneous labour if IOL is suggested at 39 weeks. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Powys Teaching Health Board | Guideline | 007 | | 1.2.6 offer increased fetal monitoring for women choosing not to have IOL – does this mean from 39 weeks for the group in 1.2.4 and then 41+0 for those in 1.2.2? | Thank you for your comment. The recommendation in 1.2.4 has been withdrawn, and that at 1.2.2 amended, so there are likely to be fewer women to whom this monitoring recommendation now applies. |
| Powys Teaching Health Board | Guideline | 012 | | 1.2.12 -pre-labour ROM – IOL ASAP why? What is your clinical research recommendations to back this up? | Thank you for your comment. The management of PROM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, and are based on evidence identified during the development of the 2008 version on the guideline. However, the recommendations in the induction of labour guideline are in accordance with the intrapartum care guideline, as both recommend expectant management for 24 hours and then induction of labour, but women may not wish to wait for 24 hours and so are given the option of an earlier induction. |
| Powys Teaching Health Board | Guideline | 024 | 011 | We feel concerned at the level of detail that is based on the <u>'knowledge and experience of the committee'</u> | Thank you for your comment. NICE guidelines are based on the committee's interpretation of the evidence and where there is a lack of evidence, the committee may decide to make or augment recommendations based on their knowledge and experience. This is particularly the case, as happened here, for recommendations on information and advice where there may be a lack of evidence. |
| Royal College of Midwives | Guideline | General | General | The RCM welcomes an update to the Inducing Labour NICE Guideline, however the language, recommendations, and methodology of the proposed draft guideline lack the usual high standards we expect from NICE. The implication of | Thank you for your comment. We have fully considered all the comments, edits and suggestions made by the RCM and many other stakeholders and have substantially amended the guideline. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>those recommendations on service provision, midwifery workforce, safety, long term clinical and phycological outcomes for women and babies, and experience of care for women and their families has not been fully considered.</p> <p>We strongly recommend revising the draft guideline to account for the comments, edits, and suggestions we have provided below.</p> <p>The RCM response was informed by consultation with our members via the RCM Consultant Midwives Forum, RCM Heads and Directors of Midwifery Forum and the RCM Professorial Group.</p> | |
| Royal College of Midwives | Guideline | General | General | <p>We regret to note an increased emphasis on risk which permeates this new version of the guideline, e.g. the requirement for women declining IOL to 'revise their option' or notify changes to their decision as soon as possible.</p> <p>We would like to point out that the Keulen study authors explicitly say that the results of their trial, which show a small improvement in perinatal outcomes in the IOL arm, can be interpreted in different ways and that it could be argued that a change in guidance to advise induction of labour for all women at 41+0 weeks, involving high number needed to treat (NNT), might be too rigorous. They state: "...as with every intervention in the natural birth process, the decision to induce labour must be made with caution, as the expected benefits should outweigh possible adverse effects for both mother and child."</p> | <p>Thank you for your comment. The recommendations in the guideline reflect that decisions, circumstances and preferences may change over the course of a pregnancy and that women should not be bound to a decision made at an earlier time, and that she may wish to change that decision if her circumstances change.</p> <p>Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction.</p> |
| Royal College of Midwives | Guideline | General | General | <p>This draft guideline seems to contain an exceptionally high number of recommendations based on the "knowledge and experience" of the committee. We argue that good observational study and qualitative reviews should be prioritised over the experience of individual committee</p> | <p>Thank you for your comment. We agree that in some cases observational studies can provide useful evidence but, for effectiveness review questions, these are usually used only if there is insufficient evidence from randomised controlled trials (RCTs) as these provide higher quality</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>members, particularly as they offer data on long term outcomes and insight on women's experience of care. An evidence-based NICE guideline should be based on robust research evidence, not the knowledge and experience of a small group of committee members, not least because the new recommendations have significant implications for women and their partners and service providers.</p> <p>The rigor of the guideline is compromised by the number of recommendations based on the "experience and knowledge" of the committee. Furthermore, membership of the committee making the recommendations, and conflict of interest statements, as well as professional and other affiliations should be clearly listed and easily located.</p> | <p>evidence. Qualitative reviews are prioritised if the review question relates mainly to the views or opinions of patients or service users. For 3 of the 4 review questions included in this guideline update, RCTs were available and so observational data were not reviewed as well. For the 4th question neither RCT nor observational data was identified. However, the guideline committee wished to make the guideline as useful as possible to healthcare professionals and women and so chose to develop or expand on the recommendations based on their knowledge and experience, in addition to using data from RCTs. The membership of the committee and their declarations of interest is available on the NICE website alongside the guideline documents for consultation.</p> |
| Royal College of Midwives | Guideline | 004 | 010 - onwards | <ul style="list-style-type: none"> At the time that IOL is offered to women, they should be informed that in most settings opting for IOL may preclude other options such as home birth or birth on a midwifery-led unit and will effectively limit access to midwifery-led care. Women should also be aware of how an induction of labour may impact on their experiences and perceptions of pain. Information should be tailored to each woman's specific and individual circumstances. <p>We strongly suggest considering the RCM Blue Top Guideline on induction of labour recommendations for the information on choice and consent aspects: https://www.rcm.org.uk/media/3552/midwifery-care-for-induction-of-labour-a4-2019-16pp_2.pdf The evidence and recommendations from the RCM Blue Top Guideline appropriately included qualitative review of women's experience of induction of labour; this is notably missing in the draft NICE guideline.</p> | <p>Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update and so we were unable to include qualitative data on women's birth experiences. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth, and this includes how mode of birth may impact on place of birth and considerations of likely pain. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date.</p> |
| Royal College of Midwives | Guideline | 006 | 002 - onwards | <p>Prevention of Prolonged Pregnancy: All the evidence presented in support of IOL for post-dates pregnancy is based on RCTs, which does not reflect a</p> | <p>Thank you for your comment. The review protocol agreed by the committee for this review only included RCTs as the committee were aware of a number of large, recent trials in</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | complete picture of the literature. There is a large body of observational evidence and qualitative evidence that has not been taken into consideration. We call for the committee to conduct a broader review of the evidence. Developing NICE Guidelines: The manual states that depending on the topic it can be useful to review a range of different types of evidence including observational and qualitative studies. | this area which they agreed would provide the highest quality evidence on which to base their decision. However, based on stakeholder feedback, the recommendations have been amended to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. |
| Royal College of Midwives | Guideline | 006 | 002 - onwards | 1.2.2 and 1.2.3 Prevention of prolonged pregnancy 41+0 All the evidence cited in support of these recommendations derives from RCTs. While it is essential to include RCT evidence, we believe a more cautious approach is needed when extrapolating 'universal' recommendations applicable to all women from these studies. RCTs of labour induction versus expectant management may be subject to biases, namely: - <u>Performance bias</u> by providers due to lack of blinding, based on which the committee has correctly downgraded the quality of some of the evidence. This may have led to different management of women in the two arms. For example, there may have been delays in inducing labour for women developing risk factors in the expectant management arm due to provider reluctance as the women were 'in the wrong arm'. - <u>Representativeness of the study population</u> . Only between one fifth to one third of eligible women accepted to be part of the ARRIVE, SWEPSIS and INDEPTH trials. Although the study samples were considered comparable to the general population in SWEPSIS, there may be unmeasured differences between the trial and general populations, especially as far as attitudes towards IOL are concerned. This limits the external validity of RCT findings. | Thank you for your comment. We will address your points in turn: 1. RCT evidence provides the highest quality level of evidence when comparing the outcomes resulting from different interventions and will always be preferred (when it is available) as a basis for NICE guideline recommendations. However, we recognise that other sources of data can provide additional useful information and have now included Hospital Episode Statistics and MBRRACE data to provide supplementary information in this section of the guideline. 2. The methodological limitations of the included trials were assessed with standardised checklists, reflected in the evidence report and taken into consideration by the committee when interpreting the evidence. 3. The committee considered the proportion of women who declined to participate to be within normal parameters and considered this could be due to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal. 4. We have now included the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding of the evidence reviewed. We have presented this information by parity and added supporting information, which explains how this data was derived and how to interpret it. 5. We acknowledge that some women may have been anxious or stressed as a result of study participation or the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>We note that in the SWEPSIS trial, all cases of perinatal mortality were among nulliparae, and the ARRIVE trial included only nulliparous women. In the INDEPTH study, one case involved a nulliparous woman and the other two were multiparous women.</p> <p>- <u>Different psycho/physiological responses</u> in women as a causal mechanism. Linked to the above point, we don't know whether IOL was available on request to women who didn't take part in the trials. If not, taking part in the trial would have been the only chance for women with 'low risk' pregnancy who were keen to have an IOL earlier than 42 weeks. Those women subsequently assigned to the expectant management arm may have felt more stressed about being in the 'wrong' group, or anxious about their labour not starting. Stress and anxiety are known to affect the onset and progress of labour and might have adversely impacted these women's outcomes.</p> <p>We strongly suggest reviewing this recommendation in the view of the above.</p> | <p>specific study arm they were allocated to, however these are unmeasured factors that are anticipated to be balanced across the study arms</p> <p>6. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction.</p> |
| Royal College of Midwives | Guideline | 006 | 002 - onwards | <p>1.2.3 Prevention of prolonged pregnancy 41+0)</p> <p>We suggest that this recommendation should be altered to read:</p> <p>Explain to women that scientists still disagree over the gestational age beyond which continuing the pregnancy may pose any additional risks to mother and/or baby.</p> <p>However, some recent studies, suggest that:</p> <ul style="list-style-type: none"> - Though the risks remains small, the risk of stillbirth or neonatal death in the first week of life may increase with expectant management between 41 and 42 weeks, roughly from less than 1 per 1000 pregnancies to 4 per 1000. - Though the risk of stillbirth and early neonatal death remains small, the risk of the baby needing to be admitted to | <p>Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. The supporting information explains how this data was derived and how to interpret it.</p> <p>We did not have any data on long-term outcomes and it was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>a neonatal unit may increase with expectant management between 41 and 42 weeks, roughly from 30 per 1000 pregnancies to 43 per 1000. Furthermore, admission to a neonatal unit does not usually equate to ongoing neonatal morbidity.</p> <p>An infographic should be developed to aid understanding of the figures</p> <p>We note that the SWEPSIS study, informing this recommendation, was not powered for perinatal mortality and the evidence on NICU admission from SWEPSIS, INDEPTH and another two smaller studies is of low quality (due to performance bias).</p> <p>The ARRIVE trial did not show a significant difference in NICU admission. Though, we agree with the committee that it is warranted to inform women of this evidence given the crucial nature of the outcomes in question, information should be considered low certainty at present, and women should be informed of this.</p> <p>There are other outcomes that matter to babies as well as NICU admission - e.g. short-term (skin to skin contact, breastfeeding initiation, ongoing contact with mother); and medium and long-term (breastfeeding, attachment, growth and development, health and well-being). These need to be considered and measured in trials and other studies, and if not, there is an important evidence gap regarding the baby and to the mother-baby dyad.</p> | information from the recommendations on induction for prolonged pregnancy. |
| Royal College of Midwives | Guideline | 006 | 002 - onwards | <p>Prevention of prolonged pregnancy 41+0</p> <p>The offer of IOL earlier does not take into consideration the variation in length of pregnancy, and the possible inaccuracy in due dates that could result in a higher number of babies</p> | Thank you for your comment. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the birth of preterm babies. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>being born before they are ready (and the associated long term health consequences).</p> <p>The fact that ultrasound scans (USSs) undertaken in first trimester are only accurate to +/- 3-5 days, and those undertaken in the second trimester are accurate to +/- 10 days, and that USSs tend to overestimate birthweight, should be disclosed to women. The implications for each woman's pregnancy, and decisions about the management post-dates pregnancy, should be discussed on a case-by-case basis. All care planning decisions should be in keeping with the woman's informed choices.</p> <p>Milner J, Arezina J. The accuracy of ultrasound estimation of fetal weight in comparison to birth weight: A systematic review. <i>Ultrasound</i>. 2018;26(1):32-41)</p> | |
| Royal College of Midwives | Guideline | 006 | 012 -019 | <p>The committee has acknowledged the need for further research on longer-term outcomes and studies on the impact of IOL on infant wellbeing and development. However, they repeatedly state that given the results of the SWEPSIS trial, it is unlikely that further trials of IOL versus expectant management will be conducted.</p> <p>In this regard, we feel it would be important to consider the evidence provided by observational studies. In general, observational studies comparing women who received IOL versus those who didn't, can be prone to the risk of overestimating adverse outcomes in the IOL arm if they fail to take the indication for IOL into account. However, a recent large study using linked data from Australia compared women with a 'low risk' pregnancy at term who underwent IOL without medical reason with those with spontaneous labour onset. The authors concluded that IOL for non-medical reasons (which excluded post-term) was associated with higher rates of obstetric interventions and more adverse</p> | <p>Thank you for your comment. The review carried out for this update compared earlier induction with later induction and it was not within the scope of this update to review the risks and benefits of induction compared to expectant management. However, the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>maternal, fetal and child health outcomes, including admissions to hospital for infections up to 16 years of age.</p> <p><u>Dahlen (2021) Intrapartum interventions and outcomes for women and children following induction of labour at term in uncomplicated pregnancies: a 16-year population-based linked data study</u>, <i>BMJ Open</i></p> <p>One very cautious way of informing women of these potential risks/unresolved issues would be to add the following sentence to Recommendations 1.2.3: "The research cannot yet tell us with certainty whether induction of labour is linked to any long-term adverse consequences for mothers and children."</p> | |
| Royal College of Midwives | Guideline | 006 | 020 - 026 | <p>1.2.4 IOL at 39 weeks for BMI, BAME* and age 35+</p> <p>The recommendation to induce labour for all women falling within the 'higher risk' of complication bracket early is based on the 'knowledge and expertise' of the committee (Evidence Review C page 19 lines 46). There is no robust evidence that these groups of women are indeed at "higher risk of complication in labour" as asserted in this guideline. The committee did not have sufficient evidence to recommend a particular gestational age at which to consider early induction, but agreed that it should be considered earlier than the 41+0 week (although no earlier than term, in other words 37 completed weeks). The committee decided that considering induction of labour at 39+0 weeks for women in these groups would likely reduce risks of so called prolonged pregnancy, without over-burdening NHS resources, or increasing risks to babies due to earlier birth.</p> <p>There is no evidence to suggest outcomes will improve if these groups are offered earlier induction. Subgroup analyses by the guideline authors and within the individual trials also found no differences in outcomes.</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>The committee also cites MMBRACE and audit data showing that women in these groups have worse outcomes. However, we note that it is likely that the worse outcomes consistently shown for women from ethnic minorities in high-income settings such as the UK and US, compared with white women, are due to a large extent to a constellation of biases, including institutional racism and co-existing risk factors such as poverty, poor diet and language barriers making these women more prone to complications. Furthermore, women from ethnic minorities have experienced poorer quality of maternity care and lower satisfaction (Henderson 2013 "Experiencing maternity care: the care received and perceptions of women from different ethnic groups", BMC Pregnancy & Childbirth).</p> <p>Suggesting that a whole group of people should be offered an intervention when there are likely to be large differences in risk profiles and values within this cohort could itself be considered discriminatory. There has been significant critique of this blanket risking from some within the groups concerned. It is also arguably poor medical practice to fail to individualise care offers and provision.</p> <p>Therefore, we argue against the introduction of an IOL recommendation that singles out women based on ethnicity alone. We would support the introduction of training and support to reduce racism and promote culturally sensitive care in maternity services. We also support the NHS Long Term Plan commitment to offer continuity of midwifery care to improve outcomes and mitigate predisposing social inequality.</p> <p>We strongly suggest for this recommendation to be removed.</p> <p>*This is a direct quote of the term used in the NICE update, however please consider using the Gov.Uk "Writing about</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | ethnicity' guideline, which advise against using the term 'BAME'. | |
| Royal College of Midwives | Guideline | 006 | 020 - 026 | <p>The service level implications of such recommendation do not seem to have been considered. In some regions of the UK, NHS Trusts cater for an exceptionally diverse population. In some inner city hospitals, this recommendation will result in most women being offered an early IOL for ethnicity or age criteria alone. The impact on service provision of this recommendation has not been modelled and has the potential to adversely affect the capacity of service provider to offer safe and personalised care, dramatically affecting women's experience of care. Given all the current required actions to ensure safe staffing and on listening to women and birthing people, this recommendation risks putting NHS trust in violation of the national effort to improve maternity services.</p> <p>We are concerned that this recommendation is unworkable and will place unsustainable strain on NHS resources. For example, in 2019 23% of women giving birth in Scotland were 35 years old or more so this reason alone would result in almost a quarter of women in Scotland being offered IOL at 39 weeks for this one criterion alone. https://beta.isdscotland.org/topics/maternity-and-births/births/</p> <p>We strongly suggest removing this recommendation.</p> | Thank you for your comment. As a result of stakeholder feedback the guideline no longer recommends that induction of labour be considered at 39+0 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications. The amended recommendations on timing of induction make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| Royal College of Midwives | Guideline | 006 | 014 - 019 | <p>It is essential that statements like 'increased risk' or, indeed 'increased benefit,' should not be used, especially when this is about information to be given to women and birthing people.</p> <p>Any statement relating to the information to be provided to women should make it crystal clear that this should be framed by absolute numbers, e.g. incidence per 1000, and not relative risks. This is widely acknowledged to be best practice.</p> | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | We strongly suggest rewriting this list to include absolute likelihood (risk/benefits) rather than just ' <i>increased likelihood</i> ', and reframing any sentence that uses such statements as absolute numbers of outcomes per 1000 or 100 or whatever is most relevant, throughout the guideline. | |
| Royal College of Midwives | Guideline | 006 | 004 | <p>The indication of restrictive timing (38 weeks) for the discussion on preference for birth including expectant/induction/planned caesarean does not take into consideration that the timing and content of antenatal care should be tailored to each woman's individual needs. The RCM Blue Top Guideline on Induction of labour recommendation states:</p> <ul style="list-style-type: none"> Information should be tailored to women's specific circumstances <p>We suggest removing the suggested timing of 38 weeks.</p> | Thank you for your comment. We agree that discussions about mode of birth should take place earlier in pregnancy, and we have now moved this recommendation to the section of the guideline on information and decision-making. We have also removed the proscribed weeks at which these discussions must take place so they can fit around current antenatal appointment scheduling. The recommendation already states that a woman's individual circumstances and preferences should be taken into consideration. |
| Royal College of Midwives | Guideline | 006 | 010 | <p>The service level implications of such recommendation do not seem to have been considered. In terms of midwifery workforce. A substantial increase in midwifery one-to-one care hours would be required if IOL were to be offered to all healthy women with a 'low risk' pregnancy at 41 weeks. Furthermore, the hospital stay of women would significantly increase, affecting bed flow and capacity. There are important safety implications of induction of labour on a large scale that may outweigh benefits; these have not been considered in this draft guidance.</p> <p>We strongly suggest removing this recommendation.</p> | Thank you for your comment. As a result of stakeholder feedback the guideline no longer recommends induction from 41+0 weeks. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| Royal College of Midwives | Guideline | 006 | 014 | <p>The trial evidence on mode of birth is genuinely contradictory, with some studies suggesting that there is no difference between IOL and expectant management.</p> <p>We suggest removing the sentences that refer to these risks. Specifically:</p> | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have now included tables with the estimated risks associated with a pregnancy continuing |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>- The evidence on the increased risk of cesarean birth (of low quality due to performance bias) is almost exclusively based on the ARRIVE trial, which compared IOL at 39 weeks versus 40-41, in a very different population and health system from the UK.</p> <p>- The only other studies that showed a significant improvement in cesarean rates, in favour of IOL, were those comparing 42 vs 43-week IOL (small studies generating low-quality evidence)</p> <p>- The two large relevant European studies, INDEX and SWEPSIS, comparing IOL at 41 vs 42 weeks, did not find a difference in mode of birth</p> <p>- The only study showing some evidence of a reduction in instrumental birth is the ARRIVE trial (Grobman) without the difference reaching statistical significance. The limitations in the generalisability of findings from this trial have already been noted.</p> | beyond 41+0 weeks by parity to aid understanding of the evidence reviewed. The supporting information explains how this data was derived, its limitations and how to interpret it. |
| Royal College of Midwives | Guideline | 007 | 016 - 020 | <p>This statement appears problematic and is in contrast with recommendations from RCM Blue Top Guideline on Induction of labour:</p> <ul style="list-style-type: none"> • Midwives should ensure women and their families know that they have a choice about having an induction of labour • Unless the clinical situation changes, midwives should not make frequent offers of this intervention. <p>The choice of language implies that women will want to 'revisit' their option; the same assumption is not made about the opposite scenario. Should women be offered to revisit their option during IOL process, e.g. if the IOL is not</p> | <p>Thank you for your comment. We have reworded the first of these recommendations to emphasise that women can choose whether or not to discuss their decision again. However, the committee agreed that it is important that women are advised to contact their maternity unit if they have concerns about their baby, or that some women may decide that, as they have still not gone into spontaneous labour, they wish to rediscuss their options for birth, and so this recommendation has not been changed.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>successful in establishing labour of if they change their mind after the IOL has been booked.</p> <p>We strongly suggest removing this recommendation, which has the potential to cause pressure on health professionals to pressurise women in 'revisiting' their options.</p> | |
| Royal College of Midwives | Guideline | 007 | 006 - 007 | <p>1.2.6 Monitoring for women opting for expectant management</p> <p>There is a lack of evidence informing this recommendation regarding the impact of fetal monitoring and expectant management from 41 weeks.</p> <p>Furthermore, the impact on service provision has not been considered in terms of how the service would (or could)) implement routine twice-weekly monitoring for women opting for expectant management. This is a potential overburden of available NHS resources (human resources/and facilities).</p> | <p>Thank you for your comment. Other recommendations (for example 1.2.2 and 1.2.4) have been amended so it is unlikely that the cohort of women being offered and declining induction will change significantly. This recommendation has also been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The options to do CTG and amniotic pool depth are only provided as suggestions, carried over from the previous version of the guideline, and have been in place since 2008, so it is unlikely these recommendations will have an impact on resources.</p> |
| Royal College of Midwives | Guideline | 008 | 003 - 012 | <p>This section should include the associated benefits of continuing pregnancy not just the risks. Women are not in the position of making informed choice if they are offered only the associated risks of one option.</p> | <p>Thank you for your comment. The management of PPRM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not reviewed the data on the risks and benefits of induction of labour compared to expectant management in preterm prelabour rupture of the membranes, and so have not been able to make the changes you suggest.</p> |
| Royal College of Midwives | Guideline | 008 | 021 - 029 | <p>1.2.12 and 1.2.13</p> <p>Those two sets of recommendations seem slightly confusing. Women should be offered the option for 'expectant management' OR induction of labour. Expectant management should include 24 hours. However, some women will opt for longer expectant management. Women should be given the information on associated risk</p> | <p>Thank you for your comment. The management of PROM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not reviewed the data on the risks and benefits of induction of labour compared to expectant management in prelabour rupture of the membranes, or the risks of expectant management</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | (expressed as n. per 1000) if they wait for 24 hours, 48 hours, or 96 hours, and then offered the choice between induction or waiting. These recommendations should include possible associated risk and benefits of both options (e.g. impact on place of birth). | beyond 24 hours, and so have not been able to make the changes you suggest. |
| Royal College of Midwives | Guideline | 008 | 013 - 017 | 1.2.11 preterm labour rupture of membranes after 34+ but before 37+ The evidence does not indicate any significant harm(s) to the baby from choosing immediate delivery over expectant management. Hence the service implication of immediate induction of labour should be considered: acuity of the unit, workforce, and midwifery availability for one-to-one care to safely offer immediate IOL. The informed choice(s) of the mother/parents are paramount. | Thank you for your comment. The evidence for this recommendation is in the evidence review carried out as part of the development of the neonatal infection guideline (NG195), and we agree that the evidence found harms to the baby from expectant management, not from immediate birth. It found increased neonatal infections in the expectant management group compared to the immediate birth group, and also found that immediate birth was a cost-effective strategy. The neonatal infection guideline also states that as immediate birth is current practice the impact on units will be minimal. |
| Royal College of Midwives | Guideline | 009 | 022 - 024 | This recommendation is correct, women are entitled to decline the offer of any obstetric intervention such as IOL or caesarean birth, even when it would benefit their or their baby's health. However, this applies to all interventions in any situation (so to all recommendations in this guideline) not just in the instance of women who have had a previous caesarean birth. We strongly suggest applying this recommendation throughout the guideline, not just in this instance. | Thank you for your comment. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline. |
| Royal College of Midwives | Guideline | 009 | 017 | Please use birth instead of delivery. | Thank you for your comment. We have changed this to birth. |
| Royal College of Midwives | Guideline | 010 | 019 - 029 | We welcome the careful framing of the evidence regarding macrosomia. We suggest reviewing the recommendation to include absolute risk numbers in this section. | Thank you for your comment. We have added more details on the absolute risks as you suggest. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|-------------|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Royal College of Midwives | Guideline | 010 | 017 - 018 | 1.2.21 Fetal growth restriction needs to be clearly defined- e.g. below the 3rd percentile. The agreed definition of fetal compromise should also be clearly defined here. The evidence of absolute risks of all available options should also be presented to women and included here. | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add a definition of confirmed fetal compromise. |
| Royal College of Midwives | Guideline | 010 | 009 | Please use birth instead of delivery. | Thank you for your comment. We have changed 'delivery' to 'birth'. |
| Royal College of Midwives | Guideline | 011 | 012 - 021 | We welcome the thoughtful recommendations for women experiencing intrauterine fetal death. | Thank you for your comment. |
| Royal College of Midwives | Guideline | 012 | 001 - 003 | This recommendation should include the possible associated risks and benefits of immediate offer of IOL or caesarean birth versus expectant management in the event of intrauterine fetal death and SROM. Infection and bleeding should also be better defined here, is the recommendation referring to APH? Is infection referring to signs of sepsis? We suggest revising this recommendation and possibly dividing it into separate sections | Thank you for your comment. It was not within the scope of this guideline to review the risks and benefits of different modes of birth after intrauterine fetal death so we are not able to provide more detail on this, or on the definitions of infection or bleeding. |
| Royal College of Midwives | Guideline | 005 and 007 | 022 and 003 | Recommendations 1.1.4 and 1.2.5 on informed choice: These recommendations to support women whatever their choice are in direct contrast with Rec 1.2.7 (see also Evidence Review C p.20 line 33 onwards), which states that women should be given opportunities to revisit their decision at least weekly. Continued insistence that women might revisit their decision may be interpreted as coercive and even lead health professionals to act unethically and break the law, as per the Montgomery & Lanarkshire ruling. | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>They are also in contrast with recommendations from RCM Blue Top Guideline on Induction of labour which clearly state:</p> <ul style="list-style-type: none"> • Midwives should ensure women and their families know that they have a choice about having an induction of labour • Unless the clinical situation changes, midwives should not make frequent offers of this intervention. <p>It is not clear that women who have made the decision to accept induction should also be able to change their minds at any point</p> <p>It is also counter to the NMC standard for midwives, expected by the regulator of all midwives - 'In partnership with the woman, use evidence-based, best practice approaches to plan and carry out ongoing integrated assessment, individualised care planning and evaluation for both the women and the newborn infant, based on sound knowledge of normal processes and recognition of deviations from these (Standard 3.23)</p> | |
| Royal College of Midwives | Guideline | 013 | 003 - 009 | <p>The timing of the offer of membrane sweeping should be carefully considered here.</p> <p>If IOL is to be routinely offered at 41 weeks and 39 weeks for some groups of women, is this recommendation stating that most women should be offered a sweep between 38-39 weeks of pregnancy? Given the variation in length of pregnancy and the inaccuracy with regard to days of gestational length in dating pregnancy by ultrasound scan, what is the evidence for the risks and benefits of late prematurity in such circumstances?</p> <p>There are service implications to be considered too in terms of offer earlier sweeping of the membranes. There is low quality evidence to suggest an increased risk of pre-labour</p> | <p>Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps. However, the recommendations have been clarified to state that membrane sweeps should be discussed after 39 weeks (as opposed to 'from 39 weeks'). There was never any suggestion they should be offered between 38-39 weeks. Also, as the timing is after 39 weeks the committee agreed that the risk of later prematurity was very unlikely.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>rupture of membranes for women having a membrane sweep.</p> <p>Avdiyovski H, Haith-Cooper M, Scally A. (2019) Membrane sweeping at term to promote spontaneous labour and reduce the likelihood of a formal induction of labour for post maturity: a systematic review and meta-analysis, Journal of Obstetrics and Gynaecology, 39:1, 54-62, DOI: 10.1080/01443615.2018.1467388</p> | |
| Royal College of Midwives | Guideline | 013 | 005 - 006 | <p>The absolute number should be provided to women, from the Cochrane review on membrane sweeping offered at term 1:8 women will go into spontaneous labour after a sweep. There are possible side effects associated with receiving a sweep as well as possible benefits; all should be listed for women to make an informed choice.</p> <p>We strongly suggest revising this section in line with RCM Blue Top Guideline on Induction of labour:</p> <ul style="list-style-type: none"> • Clear and understandable information should be presented about the risks and benefits of a sweep and the procedure should be explained in detail. • Membrane sweeps should be discussed in an antenatal appointment prior to 40 weeks so that women have time to make considered decisions. • Side effects of membrane sweeps, such as pain during the procedure and light vaginal bleeding and cramps afterwards should be discussed with women prior to consent for the procedure. This will support women to make an informed decision about a sweep and may alleviate worry if women experience these side effects. • If a woman declines membrane sweeping, this decision must be respected and supported. • Unless the clinical situation changes, midwives should not make frequent offers of this intervention. | <p>Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps. Thank you for sharing the RCM blue top recommendations with us, which are in-line with the NICE recommendations.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Royal College of Midwives | Guideline | 014 | 001 - 010 | This section should include absolute numbers and should be framed in the context of giving information on uterine activity, hyperstimulation and IOL reversal to women. | Thank you for your comment. There was evidence from the systematic review on the rates of hyperstimulation with dinoprostone and misoprostol so this has been added in a table. There was no evidence on the reversal of hyperstimulation so we have been unable to include this. |
| Royal College of Midwives | Guideline | 015 | 005 - 025 | This section listing induction agents implies that all women will be familiar with such technical language. Should women be informed of what's indicated and available in terms of choice rather than a list of 'not recommended' induction of labour methods? | Thank you for your comment. We have amended this recommendation to state that it is for information only, and that these methods of induction do not all need to be discussed with women. |
| Royal College of Midwives | Guideline | 016 | 016 -017 | The recommendation on facilities assessment (access to CTG machine) should include a workforce assessment. It is not just about the availability of equipment, it is about having an adequate workforce to facilitate safe induction of labour in the appropriate setting, with availability to one-to-one care in labour and CTG interpretation. An increase in the number of inductions may have an impact on the care of women and babies in spontaneous labour. This should be modelled. | Thank you for your comment. We have recognised that an increasing number of inductions will require some additional resources and this has been discussed in evidence review C on the timing of induction. |
| Royal College of Midwives | Guideline | 017 | 017- onwards | <p>The terminology may need revising as 'outpatient induction' is completely inaccurate as a reflection of the process. And, whilst in common usage, the term has the potential to be misleading.</p> <p>In some settings, women will attend a maternity unit for cervical priming and subsequently be offered the opportunity to return to their home to await events. They will then return to the maternity unit once labour is established or for subsequent stages of induction of labour. It is important that women are offered clear information about which components of the process may be available to them at home and where those occur in the sequence of events.</p> | Thank you for your comment. The committee discussed whether there was better terminology but agreed that the procedure - although it required a visit to an obstetric unit - was commonly referred to as 'outpatient induction' and to change this terminology would be confusing. The recommendations already state that a plan must be agreed with the woman and so the committee were content that it would be clear to the woman which stages of the process took place in which location. |
| Royal College of Midwives | Guideline | 017 | 027 | The recommendation reads "Ask women to contact their obstetrician/midwife" however often obstetricians do not provide the first point of contact in the UK maternity system; it is more likely to be their midwife or a midwife on the helpline/out-of-hours service. | Thank you for your comment. We have amended this recommendation to state 'midwife, maternity unit or obstetrician'. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-------------------|---------|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | The recommendation should read: Ask women to contact their midwife, maternity unit, or obstetrician. | |
| Royal College of Midwives | Evidence review C | 018 | 001 - 003 | <p>On women's quality of life/satisfaction:</p> <p>The committee have noted the lack of trial evidence on women's quality of life and limited amount of evidence on satisfaction with care (available only from the Grobman trial, the limitations of which have been noted). We believe it would be important to conduct a full review of the evidence on satisfaction and experience to include observational and qualitative studies. Recent examples include a cohort study from Finland (Adler K 2020, BMC Pregnancy & Childbirth) and a qualitative meta-synthesis (Akuamoah-Boateng 2018, Midwifery).</p> <p>This is particularly important given that the trial evidence should be considered in the context of women declining to be part of such trials. Sixteen thousand women declined to take part in the ARRIVE trial alone, and only one fifth to one third of eligible women accepted to be part of the ARRIVE, SWEPSIS and INDEPTH trials.</p> | <p>Thank you for your comment. The committee acknowledged the paucity of evidence for the outcome maternal satisfaction in this review. However, this was still taken into consideration whenever reported and the committee included 2 lay members with lived experience of induction of labour and wider experience of representing people using maternity services. It was not within the scope of this update to review observational and qualitative evidence on women's experiences but, based on stakeholder feedback, the recommendations have been amended to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected.</p> <p>The committee acknowledged the proportion of women that declined to participate in the included trials, but considered it within normal parameters and noted that this may have been related to the burden associated with trial participation, which is a factor that reduces engagement and increases withdrawal.</p> |
| Royal College of Midwives | Evidence review C | 018 | 020 onwards | <p>The committee notes that they did not review the full body of evidence on risks by gestational age e.g. cohort studies. How is the information from this body of evidence to be taken into consideration for a full discussion of risks, if the guideline does not draw upon it? Where else can this information be found to assist clinicians to discuss the pros and cons of IOL with women?</p> | <p>Thank you for your comment. It was not within the scope of this update to review the entire body of evidence that could inform a full discussion of the risks at each week (for example non-comparative cohort or cross-sectional studies that report adverse event incidence at each week). However, we have now included the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding of the evidence reviewed. The supporting information explains how this data was derived and how to interpret it. In addition, based on stakeholder feedback, the recommendations have been amended to include the factors that should be taken into consideration</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-------------------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. |
| Royal College of Midwives | Evidence review C | 018 | 039 | <p>"More women with low-risk pregnancies are requesting inductions": What is the source of this statement?</p> <p>How far is this a request and how far is it just recorded as such? What underpins such requests? We note that the commonly heard rhetoric that caesarean birth rates are going up due to maternal request has never been proven, despite a range of survey and qualitative studies examining this claim.</p> <p>We do not believe that such anecdotes should be cited in an evidence review without supporting data.</p> <p>We also note that some women will also request not to have inductions. Shouldn't their views carry the same weight?</p> | <p>Thank you for your comment. As reflected in the discussion, this statement is based on the committee's experience and it provides the rationale as to why, according to the committee, it would be useful to review evidence on the optimal timing of induction. The committee agreed that some women may request not to have an induction and have added a recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected.</p> |
| Royal College of Midwives | Evidence review C | 019 | 005 - 006 | <p>Increase of caesarean birth risk:</p> <p>We advise removal of this sentence. This evidence is of low quality and is based on the ARRIVE trial (Grobman), which has limited generalisability to the UK population (young and high BMI study population of largely non-white ethnicity). The two large European trials SWEPSIS and INDEPTH (Keulen and Wennerholm), which the perinatal death recommendations are based on, found no difference in caesarean births. The 35/39 trial found no difference in either caesarean birth or adverse outcomes</p> | <p>Thank you for your comment. Evidence statements are short summaries of the evidence identified in the systematic review, and report the number of participants, the direction of the effect and quality of the evidence, therefore these cannot be removed.</p> <p>The trial by Grobman 2018 did show a clinically important difference for caesarean birth in favour of earlier induction: lower incidence in the 39 week induction group compared to 40-42 week induction group. Keulen 2019 and Wennerholm 2019 were meta-analysed with 2 more trials (Gelisen 2005 and Heimstad 2007), and showed no clinically important difference between the 41 week and 42 week induction groups for caesarean birth.</p> <p>We have now included the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-------------------|---------|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | <p>understanding (in Appendix A). The supporting information explains how this data was derived and how to interpret it. The committee agreed that the evidence reviewed had limitations and this has now been reflected in the quality of the evidence section.</p> <p>We are unclear what the 35/39 trial is, so we cannot address your last point.</p> |
| Royal College of Midwives | Evidence review C | 019 | 007 - 008 | <p>Increase in NICU admission risk:</p> <p>The statement here should add that the evidence of increased risk of NICU admission for IOL at 41 vs 42 weeks is of very low quality.</p> | <p>Thank you for your comment. We have now included the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding. The supporting information explains how this data was derived and how to interpret it. The committee agreed that the evidence reviewed had limitations and this has now been reflected in the quality of the evidence section.</p> |
| Royal College of Midwives | Evidence review C | 019 | 009 | <p>Increase in instrumental birth risk:</p> <p>We advise removal of this sentence. This evidence is of very low quality and is based on the ARRIVE trial (Grobman) in which the finding did not reach statistical significance.</p> <p>The trial has limited generalisability to the UK population (very young and obese study population of largely non-white ethnicity). The two large European trials SWEPSIS and INDEPTH (Keulen and Wennerholm) which the perinatal death recommendations are based on, found no difference in mode of birth.</p> | <p>Thank you for your comment. Based on stakeholder feedback, a possible increase in assisted vaginal birth has now been removed. We have now included the estimated risks associated with a pregnancy continuing beyond 41+0 weeks to aid understanding of the evidence reviewed. The supporting information explains how this data was derived and how to interpret it.</p> |
| Royal College of Midwives | Evidence review C | 019 | 019 onwards | <p>Increase of perinatal mortality risk:</p> <p>For 41 vs 42 weeks, evidence of perinatal mortality is largely driven by the Wennerholm SWEPSIS trial which was stopped early, and the sample recruited was not powered for perinatal mortality. We note that all deaths in that trial occurred in hospitals outside of the Stockholm region, where there was a different protocol for managing post-term pregnancies (involving a routine USS at 41 weeks in Stockholm). Based on these two issues, we question</p> | <p>Thank you for your comment. The committee specifically discussed the quality of the evidence from the SWEPSIS study (Wennerholm 2019). The strengths of this study include its large size and relevance to this question. However, the fact that the study was terminated early due to ethical concerns and never reached the sample size intended to power its primary endpoint was a limitation, which may have led to an overestimation of the treatment effect in the intervention group and decrease the precision of the results. Based on stakeholder feedback, The</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-------------------|---------|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | whether the evidence is high quality or whether it might be appropriate to downgrade it. | GRADE assessment of perinatal death for the comparison 41 versus 42 weeks has now been downgraded due to risk of bias. |
| Royal College of Midwives | Evidence review C | 020 | 017 onwards | Evidence supporting IOL at 39 weeks for women in at risk categories: We suggest that the committee remove or adapt this paragraph to reflect the removal of Rec 1.2.4 as suggested above. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Royal College of Midwives | Evidence review C | 021 | 004 - 006 | On IOL at 39 weeks for higher-risk groups: The recommendation in the main draft guideline does not read as a research recommendation but rather as a practice recommendation. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. The research recommendation relevant for these subgroups of women remains in evidence review C, appendix L |
| Royal College of Midwives | Guideline | 031 | 012 (Table 1) | The suggested change from the previous guideline version 'women with uncomplicated pregnancies should be given very opportunity to go into spontaneous labour' to women with uncomplicated pregnancies should be offered induction 'is a complete change in emphasis, that implies induction of labour is the norm, and that spontaneous onset of labour is not. This illustrates the apparent underlying assumption in the guideline that induction is normative, and the physiological process of labour is not. As stated in the RCM Blue Top Guideline on Induction of labour, there is evidence that women can feel pressured into accepting an induction and therefore detailed, evidence-based discussion is essential to support women to make the choices that are right for them. Some women do not understand the process of IOL and do not feel involved in the decision-making process. This can negatively impact on their experience. | Thank you for your comment. We will address your points in turn. 1. Based on stakeholder feedback we have reinstated this recommendation into the guideline. 2. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. 3. We have added an additional recommendation to state that women can decline the offer of induction, or can change their minds, and that their decision should be supported. 4. NICE recommendations provide advice on evidence-based practice but always emphasise that preferences and individual circumstances should be taken into account and so do not remove the focus on personalised care. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>This becomes even more likely if health professionals assume that that IOL constitutes the usual and acceptable situation. There is no other area of health care in which an invasive intervention is considered normative for all healthy people who do not meet certain average growth or development targets, just in case they might experience a risk that is very small. Under these conditions every effort should be made to ensure that women are not stigmatised if they decide to continue their pregnancies. Detailed, compassionate, supportive discussion is essential to support women to make the choices that are right for them, and that they are empowered to change these decisions if they change their minds, without fear of adverse responses from staff.</p> <p>And again, this approach puts midwives in contravention of the NMC standards which require them to provide individualised care for all women and babies.</p> <p>Coates R, Cupples G, Scamell A, McCourt C. (2018) Women's experiences of induction of labour; qualitative systematic review and thematic synthesis. Midwifery 69: 17-28 https://doi.org/10.1016/j.midw.2018.10.013</p> <p>Lou S, Hvidman L, Uldbjerg N et al. (2018) Women's experiences of post term induction of labour: A systematic review of qualitative studies. Birth (Early View) https://doi.org/10.1111/birt.12412</p> | |
| Royal College of Midwives | Guideline | 034 | Table 1 | <p>1.5.1.2</p> <p>The recommendation that 'the practice of induction of labour in an outpatient setting should be audited continuously' has been removed. There seems to be an assumption that because outpatient setting IOL is becoming more common, it does not need auditing. However, this assumption is unacceptable: practices should be based on good quality evidence, especially those with potential adverse consequences.</p> <p>We strongly suggest for this recommendation to be reinstated.</p> | <p>Thank you for your comment. The committee agreed that more research was needed into the benefits and risks of outpatient induction and so carried over a research recommendation from the previous version of the guideline, but not that this practice should be continuously audited in all units.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------------------|-------------------|---------|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Royal College of Midwives | Guideline | 045 | Table 2 | <p>1.6.2.3/1.6.2.4/1.6.2.5 This seems to be a peculiar interpretation of the evidence by the committee.</p> <p>There is plenty of evidence on labour support offered by birth attendants, including carers and healthcare professionals. Advising women to use their own coping strategies along with other forms of pain relief is not paternalistic. It is simply recognising that most women have the power to cope using such strategies, and many attend antenatal classes for this very reason. It is important for providers to facilitate women's chosen method of support, coping strategies and analgesia, including offering or making available non-pharmacological methods such as such hydrotherapy.</p> <p>We suggest keeping the previous recommendations, as the rationale for their removal does not seem based on evidence, but on how they sounded to the committee.</p> | Thank you for your comment. This recommendation was in the section on pain relief and so the committee agreed it should just focus on the pain relief methods available, and cross reference to the Intrapartum care guideline, where much more detail on pain relief is included. |
| Royal College of Midwives | Evidence review C | 078 | Table 20 | <p>GRADE TABLES: We suggest that the level of indirectness for the Grobman study should be "serious" due to differences between the study population (very young and obese study population of largely non-white ethnicity, arguably not low-risk) and the general UK population of low-risk women. This would downgrade the quality of evidence arising from this trial for all relevant outcomes.</p> | <p>Thank you for your comment. The committee agreed that the population included in Grobman 2018 and the population of interest pre-specified in the PICO criteria of this review question were comparable and the extent of differences did not warrant to downgrade for indirectness as this is usually done when >1/3 of the population included in the study is different to the population of interest.</p> <p>However, as reflected in the committee's interpretation and discussion of the evidence, the trial by Grobman 2018 was downgraded for risk of bias as it was not possible to blind participants/personnel and for imprecision due to wide confidence intervals, as appropriate.</p> |
| Royal College of Nursing | General | | | <p>Thank you for the opportunity to contribute to this guideline. We do not have any comments to add on this occasion.</p> | Thank you for your comment. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 001 | 1.1 | <p>'early on' – perhaps this could be a little more specific. After booking scan...? After FAS scan? Early on prior to the midway point of the pregnancy.</p> | Thank you for your comment. We have not provided a specific time in pregnancy at which discussions about mode of birth should start as this may vary between women, but we have clarified that in most cases (if the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------------------|-----------|---------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | woman wishes) this will be an ongoing conversation during pregnancy and not a one-off discussion. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 004 | 008 1.1.2 | All studies referenced fail to show a significant rise in Assisted vaginal birth (AVB) with IOL. This point should be removed or rephrased to say that 'this is a possible risk but not confirmed by research'. The reference to third degree tears should be removed as it is based on assumed but non-significant rise in AVB. These recommendations are likely to raise maternal anxiety and reduce the uptake of induction of labour. This may be detrimental to maternal and fetal wellbeing. These may lead to tocophobia and related caesarean section for this indication. | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update. The data you are referring to were part of a separate review that compared earlier induction with later induction. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth and we have amended the language to suggest that there may be a need for assisted vaginal birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 006 | 1.2.4 | Whilst induction of labour has been shown to safely reduce the incidence of poor perinatal outcomes, especially close to the expected time of delivery, there needs to be a clear appreciation of the benefits as well as the possible disadvantages outside of perinatal outcome. Stratifying risk by race alone is a blunt tool to use, and although highlighting higher risk is important, it does not move our understanding further as to why this group of women are at greater risk. It is vital a person's individual needs and preferences are taken into account and they have the opportunity to discuss the options with a healthcare professional so they can make a truly informed decision. Women must always feel that have and retain agency thus it is important to spell out transparently, why certain interventions are suggested. It is important to remind women that: -Black and Asian women have a greater risk of SB -We are poor at preventing SB closer to term -IOL prior to 40 weeks reduces risk of term SB -IOL between 37-40 weeks not associated with higher CS rate -Women's choice is paramount | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------------------|-----------|---------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | The research recommendation on understanding why disparities in outcomes for this group of women exists is essential so that we can work to better identify at risk pregnancies outside of race and reduce negative outcomes more effectively. | |
| Royal College of Obstetricians and Gynaecologists | Guideline | 006 | 1.2.4 | A member of RCOG's Women's Network (PPI group) expressed concern about this point in relation to Black, Asian and minority ethnic women, and referred to women they have come across who have been pressured to have induced labour when they did not want to as they felt it was not necessary. It was stressful for women to be heard. A blanket recommendation like this was felt to be likely to make matters worse with a without considering the needs for each woman, therefore exacerbating inequalities. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 006 | 003 1.2.1 | Planned Caesarean section for prolonged pregnancy as the only indication needs further clarification. A caesarean section can have significant morbidity associated with it. The decision should not be taken lightly | Thank you for your comment. Based on stakeholder feedback we have now moved this recommendation to the section of the guideline on information and decision-making. We have also removed the proscribed weeks at which these discussions must take place so they can fit around current antenatal appointment scheduling. We have also included a link to the NICE guideline on caesarean birth (NG192) as full details of the risks and benefits of caesarean birth are included in this guideline. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 006 | 003 1.2.1 | Reconfirm – this implies that this is not an opportunity to revisit the prior decision and give a change to change options. Either CONFIRM or REVISIT would avoid this instead o RECONFIRM. | Thank you for your comment. Based on stakeholder feedback we have now moved this recommendation to the section of the guideline on information and decision-making, and amended the wording to say 'confirm a woman's preferences for birth, which may have changed since earlier discussions.' |
| Royal College of Obstetricians and Gynaecologists | Guideline | 006 | 010 1.2.2 | This recommendation of IOL at 41 weeks will have a huge resource implication. We are struggling to offer timely IOL with the current guidelines. The evidence behind the recommendation is strong and this guideline should be accompanied by funds for maternity units to increase capacity for IOL | Thank you for your comment. As a result of stakeholder feedback the guideline no longer recommends induction from 41+0 weeks. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------------------|-----------|---------|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 006 | 010 1.2.2 | The wording is confusing - suggest a re-phrase. This point has wide ranging implications for a large number of women. "In uncomplicated singleton pregnancies, offer IOL to take place as soon as possible after 41+0 weeks." | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 006 | 012 1.2.3 | A possible increase in AVB should be removed as this is non-significant according to all the studies cited. | Thank you for your comment. Based on stakeholder feedback, a possible increase in AVB has now been removed. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 006 | 020 1.2.4 | These are a large proportion of our women. This will lead to a large number of women having IOL which as detailed above carries its own risks. These recommendations are not evidence based and will not be deliverable in current setting | Thank you for your comment. As a result of stakeholder feedback the guideline no longer recommends that induction of labour be considered at 39+0 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications. The amended recommendations on timing of induction make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 007 | 006 1.2.6 | The twice weekly CTG and liquor volume monitoring is mentioned here as an example, but the knock on implication is that an abnormality in the CTG or LV would then persuade the woman to change her mind to have IOL is not addressed. This recommendation is saying that in women who decline IOL in this scenario, we should support her with XYZ monitoring to then be persuaded to start the process of IOL with a low LV. The later statements making clear that the CTG has no reassuring predictive value, questions the logic of this recommendation. | Thank you for your comment. This recommendation has been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find this reassuring. Suggestions of what monitoring could be offered is provided but there is no evidence to confirm that monitoring can improve outcomes. The following recommendations deal with the situation where a woman changes her mind (either based on monitoring, or because she has other concerns about her pregnancy |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------------------|-----------|---------|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | continuing), and that this change of mind should be supported. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 007 | 018 1.2.8 | Weekly review by health professional will increase the number of appointments in community or hospital. Is there any evidence that these interventions are helpful? This should be carried out for women declining IOL at 41 weeks. But this is difficult to justify for soft indication such as BMI 31 with no other risk factors. | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again, and have removed the suggested frequency of at least once a week. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 007 | 018 1.2.8 | This appears biased. It seems like if the woman changes her mind, then phone immediately to get IOL arranged. Earlier there is the discussion of risk/benefit counselling of the woman. But if the decision goes in the direction hoped for (by the maternity unit/NICE), then this risk/benefit discussion can be circumvented. Logically there should be a repeat discussion to ascertain her reasons for changing her mind and an updated discussion of risk/benefit. Is this recommendation only applicable to women where IOL is indicated and then declined? This doesn't not come across at all when this is written like this. Contacting the maternity unit 24/7 might mean a decision made by a senior doctor could be reversed by a well meaning but uninformed practitioner at 3am when she attends the obstetric triage department. | Thank you for your comment. If a woman decides to decline induction and await spontaneous labour, there may be situations where, a few days or a week later, she wishes to reconsider her decision and her options for birth, or if she has concerns about her baby. In this case the committee agreed that she should be advised to contact her midwife or maternity unit. The discussion about the risks and benefits of mode of birth will have already taken place when induction was declined, but as you suggest, may need to be re-discussed if the woman changes her mind. The decision to be induced or not is not made by a senior doctor - it is the woman's decision. The healthcare professionals should then support the woman to determine how and when that induction should take place. There is nothing in the recommendation to state that it must be immediate. However, we have amended the recommendation to clarify that there is only urgency to contact the maternity service if the woman has concerns about her baby. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 008 | 003 1.2.10 | Suggestion to rephrase : ...as PPRM between 34+0 and 36+6 weeks, discuss with her the.... | Thank you for your comment. As the other recommendations in this section all refer to 37+0 weeks we have not amended it in this instance. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 008 | 019 1.2.12 | Suggestion to rephrase to make the implication clearer for the second bullet point: induction of labour after 24hrs expectant management. | Thank you for your comment. The action to be taken after 24 hours of expectant management is described in the following recommendation so we have not made this change. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------------------|-----------|---------|---------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Royal College of Obstetricians and Gynaecologists | Guideline | 009 | 017 1.2.17 | Can an alternative to the term 'delivery' be used here. | Thank you for your comment. We have changed this to birth. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 010 | 002 1.2.18 | This reminds me of the maternal request for CS recommendation in NICE. Would it be beneficial in this setting to use the same structure for this intervention as was used for CS. And would this included the comment about referring to another practitioner who would be willing to consider the request? | Thank you for your comment. The maternal request for Caesarean birth recommendations are currently being updated (see the NICE website page for NG192) so we do not propose to update the induction of labour recommendations to be in-line with these at the present time. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 010 | 006 1.2.19 | Position -> presentation? The subsection title says breech presentation. | Thank you for your comment. We have amended the title of this section to 'position' to ensure continuity of terminology |
| Royal College of Obstetricians and Gynaecologists | Guideline | 010 | 008 1.2.20 | Position -> presentation? The subsection title says breech presentation. | Thank you for your comment. We have amended the title of this section to 'position' to ensure continuity of terminology |
| Royal College of Obstetricians and Gynaecologists | Guideline | 010 | 008 1.2.20 | Can an alternative to the term 'delivery' be used here. | Thank you for your comment. We have changed 'delivery' to 'birth'. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 010 | 017 1.2.21 | Not all women with FGR will benefit from a Caesarean section. There should be greater detail of high risk FGRs such as abnormal dopplers. FGR with close monitoring can lead to normal birth in women who have had previous vaginal births. Hormonal methods should be avoided | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add more details about induction methods for this indication. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 010 | 017 1.2.21 | There are some situations where IOL is in equipoise for fetal outcomes at preterm gestations, with a very much higher maternal morbidity. Could some gestation thresholds be added to this recommendation or could the wording be changed to reflect this? | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add more details about induction methods for this indication. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 010 | 020 1.2.22 | At what gestation should women be offered IOL for macrosomia. Evidence ranges between 38 and 41 weeks. | Thank you for your comment. The committee discussed whether it was possible to define the best time to induce labour in suspected fetal macrosomia but the evidence included induction at a range of gestational ages and it was not possible to identify the preferred gestational age. The committee also considered this would be an |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------------------|-----------|---------|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | individualised decision based on the estimated size of the baby, the woman's clinical circumstances and her preferences. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 010 | 027 1.2.22 | Last bullet point: Consider rephrase: There is evidence to show the risk of perinatal death, brachial plexus injury, and caesarean birth is the same between these two groups. | Thank you for your comment. We have reworded this as you suggest. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 011 | 003 1.2.22 | Why are we stating to support clinical trials here if available? There is no specific reason for the statement in this recommendation. This can be stated after every single recommendation in almost every single guideline. All trials in the UK have a robust process of research governance and ethics approval so this statement is superfluous. | Thank you for your comment. This group was highlighted for inclusion in clinical trials as the committee were aware of an ongoing clinical trial (Big Baby) which will provide specific data on the role of induction in suspected fetal macrosomia. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 011 | 009 1.2.24 | I had to read this a few times to get what I think the meaning is. è Do not offer IOL to women with a history of precipitate labour, with the indication being the intention of avoiding an unattended birth. If this is correct – could the wording be clarified please. It could be read as, avoid IOL in all women with history of precipitate labour. | Thank you for your comment. Rewording this as a 'Do not...' or 'Avoid...' recommendation would mean that women with a history of precipitate labour could not be induced, even if they had a medical reason this this pregnancy requiring induction. The current wording highlights that they should not be induced SOLELY to avoid unintended labour. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 011 | 017 1.2.26 | Expectant management should be based on the cause of IUD. The causal factor may be detrimental to the woman's health over the next 2-3 days. | Thank you for your comment. The following recommendation provides advice on action to be taken if there are concerns about the woman's health. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 011 | 017 1.2.26 | Often with IUD there can be a request from an acutely distressed woman for a CS. This might relieve some of the acute distress and avoid labour, however the risk of CS pain, and additional problems in a subsequent pregnancy have to be considered. Supporting the woman's decision here is, (although hard to say, and sounds very paternalistic) not always the right thing to do. Supporting the decision as describes here does not allow time for reflection for the woman and her partner. | Thank you for your comment. As with all other discussions and decisions in this guideline, women should be provided with the factors they need to take into account when making their decision, but the final decision can only be made by them. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 012 | 006 1.2.28 | This sentence lacks clarity. If a woman with an IUD choose an induced labour, offer oral mife 200mg. This is followed by vaginal dinoprostone, | Thank you for your comment. The doses and timing of administration are as specified in the summary of product characteristics (SPC) for mifepristone. The detail has now |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------------------|-----------|---------|---------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | vaginal misoprostol, or oral misoprostol between 36 and 48 hours later. I was not sure of the evidence base for the 36hr delay to misoprostol. I cannot see this justification in the subsequent table in the draft. Is it acceptable (although potentially less efficacious) to have miso from 12-24hrs post mifepristone? | been removed from the recommendation because the recommendation says to base the choice and dosage of dinoprostone or misoprostol on clinical circumstances and national protocols. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 012 | 013 1.2.29 | Is it not clear from the sentence what the comparator group is. Clarify please. IUDF + prev CS vs IUDF without CS vs Prev Cs with alive baby. If the comparator is Prev CS with alive baby, then this recommendation is not specific to women with IUDF and is the same as the recommendation for women with live babies. | Thank you for your comment. This recommendation was based on the committee's knowledge and experience, that women with a uterine scar would be more likely to have a uterine rupture than women with a non-scarred uterus, and that this would apply whether or not the birth was of a live baby, or following an intrauterine fetal death. However, in order to make the recommendation more helpful, we have used the same wording as that used for women who are giving birth to a live baby and who have had a previous caesarean birth, which suggests that methods used for induction will need to take into account the risk of uterine rupture, for example by using mechanical methods. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 012 | 021 1.2.31 | Is the word contraindicated correct here? It seems like unlicensed might be more appropriate. Are there gestational cut offs, similar to those in the FIGO document on misoprostol, which are applicable to women with a uterine scar. Uterine scar is a broad term. Would previous CS be better. Specific cases of intramural myomectomy would generally avoid IOL regardless. | Thank you for your comment. These preparations are contraindicated, and not just unlicensed, so we are unable to recommend them, even at reduced doses as suggested by FIGO. However, in order to make the recommendation more helpful, we have used the same wording as that used for women who are giving birth to a live baby and who have had a previous caesarean birth, which suggests that methods used for induction will need to take into account the risk of uterine rupture, for example by using mechanical methods. The section of the guideline relates only to women who have had a previous caesarean birth, but explains that it is the uterine scar resulting from this which increases the risk of uterine rupture. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 013 | 010 1.3.2 | Consent is not obtained. Consent is given. GMC says so. I am not sure why this specific procedure requires consent, as compared to everything else which requires some form of consent. Is there a feeling from the committee that membrane | Thank you for your comment. We have reworded this recommendation to ensure there is a discussion with women and that if they agree to membrane-sweeping, consent is obtained. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------------------|-----------|---------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | sweeping without consent is a feature of current UK practice? I think if that is the case, then a sentence here is an inadequate response. | |
| Royal College of Obstetricians and Gynaecologists | Guideline | 016 | 009 1.5.1 | This statement states the what examination to perform BUT not the findings of such examination that would impact on the subsequent care of the woman. This implies that examining and finding a transverse lie, followed by bishop score then prostaglandin... "would be in keeping with NICE guidance". I presume the examination is to detect contra indications for IOL – this should be explicitly stated for clarity. | Thank you for your comment. The recommendation has been reworded to clarify that these assessments are to ensure the position of the baby and the woman's condition are suitable to proceed with the induction. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 017 | 013 1.5.8 | No mention of morphine. Why are these three specific options written here when the whole NICE intrapartum guideline is quoted above. Suggest delete. | Thank you for your comment. Morphine would be included in the term 'simple analgesia' but we have left these examples in place, as the committee wished to emphasise that simple analgesia and labour in water can still be used after induction and it should not be assumed that all women will need an epidural. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 018 | 010 1.7.1 | If hyperstimulation occurs do A and B, but this section does not say that a fetal assessment should take place – which it definitely should say explicitly – even if it could be argued that hyperstimulation vs tachysystole includes fetal assessment. | Thank you for your comment. We have added in this text as you suggest. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 018 | 022 1.7.4 | Offering a rest period. It would be more helpful if a minimum rest period could be specified until further PG could be given. | Thank you for your comment. Unsuccessful induction was not included in the scope of this update, and therefore the committee were unable to make any more detailed recommendations in this guideline. However, as you have identified this as an area of uncertainty we will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 018 | 022 1.7.4 | I think changing further to second attempt would be clearer. This might avoid an uninformed practitioner providing a third, fourth round of IOL which again would be "in keeping with NICE" | Thank you for your comment. The committee agreed that in some women more than 1 additional attempt to induce labour might be used, and so did not specify that there should only be 2 attempts. |
| Royal College of Obstetricians and Gynaecologists | Guideline | 019 | 002 1.7.5 | This is called antepartum haemorrhage. The text refers to a specific contraindication to IOL or labour, of a placenta praevia. | Thank you for your comment. We have amended this heading to include placenta praevia or low-lying placenta. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------------------------------|-----------|---------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Royal College of Obstetricians and Gynaecologists | Guideline | 019 | 017 1.7.7 | If uterine rupture is suspected in any labour then a cat 1 Cs is needed. The term suspected is broad. Uterine rupture has signs and symptoms, which overlap with normal labour. In the event of an adverse outcome this statement opens the practitioner to a high chance of criticism. I think it would be better to delete this recommendation entirely, or significantly re-word it. I would favour the former. | Thank you for your comment. The committee agreed that uterine rupture would usually only occur in women who had a uterine scar, and who would be closely monitored because of this. They also agreed that uterine rupture can be suspected in labour but can only be confirmed once surgery commenced, and it was important to retain this recommendation to alert people to the possibility of uterine rupture during induction and the action required. |
| Royal College of Paediatrics and Child Health | General | | | Thank you for inviting the Royal College of Paediatrics and Child Health to comment on the Inducing labour guideline update. Please note that the RCPCH did not receive any comments for this consultation. | Thank you for your comment. |
| Royal Free Maternity Voices Partnership | Guideline | General | General | Nothing about us, without us! The draft guidelines do not include or reflect the 'woman's voice'. This is not a co-produced document. We urge NICE to set up a steering group of people with lived experience of the maternity service and to collaborate with MVPs across the country to ensure that the guidelines are fit for purpose. Incidentally, co-production alongside people with lived experience should be a hygiene factor for NICE guidelines across the board | Thank you for your comment. The committee included 2 lay members with lived experience of induction of labour and wider experience of representing people using maternity services. The consultation process is the method we use to obtain input into the guideline from a wide range of stakeholders and individuals, and to ensure that the guideline is fit for purpose. This guideline received almost 3000 comments in this way, and each one was read and considered by the committee in order to amend and improve the guideline. |
| Royal Free Maternity Voices Partnership | Guideline | General | General | The evidence base for the Inducing Labour guidelines are too narrow. What's more, an upfront exploration around the long-term outcomes and negative consequences of induction are not referenced. There are risks to all decisions and the risks surrounding an increase in induction rates need to be addressed. As the draft guidelines currently stand, the 'business as usual' approach to inductions will mean that women and their families may be denied the right to make informed choices | Thank you for your comment. It was not within the scope of this guideline to review the risks and benefits of induction of labour compared to expectant management, so we have not been able to provide detailed information on risks and benefits, but the committee have expanded the section on information and decision-making to include the factors that should be taken into consideration when making this decision, and that the woman's decision should be respected. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Royal Free Maternity Voices Partnership | Guideline | General | General | The suggested changes to offer induction in later pregnancy as routine, ignores qualitative and quantitative data around the inaccuracy of 'due' dates. As Sara Wickham states in her analysis: 'The offer of an earlier induction will mean more babies will be born before they are ready. These babies will be at risk of long term health issues as a result.' | Thank you for your comment. The recommendations about induction of labour for prolonged pregnancy have been amended to make the emphasis a discussion of the risks and benefits with the woman, so that she can make her own decision, and to include information about rates of spontaneous labour at different gestational ages. However, the committee agreed that dating scans were usually accurate to within a few days and therefore there was not a great deal of uncertainty around due dates. |
| Royal Free Maternity Voices Partnership | Guideline | 006 | 1.2.4 | The suggested changes to offer induction in later pregnancy as routine, ignores qualitative and quantitative data around the inaccuracy of 'due' dates. As Sara Wickham states in her analysis: 'The offer of an earlier induction will mean more babies will be born before they are ready. These babies will be at risk of long term health issues as a result.' | Thank you for your comment. The recommendations about induction of labour for prolonged pregnancy have been amended to make the emphasis a discussion of the risks and benefits with the woman, so that she can make her own decision, and to include information about rates of spontaneous labour at different gestational ages. However, the committee agreed that dating scans were usually accurate to within a few days and therefore there was not a great deal of uncertainty around due dates. |
| Stockport Maternity Voices Partnership | Guideline | General | General | Coproduction: The document does not appear to reference consultation with women, birthing people or their families either directly or through the Maternity Voices Partnership yet service users are the biggest stakeholder group as they are the pregnant people being offered induction. The lay representatives on the committee do not appear to have engaged with any service users to form their opinions. Without consultation and coproduction with the users of a service it is impossible to develop guidelines for such service that meet <i>all</i> stakeholders needs. | Thank you for your comment. The committee included 2 lay members with lived experience of induction of labour and wider experience of representing people using maternity services. The consultation process is the additional method we use to obtain input into the guideline from a wide range of stakeholders and individuals, and to ensure that the guideline is fit for purpose. This guideline received over 3000 comments in this way, and each one was read and considered by the committee in order to amend and improve the guideline. |
| Stockport Maternity Voices Partnership | Guideline | General | General | Evidence: The guidance draws on too narrow an evidence base. Qualitative and quantitative data for the areas within have not been included. Some of the studies used have widely accepted flaws (ARRIVE, SWEPSIS) yet these have not been highlighted. Statements included in the guidance are not referenced which makes scrutiny difficult and many are referenced as "experience of the panel" which is not representative of all knowledge, peer-reviewed for accuracy | Thank you for your comment. The review questions included in this update of the guideline used evidence from randomised controlled trials which is a high level of evidence, and no questions were prioritised for a mixed methods review to include qualitative data. The methodological limitations of the ARRIVE and SWEPSIS trials were reflected in the evidence report and taken into consideration by the committee when interpreting the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | and comes last in the hierarchy of quantitative evidence. There are no references to qualitative evidence. There is no discussion about quality of evidence, long-term outcomes, negative consequences of induction, pain experience, or women and birthing people's experiences of induction making the guidance one-sided and heavily weighted towards people choosing induction and without which a person cannot make a truly informed decision. | evidence. NICE guideline recommendations are not referenced individually, but the evidence behind each recommendation is summarised in the rationale section of the guideline, and is available in full in the supporting Evidence review. However, where there is a lack of evidence the committee do use informal consensus to make recommendations and this is an accepted part of the NICE methodology. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. |
| Stockport Maternity Voices Partnership | Guideline | General | General | Iatrogenic Harm: The guidance does not mention iatrogenic harm that induction methods can cause. This means that people cannot make informed decisions about their pregnancies or births. This guidance should be unbiased and evidence based and it feels weighted towards people following an induction pathway. | Thank you for your comment. A comparison of risks and benefits of induction of labour with other modes of birth was not included in the scope of this update so we have not been able to include detailed information on the risks of induction. However, the committee have updated the section on information and decision-making to include more details on the factors that need to be taken into consideration. |
| Stockport Maternity Voices Partnership | Guideline | General | General | Language Used in the Guidance: Where "risks" are highlighted the actual risks should be identified (including population level figures) in order for the pregnant person to be able to make informed decisions about their care. | Thank you for your comment. Where evidence reviews have been conducted and these data are available (in the sections on prolonged pregnancy, macrosomia, and hyperstimulation) they have been added to aid discussions and decision-making. |
| Stockport Maternity Voices Partnership | Guideline | General | General | Communication: The guidance highlights the importance of having early discussions about mode of birth. The lived experience is that this, and thorough unbiased, evidence-based conversations do not always happen; this document should reflect this and stress the need for the importance of early conversations to enable planning, manage expectations and to reflect the NHS obligation to provide | Thank you for your comment, which we note relates to implementation of the guideline, so we have passed this on to the team at NICE who plan implementation support. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>personalised care.</p> <p>Quotes from service users:</p> <p><i>"I do note that the guidance does indicate that mode of birth should be discussed early on but I didn't have any conversations around birth until 36 weeks"... "I wanted to have it right from the beginning and talk about it through my pregnancy"... "I think that in an ideal scenario where we all receive and can give individualised care, understand the research, risk, and have lots of time etc. these recommendations would all be fine and there would be a measured and balanced conversation about IoL. This is not the case though"</i></p> | |
| Stockport Maternity Voices Partnership | Guideline | General | General | <p>Gestation: The guidance overrides the idea of a pregnancy's usual gestation period being between 37-42 weeks, allowing for natural differences between people. The guidance within this section is contradictory and confusing for the birthing person. If, as the document correctly states, "labour usually starts naturally by 42 weeks" why is so much emphasis given to ending a pregnancy before this point, and at 39 weeks for many groups of people?</p> <p>Quotes from service users:</p> <p><i>"I'm also not sure what the point of 'term' being from 37-42 weeks is if anything from 41-42 weeks is considered so risky that induction needs to be routinely offered"... "I'm quite nervous about the expectation that the baby should be delivered at 39 weeks because I think it would make another c-section much more likely for me"... "I really struggle to understand why this [pregnancy not going beyond 41 weeks] is being recommended when the committee have acknowledged [that women might feel forced into an unwanted medical intervention...and while the committee agreed that the risk of perinatal mortality, NICU admission</i></p> | Thank you for your comment. The recommendations on timing of birth in prolonged pregnancy have been amended and now include a focus on discussing the risks and benefits with women so they can make their own choice about induction. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <i>and caesarean birth increases over time with a prolonged pregnancy, the absolute risk remains low] it makes it seem like they either do not care about this possible harm or have decided that the low absolute risk of mortality and NICU admission is worth the more likely risk from these recommendations of coercion and harm to women."</i> | |
| Stockport Maternity Voices Partnership | Guideline | General | General | <p>Spontaneous Labour: Removal of the recommendation for "women with uncomplicated pregnancies to be given every opportunity to go into spontaneous labour" to be replaced with "women with uncomplicated pregnancies should be offered induction" erodes trust in women and birthing people's ability to fulfil a physiological function. Although the guidance does use the word "offer" the lived reality is that offers rarely seem like offers due to the cultural imbalance of power within medical settings.</p> <p>Quotes from service users:</p> <p><i>"I would have found it very hard to turn down induction if offered in the way described in the guidance despite the increased risks of tearing etc and I would have found it very stressful to make that choice. I would hope that any information provided acknowledges the stress of this type of decision making and provides suitable weight to issues such as birth preferences, tearing, pain etc which can feel like selfish considerations when weighed against fetal wellbeing but actually can be really important"..."</i> Overall, I feel like offering sweeps from 39 weeks and induction to everyone from 41 weeks gives the impression that women more often than not need medical help with birth and labour"</p> | <p>Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's</p> |
| Stockport Maternity Voices Partnership | Guideline | General | General | <p>Methods of Induction: The guidance includes statements about the process of induction that are contradictory and confuse understanding of what induction of labour actually is. An induction is an artificial attempt to end a pregnancy without waiting for spontaneous labour. Stating that something that does not occur naturally (a sweep) is not part</p> | <p>Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, or the optimal timing. However, the recommendations have now been</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>of the labour process is incorrect and misleading, giving weight to a culture where interventions as the norm rather than the exception to prevent harm.</p> <p><i>"A membrane sweep is listed under methods of induction but then says that it is important to explain to women, 'that membrane sweeping might make it more likely that labour will start naturally', - but a membrane sweep has been performed which is a method of induction so this isn't labour starting naturally. This is in danger of almost seeming to deliberately obfuscate to women that a sweep is a method of induction, despite it being listed in this section."</i></p> <p>Mechanical methods of induction of labour are stated in the guidance to be used if "pharmacological methods are not suitable" however there doesn't seem to be consideration given to mechanical methods of induction which can be effective without having the potential to cause hyperstimulation or to personal preference.</p> | <p>clarified to state that membrane sweeps are a method of induction.</p> <p>Mechanical methods are included in the guideline as an option for induction but there was evidence that they were not as effective at leading to vaginal birth in 24 hours as pharmacological methods. However, they can be used if women prefer them.</p> |
| Stockport Maternity Voices Partnership | Guideline | General | General | Planned Caesarean: There is no reference to planned caesarean as an alternative option to induction. This should be rectified. | Thank you for your comment. Where appropriate we have now added that caesarean birth may be an option, as an alternative to induction if birth is indicated. |
| Stockport Maternity Voices Partnership | Guideline | General | General | Black, Asian and Minority Ethnic Pregnancies: The guidance to "consider induction in women with otherwise uncomplicated pregnancies who are at higher risk of complications associated with continuing pregnancy, e.g. Black, Asian and minority ethnic background" fundamentally ignores the reasons for poorer health and mortality outcomes in these women and birthing people. Combatting systemic and institutionalised racism may be out of scope for this consultation (although arguably actively working to dismantle the systems that create this disparity should be within every scope of every policy in every organisation) however pathologizing women from these ethnicities using induction of labour as a tool that has risk of iatrogenic harm is not a solution. There are no stakeholders on the | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|----------------------------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | committee that represent people from Black, Asian and other ethnic minorities. | |
| Stockport Maternity Voices Partnership | Guideline | General | General | Staffing: An increase in induction of labour (from an already high point of c.42% locally) will impact on the workload of staff. Staffing numbers are unlikely to be increasing soon. There are serious concerns about the ability of staff to be able to provide the safe standard of care that they want to, and that all service users have the right to, with increased medicalisation of birth based on low or no evidence. | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. It may be that the new recommendations will encourage some women to have an earlier induction than they would previously, but a substantial change in the number of induced labours is not anticipated with the revised recommendations. |
| Stockport Maternity Voices Partnership | Guideline | General | General | The impact of these guidelines on women, birthing people and their families has the potential to be huge. It is imperative that NICE acts with integrity and transparency by ensuring that guidance is created by looking at all available evidence and by listening to the experiences of service users to create guidance that accurately reflects research, the reality of care given and the needs of the pregnant person. Guidance needs to take into account the results of the Parliamentary report into the safety of maternity services in the UK and include recommendations for continuity of carer, listening to women and birthing people, taking a wider view of the social determinants of poor maternity outcomes, etc. | Thank you for your comment. Based on stakeholder feedback, the guideline has been extensively revised and now has an increased focus on discussion of risks and benefits, allowing women to make their own decisions and supporting those decisions. |
| Stockport Maternity Voices Partnership | Guideline | 001 | 004 | Inclusivity: The exclusion of naming birthing people who do not identify as women for the sake of "simplicity" is egregious. All organisations and the work they produce should be inclusive and representative, especially when the groups of people being erased by "simplistic" language are those who suffer worse care and outcomes than majority groups. There are no stakeholders on the committee that represent LGBT+ organisations. | Thank you for your comment. To ensure consistency between NICE guidelines the NICE editorial team have developed a more inclusive description and rationale for the use of the terminology relating to the intended population for maternity and obstetric guidelines, guidelines, and this is included in the introductory information at the beginning of the guideline. |
| Stockport Maternity Voices Partnership | Guideline | 004 | 001 | The pregnant person is not "involved in" discussions about their care, it is their absolute right to be the decision-maker. To suggest, imply or not strongly state otherwise erodes that | Thank you for your comment. The pregnant person is involved in discussions about their care as this is a 2-way process of sharing information and preferences, but we have clarified in several places in the guideline that it is the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-------------------|-----------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | person's body autonomy. The document as a whole needs to strengthen this position. | woman's decision whether or not to proceed with an induced labour. |
| Swansea Bay University Health Board | Guideline | General | General | The whole document is a serious step towards medicalisation of pregnancy, without an evidence-based and proven benefit. This document, in parts, is not a prudent approach to maternity service provision, particularly as we want to protect our internationally celebrated NHS. The draft guideline's recommendations support a 'too much too soon' approach, which we know can worsen perinatal outcomes and does not support global strategic concern. Our evidence based clinical guidelines must support us at an individual, unit and national level to navigate the pitfalls of 'too little too late', as well as 'too much too soon'. This is summed up in the Committees decision to remove the recommendation that 'Women with uncomplicated pregnancies should be given every opportunity to go into spontaneous labour'. This is a fundamental move away from physiological birth which may have catastrophic effects on maternal and perinatal health and wellbeing. | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have also added an additional recommendation to emphasise that whether or not to have an induction is a woman's choice and that choice should be respected. We have also reinstated the recommendation that says 'Women with uncomplicated pregnancies should be given every opportunity to go into spontaneous labour'. |
| Swansea Bay University Health Board | Guideline | General | General | The recommendations, if published in this guideline, will lead to SIGNIFICANTLY more women requiring interventions and monitoring. This will lead to increased demand on resources. We have a concern as a unit that as more women receive intervention, resources will be redirected from those who need the care the most. Not receiving the level of care required as resources are spread out could lead to an increase in poor outcomes. It is not a Prudent approach to healthcare. | Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |
| Swansea Bay University Health Board | Evidence Review C | 019 - 020 | 046 -003 | We feel concerned at the level of detail and recommendations that are based on the 'knowledge and experience of the committee' as outlined and acknowledged by the committee themselves. We feel this is unacceptable when considering the vast implications of these recommendations. | Thank you for your comment. The recommendations are based on a systematic review of the evidence. However, where there is a lack of evidence the committee do use informal consensus to make recommendations and this is a standard part of the NICE process. The committee included 2 lay members with lived experience of induction of labour and wider experience of representing people |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | using maternity services. The consultation process is the method we use to obtain input into the guideline from a wide range of stakeholders and individuals, and to ensure that the guideline is fit for purpose. This guideline received about 3000 comments in this way, and each one was read and considered by the committee in order to amend and improve the guideline. |
| Swansea Bay University Health Board | Guideline | 004 | 008 | <p>Women's experience related to IOL – we note there is no evidence that has been considered regarding maternal quality of life and just one on satisfaction/experience of care – this is a key element and not only for the mother but also the partner too.</p> <p>True 'evidence-based practice' considers patient experience and preference as one of the 3 'pillars', and as most research considering women's experience is considered 'low-quality' by NICE and GRADE' (as qualitative methods are most suited to explore this). The consequence of this is that women's voices are therefore not given equitable standing within guideline development, including this one. We have qualitative evidence that women's experience of induction of labour is largely a negative experience. This is not included in the draft and the statement that is there, is too ambiguous, not reflecting the evidence. The negative psychosocial effect of induction of labour must be included in this section.</p> | <p>Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update and so we were unable to include qualitative data on women's birth experiences. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth, and this includes how mode of birth may impact on place of birth and women's experiences of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date.</p> |
| Swansea Bay University Health Board | Guideline | 005 | 015 | <p>1.1.4 Recommend the use of absolute number for example. '1 in 1000' where increased or decreased risk is described to aid discussion and informed decision-making.</p> <p>To support clinicians to have appropriate and meaningful discussion with families relating to the decision to continue with pregnancy versus have IOL it would be helpful to have the statistics for continuing pregnancy versus IOL in a comparison table to be able to compare the risks and benefits of each option. Neither appear without some risk and a comparison might help women to decide what is an acceptable risk for them.</p> | <p>Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on these outcomes. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| Swansea Bay University Health Board | Guideline | 006 | 001 - 020 | <p>New evidence to be considered that will impact recommendations in the draft guidance: Intrapartum interventions and outcomes for women and children following induction of labour at term in uncomplicated pregnancies: a 16-year population-based linked data study BMJ Open – Dahlen et al. (2021).</p> <p>Considered IOL v's Spontaneous labour onset in uncomplicated term pregnancies with live births. Australian study - Just under 500,000 births. 15% had IOL for non-medical reasons. Primiparous women with IOL – more likely to have instrumental birth, IP caesarean section (29% for IOL versus 13.8% for spontaneous labour), more likely to have an epidural in labour, more likely to have an episiotomy and more likely to have a postpartum haemorrhage. The trend was similar for multiparous women except for caesarean section which was lower. Incidences of neonatal birth trauma, resuscitation and respiratory disorders were higher for the IOL group. admissions for ear, nose and throat infections, respiratory infections and sepsis were also higher for the IOL group to age 16. Didn't include women over age 35.</p> | <p>Thank you for your comment and for the reference provided. We have checked it to ensure there is nothing we have missed that should have been included. Dahlen 2021 is not eligible for inclusion because it did not compare different induction strategies and it is not a RCT. For further details regarding inclusion and exclusion criteria of studies, please see the review protocol in appendix A of evidence report C.</p> |
| Swansea Bay University Health Board | Guideline | 006 | 012 - 019 | <p>Service implications where there are locally already frequent delays with women awaiting IOL due to resources. Service impact of IOL at 41 weeks – 11% of our population labours at or over 41 weeks. The reductive impact this would have on midwifery-led services cannot be underestimated.</p> | <p>Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction. It may be that the new recommendations will encourage some women to have an earlier induction than they would previously but substantial service implications are no longer anticipated with the revised recommendations.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Swansea Bay University Health Board | Guideline | 006 | 012 - 019 | 1.2.3 - 41/40 GESTATION FOR ALL SINGLETON PREGNANCIES if this is being offered it would be helpful for the guideline to state the actual statistics for the increased likelihood for adverse outcomes should they continue with pregnancy until 42+0 weeks (which is stated as being the point up to at which the labour will normally start) | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. |
| Swansea Bay University Health Board | Guideline | 006 | 002 | Guidance on how EDD is calculated – from dating scan, LMP this should be acknowledged and clarified in the guideline | Thank you for your comment. The NHS uses the 12 week dating scan to determine the gestational age of the baby and hence its due date, so we have included this in the guideline. |
| Swansea Bay University Health Board | Guideline | 006 | 009 | 1.2.1 Recommending elective caesarean section without an indication as a choice of mode of birth. We have significant concern around the overall tone and acceptance of caesarean section as a routine 'option' on the menu for women. Currently the document suggests modes are comparable, the stakeholder group argue that physiological process is not comparable with a surgical procedure even where the outcome, i.e. the birth of the baby, is the same. To set this as an acceptable social context is derogatory to the nature and complexity of the physiological process of birth. The influence of the under tones in this suggestion may alter perceptions of birth, promoting interventionist approaches in the absence of clinical concern. | Thank you for your comment. The committee agreed that women need to be informed of the different modes of birth that are available to them, so they can make an informed decision. This has been reinforced by the Montgomery ruling and the Ockenden report, and it is necessary to provide women with an opportunity to discuss their preferences for mode of birth and to make an informed decision, and this is a position that is supported by this guideline. However, the committee agreed that discussions about mode of birth should take place earlier in pregnancy, and we have now moved this recommendation to the section of the guideline on information and decision-making. |
| Swansea Bay University Health Board | Guideline | 006 | 012 | The guideline does not comment on the long term implications of induction of labour, which may support women in their choices as they weight up risk/benefits. Consider: Seijmonsbergen-Schermerms et al (2019) and the Millenium Cohort Study (2021). http://dx.doi.org/10.1136/archdischild-2020-320213 | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | <p>added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. We have checked the references provided individually to ensure there is nothing we have missed that should have been included. Please see below for further details:</p> <ul style="list-style-type: none"> - Seijmonsbergen-Schermer et al (2019) is a 'BJOG perspectives' letter to the editor publication, and only full text studies are eligible for inclusion - Millenium cohort study (Alterman 2021): is a longitudinal study which assessed the association between gestational age at birth and special education needs later in life. Is not eligible as is it not a RCT, did not compare different timings of induction and is a single-arm study, therefore is not eligible for inclusion. <p>For further details regarding inclusion and exclusion criteria of studies, please see the review protocol in appendix A of evidence report C.</p> |
| Swansea Bay University Health Board | Guideline | 006 | 017 | <p>1.2.1.1 In line with WHO and ICM, our Health Board recognises and values childbirth as a normal, physiological process, one that can be accomplished without complication or intervention. We understand that intervention without just cause leads to an increase in morbidity and mortality. For women without additional needs in pregnancy, the recommendations within this guideline will lead to increased interference in the normal physiological process of pregnancy and therefore morbidity and mortality. Recommending intervention because it doesn't appear to worsen outcomes rejects this philosophy of childbirth as a physiological/psychosocial event.</p> | <p>Thank you for your comment. There was evidence that some risks increased with increasing gestational age. However, based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based.</p> |
| Swansea Bay University Health Board | Guideline | 006 | 020 | <p>This guideline is going to impact on a large number of our women, especially with suggestion of IOL for women with BMI over 30 (almost 26% of our population according to maternity database for 2020). Black, Asian or minority ethnic family background, assisted conception or women aged over 35 etc (20% population). from 39 weeks gestation. The women recommended for induction at 39 weeks in this</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | section are not being provided with an optimum chance of spontaneous labour. | |
| Swansea Bay University Health Board | Guideline | 006 | 020 | Is there evidence/data available on how long on average the IOL process takes based on gestation at onset of IOL? This is important information for families to understand. | Thank you for your comment. As part of the scope of this update, the committee did not look for any evidence on the length of the induction process and so we are unable to add this information to the guideline. |
| Swansea Bay University Health Board | Guideline | 006 | 010 & 011 | <p>ARRIVE trial – the trial did not show a difference in the primary outcome of mortality/morbidity for the neonate, although it did show a reduction in the secondary outcome for caesarean section rates. The concern here is that IOL is being presented as an alternative to continuation of pregnancy, any discussion or recommendation should make it clear that in accordance to this study there was no increase in adverse perinatal outcome in either arm of the study. The study was also conducted on low risk nulliparous women, caution should be present when generalising to multiparous women. The extent of bias and limitations within the study suggest we should be cautious if we are to base national recommendations on this evidence.</p> <p>It is noted in the evidence review that the evidence around caesarean birth is of low quality. Furthermore the instrumental/operative birth showed no clinically important difference, but because it has neared statistical significance it is being used in favour of earlier IOL.</p> <p>Suggest revision of this recommendation, based on this one trial conducted in a completely different healthcare system, with poorer maternal outcomes, without consideration of newer research available (as below).</p> <p>Within the stakeholders, own Health Board, reducing the gestation for recommended IOL for post-dates alone to 41 weeks from 41+5/6 would mean an increase in offered annual induction of labour of around 11 %, 367 women in 2020 spontaneously laboured and birthed after 41 weeks according to our maternity data system.</p> | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have now included tables with the estimated risks associated with a pregnancy continuing beyond 41+0 weeks by parity to aid understanding of the evidence reviewed. The supporting information explains how this data was derived, its limitations and how to interpret it. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>In our local maternity unit with 3500 deliveries per year, this will mean an extra 30 – 35 IOL a month. Including >35 years, BMI >30 can increase this further. This will have serious implications for ensuring adequate staffing, bed space, delays in transferring women to LW for continuation of IOL leading to increased risk to mothers and babies. In addition, patient dissatisfaction and increased complaints will be inevitable.</p> <p>Maternity Care in Wales: A five year vision for the future (WG,2019) advises that within Health Boards at least 45% of women should be suitable for a midwifery led birth in a midwifery led setting. The rationale for this recommendation this is based on the know reduction in intervention and adverse outcome (NICE, 2014, Sandal 2016) in these models. The stakeholder group were glad to see mention of the impact of birth environment where IOL is accepted, however this is not weighted appropriately for women to fully understand the potential impact of choice of IOL, where birth would often need to occur in the obstetric setting. It is also felt that none of the evidence base compares IOL versus spontaneous labour in midwifery led settings only. From the empirical evidence base it may be concluded that environment may influence findings. A call for this research should be made for recommendations to be considerate of the important variable/intervention of intended place of birth and a midwifery led model of intrapartum care.</p> | |
| Swansea Bay University Health Board | Guideline | 007 | 013 | <p>Not available for comment. The loose language here is unhelpful. If there is no evidence for recommendation, then make no recommendation. Twice weekly CTG and max amniotic pool depth – where IOL declined potential resource issue if at least additional 11% of women offered IOL for post dates.</p> | <p>Thank you for your comment. Other recommendations (for example 1.2.2 and 1.2.4) have been amended so it is unlikely that the cohort of women being offered and declining induction will change significantly. This recommendation has also been amended to state that the option of additional fetal monitoring should be discussed with the woman, and the limitations of this monitoring explained. It is then her choice whether to be monitored or not, as some women may find intermittent monitoring reassuring. The options to do CTG and amniotic pool</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | depth are only provided as suggestions, carried over from the previous version of the guideline, and have been in place since 2008, so it is unlikely these recommendations will have an impact on resources. |
| Swansea Bay University Health Board | Guideline | 007 | 013 | 1.2.6 offer increased fetal monitoring for women choosing not to have IOL – does this mean from 39 weeks for the group in 1.2.4 and then 41+0 for those in 1.2.2? If so, there is no recommendation on timings/frequency, and no evidence on which to base these. | Thank you for your comment. The recommendation in 1.2.4 has been withdrawn, and that at 1.2.2 amended, so there are likely to be fewer women to whom this monitoring recommendation now applies. |
| Swansea Bay University Health Board | Guideline | 007 | 016 | This statement feels coercive and unnecessary. We can accept 1.2.8, statement 1.2.7 is not necessary. | Thank you for your comment. We have reworded this recommendation to emphasise that women can choose whether or not to discuss their decision again. |
| Swansea Bay University Health Board | Guideline | 008 | 021 | What is the evidence for induction of labour at point of ruptured membranes in the absence of risk factors? NICE IP guidelines suggest where labour is established before 24 hours women remain midwifery with 60% of women labouring within 24 hours: Cost evaluation/experience and outcome evaluation required. | Thank you for your comment. The recommendations in the induction of labour guideline are in accordance with the intrapartum care guideline, as both recommend expectant management for 24 hours and then induction of labour, but women may not wish to wait for 24 hours and so are given the option of an earlier induction. No economic evaluation was undertaken as the evidence underpinning this recommendation was not part of the guideline update and the wording of the recommendation was only amended to provide greater clarity. |
| Swansea Bay University Health Board | Guideline | 010 | 020 | Suggest using the Cochrane 39 weeks definition. | Thank you for your comment. The studies included in the Cochrane review used a variety of different definitions for fetal macrosomia. While all trials reported that they estimated the fetal weight with ultrasound, different definitions were used. Two trials used estimates based on centile (>95th or 97th centile) and two used estimated fetal weight (4000-4500g and 4000-4750g). The committee specified that these recommendations apply to an estimated weight of the fetus above the 95th percentile at or after 36 weeks of gestation, which is in line with Boulvain 2015, and therefore they used this as their definition. |
| Swansea Bay University Health Board | Guideline | 013 | 002 | This is not available for comment?? 39/40 Membrane sweeping – the evidence within the document does not appear to suggest anything around | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------------------------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | timing of membrane sweeping – what frequency is being suggested. Advantages/disadvantages Service provision implications should be calculated. | so have been unable to revise the recommendations on the risks and benefits, timing or frequency. As the recommendations for membrane-sweeping have been in place since 2008, the committee did not believe the minor changes to the recommendations would be a challenge to maternity services. |
| Swansea Bay University Health Board | Guideline | 013 | 002 | 39/40 membrane sweeping and IOL – this gestation is not in line with the NICE schedule of antenatal care – is this going to change if so again there may be a cost implication? Only 10% of women labour before 39 weeks, therefore most women would be offered sweeps. | Thank you for your comment. The recommendations have been clarified to state that membrane sweeps should be discussed after 39 weeks (as opposed to 'from 39 weeks'), but this is a discussion, not an offer recommendation, so it is not likely that most women will have a sweep and therefore there is unlikely to be a significant cost implication. |
| Swansea Bay University Health Board | Guideline | 015 | 024 | Consideration should be given to the use of mechanical methods of IOL as a 1 st line in most women. Products like Dilapan are used with good effect nationally – why is this not recommended within these guidelines? By comparison, outpatient IOL is based on audit findings and we would suggest recommendations around the use of Dilapan to be considered based on audit findings also. | Thank you for your comment. Based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour, so they have been removed from this list. |
| Swansea Bay University Health Board | Guideline | 024 | 010 | The committee have used the Cochrane review (bouvain 2016) to make recommendations in relation to suspected fetal macrosomia. The Cochrane review clearly identifies that IOL should be undertaken before 39/40 for it to have any impact on birth weight, shoulder dystocia or fractures. IOL after this gestation had no impact. | Thank you for your comment. The committee discussed whether it was possible to define the best time to induce labour in suspected fetal macrosomia but the evidence included induction at a range of gestational ages and it was not possible to identify the preferred gestational age. The committee also considered this would be an individualised decision based on the estimated size of the baby, the woman's clinical circumstances and her preferences. |
| The Breastfeeding Network | Guideline | 004 | 008 - 020 | The guidance here mentions an increased risk of assisted vaginal birth. This is associated with lower rates of breastfeeding (Chien et al, 2007) possibly due to delayed initiation of breastfeeding as a result of increased birth trauma, pain, need for stitches etc. Induced labour may be more painful than spontaneous labour, in part as a result of the increased risk of intervention. Research has shown that pethidine, | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update and so we are unable to provide specific information within the guideline on the impact of induction on breastfeeding. We have however passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>diamorphine or other opioids may interfere with breastfeeding (Sze Lok Fan et al., 2020). Induction with prostaglandin (dinoprostone) gel, which is one of the recommended methods if Bishop score is six or below, has also been associated with lower breastfeeding rates at one and three months (Zanardo et al, 2017). Use of intravenous oxytocin as a method of induction could interfere with establishing breastfeeding. Endogenous oxytocin is necessary for the ejaculation of milk from the breast, and there is evidence that an infusion of synthetic oxytocin could impact on endogenous oxytocin levels (Jonas et al, 2009). A review of the research into synthetic oxytocin use during childbirth showed that over 50% of studies had mixed results or found negative associations between administration of synthetic oxytocin and breastfeeding, and none showed a positive association with breastfeeding (Erickson and Emeis, 2017). Synthetic oxytocin administration alters baby's behaviour when in skin to skin contact with mother after birth and reduces chance of breastfeeding in the first hour (Cadwell and Brimdyr, 2017). A large study of almost 50,000 women showed that the chance of breastfeeding at discharge from the hospital (day 2) was diminished by 6-8% if the mother had been administered intrapartum synthetic oxytocin (Jordan et al 2009). At two months postpartum, the mothers who were most likely to be exclusively breastfeeding had received the lowest amounts of synthetic oxytocin or who had not been induced (Gu et al, 2016, Bai et al, 2013). Another study found that the risk of stopping breastfeeding by 3 months was significantly higher (2.29, 95% CI 1.41-3.74) if the mother had received synthetic oxytocin, particularly if the mother was younger than 27 (Garcia-Fortea et al 2014).</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>Based on the research described, we encourage women with their midwife or health care professional to consider impact of an induced labour on their decision to breastfeed. It should be sensitively discussed, through the preparation of a birth plan for example, that induction of labour, and the possible consequences of it, could impact on breastfeeding and extra support for the mother may be required and should be provided to her. The option of antenatal expression and storage of colostrum, for use if required postnatally, is already recommended by some NHS trusts for women with gestational diabetes. This could be extended to all women considering induction, and evaluated for efficacy.</p> <p>Women who have had a caesarean section or assisted vaginal delivery may require additional pain relief postnatally. We know, from our Drugs in Breastmilk information service, that breastfeeding mothers are frequently denied effective pain relief due to concerns about the drugs passing to the baby through her milk, resulting in unnecessary pain for the mother and the risk of premature termination of breastfeeding. There are, in fact, a number of safe and effective pain relief options for breastfeeding mothers (see https://www.breastfeedingnetwork.org.uk/analgesics/ for more information) and these should be made available to all women.</p> | |
| The Breastfeeding Network | Guideline | 004 | 008 - 020 | <p>The guidance here mentions an increased risk of assisted vaginal birth. This is associated with lower rates of breastfeeding (Chien et al, 2007) possibly due to delayed initiation of breastfeeding as a result of increased birth trauma, pain, need for stitches etc.</p> <p>Induced labour may be more painful than spontaneous labour, in part as a result of the increased risk of intervention. Research has shown that pethidine, diamorphine or other opioids may interfere with breastfeeding (Sze Lok Fan et al., 2020).</p> <p>Induction with prostaglandin (dinoprostone) gel, which is one of the recommended methods if Bishop score is six or below,</p> | <p>Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update and so we are unable to provide specific information within the guideline on the impact of induction on breastfeeding. We have, however, passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>has also been associated with lower breastfeeding rates at one and three months (Zanardo et al, 2017).</p> <p>Use of intravenous oxytocin as a method of induction could interfere with establishing breastfeeding. Endogenous oxytocin is necessary for the ejaculation of milk from the breast, and there is evidence that an infusion of synthetic oxytocin could impact on endogenous oxytocin levels (Jonas et al, 2009).</p> <p>A review of the research into synthetic oxytocin use during childbirth showed that over 50% of studies had mixed results or found negative associations between administration of synthetic oxytocin and breastfeeding, and none showed a positive association with breastfeeding (Erickson and Emeis, 2017).</p> <p>Synthetic oxytocin administration alters baby's behaviour when in skin to skin contact with mother after birth and reduces chance of breastfeeding in the first hour (Cadwell and Brimdyr, 2017).</p> <p>A large study of almost 50,000 women showed that the chance of breastfeeding at discharge from the hospital (day 2) was diminished by 6-8% if the mother had been administered intrapartum synthetic oxytocin (Jordan et al 2009).</p> <p>At two months postpartum, the mothers who were most likely to be exclusively breastfeeding had received the lowest amounts of synthetic oxytocin or who had not been induced (Gu et al, 2016, Bai et al, 2013).</p> <p>Another study found that the risk of stopping breastfeeding by 3 months was significantly higher (2.29, 95% CI 1.41-3.74) if the mother had received synthetic oxytocin, particularly if the mother was younger than 27 (Garcia-Fortea et al 2014).</p> <p>Based on the research described, we encourage women with their midwife or health care professional to consider impact of an induced labour on their decision to breastfeed. It should be sensitively discussed, through the preparation of a birth plan for example, that induction of labour, and the</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | possible consequences of it, could impact on breastfeeding and extra support for the mother may be required and should be provided to her. The option of antenatal expression and storage of colostrum, for use if required postnatally, is already recommended by some NHS trusts for women with gestational diabetes. This could be extended to all women considering induction, and evaluated for efficacy. Women who have had a caesarean section or assisted vaginal delivery may require additional pain relief postnatally. We know, from our Drugs in Breastmilk information service, that breastfeeding mothers are frequently denied effective pain relief due to concerns about the drugs passing to the baby through her milk, resulting in unnecessary pain for the mother and the risk of premature termination of breastfeeding. There are, in fact, a number of safe and effective pain relief options for breastfeeding mothers (see https://www.breastfeedingnetwork.org.uk/analgesics/ for more information) and these should be made available to all women. | |
| The Breastfeeding Network | Guideline | 006 | 010 - 026 | The recommendation has moved from standard induction at 42+0 weeks to 41+0 weeks, in uncomplicated singleton pregnancies, and from 39 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications associated with continued pregnancy. as evidence shows that the risk of c-section, perinatal death and Neonatal ICU admission as a result of induced labour are lower when induction occurs at 41+0 weeks, as compared to induction at 42+0 weeks. However, this means that an increased number of women overall will be offered induction at an earlier gestational stage, some of whom would otherwise have experienced spontaneous labour under previous guidelines. Some of these women would have experienced a spontaneous labour between 41+0 weeks and 42+0 weeks. We know that induced vaginal deliveries are associated with lower breastfeeding rates (Ahluwalia et al 2012). These women may experience increased pain, with requirement for more pain relief, | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have also replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | increased risk of assisted delivery and oxytocin interference, compared to spontaneous labour. Therefore, there is a possibility that the change in these guidelines will impact negatively on breastfeeding rates. Procedures must be put in place to ensure women are aware and are informed of the protocol and methods used to induce labour and what impact this may have on their feeding intentions for their baby as well as what support will be available. | |
| The Breastfeeding Network | Guideline | 006 | 010 - 026 | The recommendation has moved from standard induction at 42+0 weeks to 41+0 weeks, in uncomplicated singleton pregnancies, and from 39 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications associated with continued pregnancy. as evidence shows that the risk of c-section, perinatal death and Neonatal ICU admission as a result of induced labour are lower when induction occurs at 41+0 weeks, as compared to induction at 42+0 weeks. However, this means that an increased number of women overall will be offered induction at an earlier gestational stage, some of whom would otherwise have experienced spontaneous labour under previous guidelines. Some of these women would have experienced a spontaneous labour between 41+0 weeks and 42+0 weeks. We know that induced vaginal deliveries are associated with lower breastfeeding rates (Ahluwalia et al 2012). These women may experience increased pain, with requirement for more pain relief, increased risk of assisted delivery and oxytocin interference, compared to spontaneous labour. Therefore, there is a possibility that the change in these guidelines will impact negatively on breastfeeding rates. Procedures must be put in place to ensure women are aware and are informed of the protocol and methods used to induce labour and what impact this may have on their feeding intentions for their baby as well as what support will be available. | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have also replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. |
| The Breastfeeding Network | Guideline | 020 | 020 | 1.2.4 We understand there to be no evidence or justification for inducing black, Asian or minority ethnic women from 39+0 | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | weeks with otherwise uncomplicated singleton pregnancies on grounds that they may be at higher risk. Our understanding of the MMBRACE report recommendations is that much more focus needs to be given to ensuring quality obstetric care, and highest levels of communication and consultation with parents. This should happen throughout each pregnancy and be informed by evidence with an equity focus, detecting possible risk factors early. This should continue during the birth to include informed discussions on choices around interventions. BfN are deeply concerned at the implication of a new guideline to bring forward induction for women from Black, Asian and minority ethnic backgrounds with no justification this is no substitute for skilled midwifery and obstetric care. We know that induced vaginal deliveries are associated with lower breastfeeding rates (Ahluwalia et al 2012). These women may experience increased pain, with requirement for more pain relief, increased risk of assisted delivery and oxytocin interference, compared to spontaneous labour. Therefore, there is a possibility that the change in these guidelines will impact negatively on breastfeeding rates. Procedures must be put in place to ensure women from all ethnic backgrounds are aware and are informed of the protocol and methods used to induce labour and what impact this may have on their feeding intentions for their baby as well as what support will be available. | with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| The Breastfeeding Network | Guideline | 021 | 010 | We would suggest the following additional recommendations for research: More data is needed on the relationship between methods for initiation of labour (spontaneous vs induced, elective induction vs medically indicated induction, method of induction) and method of delivery (unassisted vaginal, assisted vaginal, caesarean section) and the subsequent rates of breastfeeding initiation and continuation. Research should seek to understand not just whether method of initiation of labour and delivery are linked to breastfeeding rates, but how and why they are linked, so that mothers who | Thank you for your comment. Research recommendations are made in NICE guidelines when a search for evidence has been carried out and no or inadequate evidence has been found. In this update no evidence review was carried out to look at the effects of mode of birth on breastfeeding, analgesics or expression of colostrum, so we have been unable to make research recommendations on these topics. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|---------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>require interventions such as induction and assisted vaginal delivery can then receive the best possible support to enable breastfeeding afterwards.</p> <p>More research is required into safe and effective analgesics for breastfeeding mothers, to ensure that women are not denied pain relief unnecessarily, or do not terminate breastfeeding prematurely due to excessive and avoidable pain.</p> <p>Antenatal expression of colostrum for use postnatally if required is already suggested by some NHS trusts, particularly for women with gestational diabetes. There is no evidence of any harm caused by this practice, but there is little consistent evidence on efficacy either (Foudil-Rey et al, 2021), despite anecdotal reports of it being beneficial. We would therefore recommend research into the benefits of antenatal expression of colostrum to the health of mother and baby and the establishment of breastfeeding, in all women, particularly those with pre-existing risk factors such as gestational diabetes and those undergoing an induced labour or caesarean section.</p> | |
| The Breastfeeding Network | Guideline | 021 | 010 | <p>We would suggest the following additional recommendations for research:</p> <p>More data is needed on the relationship between methods for initiation of labour (spontaneous vs induced, elective induction vs medically indicated induction, method of induction) and method of delivery (unassisted vaginal, assisted vaginal, caesarean section) and the subsequent rates of breastfeeding initiation and continuation. Research should seek to understand not just whether method of initiation of labour and delivery are linked to breastfeeding rates, but how and why they are linked, so that mothers who require interventions such as induction and assisted vaginal delivery can then receive the best possible support to enable breastfeeding afterwards.</p> <p>More research is required into safe and effective analgesics for breastfeeding mothers, to ensure that women are not denied pain relief unnecessarily, or do not terminate</p> | <p>Thank you for your comment. Research recommendations are made in NICE guidelines when a search for evidence has been carried out and no or inadequate evidence has been found. In this update no evidence review was carried out to look at the effects of mode of birth on breastfeeding, analgesics or expression of colostrum, so we have been unable to make research recommendations on these topics.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | breastfeeding prematurely due to excessive and avoidable pain. Antenatal expression of colostrum for use postnatally if required is already suggested by some NHS trusts, particularly for women with gestational diabetes. There is no evidence of any harm caused by this practice, but there is little consistent evidence on efficacy either (Foudil-Rey et al, 2021), despite anecdotal reports of it being beneficial. We would therefore recommend research into the benefits of antenatal expression of colostrum to the health of mother and baby and the establishment of breastfeeding, in all women, particularly those with with pre-existing risk factors such as gestational diabetes and those undergoing an induced labour or caesarean section. | |
| The CHOICE study | Guideline | General | General | Throughout the document there is an inappropriate reliance on expert opinion rather than evidence. We note the availability of high-quality evidence that has not been considered, for example recently published epidemiological studies which show child health and development differences even when induction of labour is conducted at term and that show benefits to children's longer-term outcomes with each week of gestation up to 42 weeks: e.g. Noble KG, Fifer WP, Rauh VA, Nomura Y, Andrews HF. Academic achievement varies with gestational age among children born at term. Paediatrics. 2012 Aug 1;130(2): e257-64); Neora Alterman , Samantha Johnson , Claire Carson, Stavros Petrou, Oliver Rivero-Arias, Jennifer J Kurinczuk, Alison Macfarlane, Elaine Boyle, Maria A Quigley. Gestational age at birth and child special educational needs: a UK representative birth cohort study. http://dx.doi.org/10.1136/archdischild-2020-320213 ; Victoria Coathup, Elaine Boyle, Claire Carson, Samantha Johnson, Jennifer J Kurinczuk, Alison Macfarlane, Stavros Petrou, Oliver Rivero-Arias, Maria A Quigley. Gestational age and hospital admissions during childhood: population | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update and so we are unable to provide data tables as you suggest. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed the references you suggest to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | based, record linkage study in England (TIGAR study). BMJ 2020;371:m4075 http://dx.doi.org/10.1136/bmj.m4075 | |
| The CHOICE study | Guideline | General | General | <p>Throughout the document there is a disproportionate emphasis on risk given the poor quality of evidence to suggest risk.</p> <p>An example of this is the rhetoric surrounding women's decision making on page 7 from line 3 onwards. E.g.: 'Offer women who decline induction of labour an opportunity to revisit their options with a healthcare professional at least once a week' (Pg 7, line 16) <i>and</i> 'Advise women to contact their maternity unit as soon as possible if they change their mind before their next appointment' (Pg 7, line 19).</p> <p>Although the word 'offer' is used, the recommendation to ask women to revisit their options – notably stating 'at least' once a week in practice means that women and their partners will not feel that they have a choice. This concern is supported by systematic review evidence on women's experiences of IOL, which shows that women generally do not feel sufficiently well informed and many did not consider that they had a meaningful choice of whether to agree to IOL or not. (Coates, R, Cupples, G, Foya V, McCourt C, Scamell M. 2018. Women's experiences of induction of labour: qualitative systematic review and thematic synthesis. Midwifery, 2018-10. DOI: 10.1016/j.midw.2018.10.013)</p> | <p>Thank you for your comment. We have reworded the first of these recommendations to emphasise that women can choose whether or not to discuss their decision again. However, the committee agreed that it is important that women are advised to contact their maternity unit if they have concerns about their baby, or that some women may decide that, as they have still not gone into spontaneous labour, they wish to rediscuss their options for birth, and so this recommendation has not been changed.</p> |
| The CHOICE study | Guideline | General | General | <p>Research gaps which need to be addressed include:</p> <ol style="list-style-type: none"> 1. Economic and organisational consequences of increasing rates of IOL, particularly relating to gestational age in low-risk pregnancies, including wider unintended safety implications via overall service impact 2. Long-term health impacts on mothers and infants | <p>Thank you for your comment. Research recommendations are made in NICE guidelines when a search for evidence has been carried out and no or inadequate evidence has been found. In this update an evidence review was carried out to determine the optimal time to induce labour in longer pregnancies and as limited evidence was found research recommendations were made to determine the optimal time for induction in all women, and to determine if this differs in certain sub-groups of women. An evidence</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------|-----------|---------|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>3. Psychological outcomes for parents, traumatic birth experiences and mother-infant bonding</p> <p>4. Research to achieve better understanding of who is at risk in relation to prolonged pregnancy vs who is not at greater risk</p> | <p>review was not carried out to compare the risks and benefits, and economic and organisational consequences of induction of labour with expectant management (including outcomes such as those you have mentioned) so it was not possible to create a research recommendation on this topic. However, the need for this review has been highlighted by several stakeholders and so this will be passed to the NICE surveillance team who are responsible for ensuring that NICE guidelines are up to date.</p> |
| The CHOICE study | Guideline | 004 | 003 (onwards) | <p>Information and Decision Making</p> <p>This section expresses important issues around informed decision making and consent, however we feel that there is a failure to acknowledge the inadequate and biased nature of the information that is available to women or offer any advice to address this. The UK Montgomery Supreme Court ruling 2015 established that reasonable care is taken to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative. A systematic review of the evidence on women's experiences found that the majority of women did not feel that had the evidence they needed to make an informed choice, and many were unaware that they had a choice.</p> <p>This proposed guideline draws only on evidence from 15 RCTs and much of the evidence is described as low quality. There is emerging evidence from epidemiological studies which show child health and development differences even in term children by gestational age – with benefits each week up to 42 weeks (Noble KG, Fifer WP, Rauh VA, Nomura Y, Andrews HF. Academic achievement varies with gestational age among children born at term. Paediatrics. 2012 Aug 1;130(2): e257-64). Further there is evidence of a 3-fold reduction in CS for women with healthy pregnancies who plan birth in a midwife unit, which is a far greater benefit, yet increase in IOL is likely to lead to a decrease in women</p> | <p>Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update and so we are unable to provide more detailed information. The fifteen studies you refer to were part of a separate review looking at earlier versus later induction. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>being able to plan birth in a MU, thus likely increasing overall CS rate with no neonatal benefit.</p> <p>If women are to make an informed decision to accept or decline the offer of IOL wider sources of evidence for short- and longer-term outcomes must be included.</p> <p>Further to this, few studies have examined psychological outcomes for women, and where their responses have been measured, this tends to be methodologically limited and mainly focused on acceptability. This is flawed in the context of trials of this type of intervention, as those who agree to participate in a non-blinded trial are more likely to consider the intervention acceptable a-priori than those who declined participation. Qualitative studies indicate higher rates of pain and distress in women undergoing IOL. There is a need for more large-scale evidence on psychological outcomes in order enable decision-making to be truly informed.</p> | |
| The CHOICE study | Guideline | 005 | 009 | <p>While this guideline makes huge strides in improving guidance on informed choice, in order to align with the UK Montgomery Supreme Court ruling 2015 and GMC consent guidance, this section should make clear that women are offered induction of labour as one of a number of options for how to proceed in pregnancy. As it stands it implies that alternative options should only be outlined if she declines induction. The importance of choice cannot be underestimated as emphasised by all current maternity care policies. In a Health Board with a major focus on informed decision making in maternity care (NHS Grampian), a 2021 service evaluation found a large minority of women perceived there to be no choice at all when induction of labour was offered. This is likely to be a major problem UK-wide.</p> <p>In 2013, a Scottish research priority setting exercise identified research relating to provision of informed choice as a priority, since many of the postnatal women participating</p> | <p>Thank you for your comment. The first two recommendations in the guideline state that women should have all options for mode of birth discussed with them during their pregnancy, and more detail regarding these discussions is provided in subsequent recommendations, so it is very clear that induction is one of a number of options. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on these outcomes. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. We have also added further recommendations to emphasise that the decision to</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>were not aware that they had had a choice about IOL: Helen Cheyne, Christine McCourt, Karen Semple. Mother Knows Best: Developing A Consumer Led Research Agenda For Maternity Care. Midwifery 29 (2013) 705–712. http://dx.doi.org/10.1016/j.midw.2012.06.015</p> <p>A systematic review of evidence on women's experiences of IOL concluded that women generally do not feel sufficiently well informed about induction and many did not consider that they had a meaningful choice of whether to agree to IOL or not: Coates, R, Cupples, G, Foya V, McCourt C, Scamell M. 2018. Women's experiences of induction of labour: qualitative systematic review and thematic synthesis. Midwifery, 2018-10. DOI: 10.1016/j.midw.2018.10.013</p> <p>In addition, there is a considerable wider literature identifying that provision of informed choice in maternity care is not optimal, even when NICE provides clear guidelines on this, supported by decision-aides. For example, Henshall et al. BMC Pregnancy and Childbirth (2016) 16:53 DOI 10.1186/s12884-016-0832-0</p> | <p>have an induction or not, rests with the woman and that decision must be respected.</p> |
| The CHOICE study | Guideline | 006 | 010 | <p><i>In uncomplicated singleton pregnancies, offer induction of labour at 41+0 weeks, to take place then or as soon as possible afterwards</i></p> <p>It is disappointing that cited evidence comes only from RCTs. These studies are under powered and all reported outcomes are immediate/short term. There are wider sources of evidence available including: Stock et al (2012) Outcomes of elective induction of labour compared with expectant management: population-based study. https://doi.org/10.1136/bmj.e2838</p> <p>Dahlen HG, Thornton C, Downe S, De Jonge A, Seijmonsbergen-Schermer A, Tracy S, Tracy M, Bisits A, Peters L. Intrapartum interventions and outcomes for women and children following induction of labour at term in uncomplicated pregnancies: a 16-year population-based linked data study. BMJ open. 2021 Jun 1;11(6):e047040. At: https://BMJopen.BMJ.com/content/11/6/e047040</p> | <p>Thank you for your comment. RCT evidence provides the highest quality level of evidence when comparing the outcomes resulting from different interventions and will always be preferred (when it is available) as a basis for NICE guideline recommendations. Randomisation reduces bias and balances known and unknown participant characteristics, allowing the attribution of any differences in outcome to the interventions under study.</p> <p>The studies by Stock 2012 and Dahlen 2021 are not eligible as these are observational studies that compared induction of labour with spontaneous onset of labour, so these are not eligible as are not RCTs. For further details regarding inclusion and exclusion criteria of studies, please see the review protocol in appendix A of evidence report C.</p> <p>The methodological limitations of the included trials were</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | This is a potential weakness in the guideline methodology used with respect to a complex intervention that may be highly influenced by personal skills, dispositions and experiences of professionals, which are likely to be influenced by preferences of patients (especially in terms of recruitment) and which cannot be blinded. The impossibility of blinding also created the risk of a nocebo effect in control groups. High quality observational studies have an important methodological contribution to evidence about interventions of this type. Variation in findings from such studies highlight the complexity and challenges of drawing general conclusions and the need for contextual understanding and awareness of complexity in interpreting findings – for example, health system and population factors that may influence outcomes; what constitutes expectant management in relevant settings and how this is delivered and experienced; rates of intervention and the potential unintended impacts of different rates on overall safety and outcomes of care. A further methodological challenge for trials of interventions which concern safety in maternity and which cannot be blinded which needs consideration in the guideline approach is the potential impact on care provided and on physiological or psychological wellbeing of patients who have agreed to participate in a trial yet are randomised to the control group. | reflected in the evidence report and taken into consideration by the committee when interpreting the evidence. |
| The CHOICE study | Guideline | 006 | 020 | Consider induction of labour from 39+0 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications associated with continued pregnancy (for example, BMI 30 kg/m² or above, age 35 years or above, with a black, Asian or minority ethnic family background, or after assisted conception). The wording above 'Consider induction of labour' implies that the health care professional is the decision maker as opposed to the woman. Induction of labour should be offered as an option to women for them to consider. No evidence is | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>given to support this very significant change in practice and it is problematic for many reasons:</p> <ol style="list-style-type: none"> 1. The impact on maternity services will be huge: we anticipate that this recommendation could lead to induction of labour rates as high as 80% in some maternity units. As an example, in Scotland in 2019 23% of women who gave birth were 35 years old or older, application of this criteria alone would result in almost a quarter of women being offered IOL at 39 weeks (https://beta.isdscotland.org/topics/maternity-and-births/births). Rhydal et al (2019) comment that with earlier IOL rates will rise by 15%-20%. Not only may this detract from the care of other women, in pregnancy, labour and after birth, but if women consent to IOL and are then kept waiting, this adds considerably to anxiety. 2. There is emerging evidence from epidemiological studies which show child health and development differences even in term children by gestational age – with benefits each week up to 42 weeks. e.g: <ol style="list-style-type: none"> a) Noble KG, Fifer WP, Rauh VA, Nomura Y, Andrews HF. Academic achievement varies with gestational age among children born at term. <i>Pediatrics</i>. 2012 Aug 1;130(2):e257-64. b) Smithers LG, Searle AK, Chittleborough CR, Scheil W, Brinkman SA, Lynch JW. A whole-of-population study of term and post-term gestational age at birth and children's development. <i>BJOG: An International Journal of Obstetrics & Gynaecology</i>. 2015 Sep;122(10):1303-11. c) Neora Alterman , Samantha Johnson , Claire Carson, Stavros Petrou, Oliver | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>Rivero-Arias, Jennifer J Kurinczuk, Alison Macfarlane, Elaine Boyle, Maria A Quigley. Gestational age at birth and child special educational needs: a UK representative birth cohort study. http://dx.doi.org/10.1136/archdischild-2020-320213.</p> <p>d) Victoria Coathup, Elaine Boyle, Claire Carson, Samantha Johnson, Jennifer J Kurinczuk, Alison Macfarlane, Stavros Petrou, Oliver Rivero-Arias, Maria A Quigley. Gestational age and hospital admissions during childhood: population based, record linkage study in England (TIGAR study). <i>BMJ</i> 2020;371:m4075 http://dx.doi.org/10.1136/bmj.m4075</p> <p>3. There is discrepancy as to whether the committee is defining Black, Asian and ethnic minority women as a "high risk group". While guidance document states they are "at a higher risk of complications associated with prolonged pregnancy", the evidence review document labels Black, Asian and ethnic minority women as a "higher risk group" (Evidence review C – Timing, Page 19, Lines 46-50). Categorising all people from Black, Asian and ethnic minority backgrounds as 'high risk' is particularly concerning. There is no evidence that this will have any impact on poor outcomes; therefore, it cannot be claimed as evidence-based guidance that known benefits of this routine intervention would outweigh known harms. In addition, women who identify (or who are identified by others) as coming from Black, Asian and ethnic minority backgrounds will routinely be presented with different options for care from other women. Given the absence of evidence for this, the recommendation risks introducing a form of racial bias into routine maternity care. There is concern that this</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>guideline is an example of 'race-based medicine', or "the system by which research characterising race as an essential, biological variable, translates into clinical practice, leading to inequitable care" (https://doi.org/10.1016/S0140-6736(20)32076-6). If Black, Asian and ethnic minority women are being regarded, as appears to be the case, as a high-risk group based on their skin colour, this implies that race is a biological variable that impacts women's pregnancy outcomes and can thus be controlled for via induction of labour. The guideline renders race and ethnicity the problem, rather than racism and discrimination, despite the recognition from the RCOG, RCM, researchers, advocacy groups, and service users themselves that these are impacting women's care. The oversight in acknowledging this when citing outcomes among Black, Asian and ethnic minority women, as well as the treatment of these women as one group, shows that the committee has failed to consider the optics of this guideline.</p> <p>4. There is concern over the potential for stigmatisation of these groups of women, in that they will be considered not fit enough to carry a pregnancy to term, based on their weight, age, race, ethnic background or fertility.</p> <p>5. There is a risk that this guidance would compound the inequity of access to choice which is already clear from a wide range of studies, further increasing existing inequity. This is particularly unfortunate given that MBRRACE enquiries show that sub-optimal care is a key factor in poor outcomes for many women. This recommendation appears to ignore the evidence in relation to sub-optimal care and instead suggest a 'solution' which is not supported by the evidence and in effect, discriminatory.</p> <p>6. The evidence base for those aged 35 and above is very limited. The most relevant study, the '35/39 trial' did not find evidence of improved neonatal outcomes. It found</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|-----------|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | a small significant decrease in CS rates; however, IOL would reduce access to midwifery units for such women, despite the evidence of a highly significant reduction in CS and operative delivery rates with no difference in neonatal outcomes. | |
| The CHOICE study | Guideline | 010 | 017 - 018 | The guideline states that 'Do not induce labour if there is fetal growth restriction with confirmed fetal compromise.' Without a definition of 'confirmed fetal compromise', this guidance is vague at best and incorrect at worst. Plenty of evidence exists showing that induction of labour in pregnancies affected by fetal growth restriction is not associated with increased incidence of fetal compromise (Please see 1. Boers et al, Induction versus expectant monitoring for intrauterine growth restriction at term: randomised equivalence trial (DIGITAT), BMJ. 2010 Dec 21;341:c7087 2. Familiari et al, Adverse intrapartum outcome in pregnancies complicated by small for gestational age and late fetal growth restriction undergoing induction of labor with Dinoprostone, Misoprostol or mechanical methods: A systematic review and meta-analysis. Eur J Obstet Gynecol Reprod Biol. 2020 Sep;252:455-467.) | Thank you for your comment. Induction of labour in cases of fetal growth restriction was not covered in the scope of this update and so we are unable to add a definition of confirmed fetal compromise. |
| The Doula Association | Guidance | 024 - 025 | 009 - 029 and 001 - 006 | The committee were aware that certain groups of women may be at higher risk of adverse events with prolonged pregnancy and that these women may benefit from earlier induction. The committee noted that in their knowledge and experience, women from the Black, Asian and minority ethnic family background, women with 25BMI of 30 kg/m ² or more, women aged 35 years or more, and women who had assisted conception were at a higher risk of adverse events in a pregnancy that was prolonged beyond term. The committee were aware that this is consistent with national audit data. DRAFT FOR CONSULTATION Inducing labour: NICE guideline DRAFT (May2021) As there was no evidence to identify the optimal timing of induction in these groups the committee made a research recommendation. How the | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. Based on stakeholder feedback we have also replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women with a higher BMI, who are older, who have had assisted conception or from certain ethnic family groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>recommendations might affect practice. The recommendations will decrease the gestational age at which induction of labour is offered to prevent prolonged pregnancy, and may increase the number of women who are offered induction.</p> <p>Why induce early at 39 weeks when trying to prevent continued pregnancy? Normal gestation is 37-42 weeks so offer induction past 42 weeks not before – in uncomplicated singleton pregnancies, why are you suggesting introducing an intervention with no known complications and side effects, that in your own words can cause a negative experience for birthing people and their babies when you can leave them to birth naturally, which is known to be more beneficial physically and mentally for them. Induction can be offered when people reach continued pregnancy, not well before.</p> <p>Induction in people with increased BMI - Caesarean birth was more common among women with obesity compared with women of normal weight following labour induction (Mantel-Haenszel fixed-effect odds ratio, 1.82; 95% CI, 1.55-2.12; $P < .001$). Maternal obesity was associated with a longer time to birth, higher doses of prostaglandins, less frequent success of cervical ripening methods, and higher dose of synthetic oxytocin, as well as a longer time to birth after oxytocin use. Therefore, why consider induction early when you know that it is more likely to cause problems and be unsuccessful thus wasting money, NHS time and causing upset and trauma to birthing people and their babies.</p> <p>35 years or above - With people who are 35 or older, the care provider's perception that a person is "high-risk" because they are older might lead to a higher chance of them having an intervention, regardless of the actual need for the intervention. So there needs to be a lot of conclusive, good quality evidence before putting this recommendation in</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>the guidelines as people are likely to be offered induction for no other reason than bias and that is not ethical. There has been one trial in induction of people aged over 35 and it indicated that induction of labour did not improve outcomes or caesarean rates, and it was too small to determine if induction could reduce the risk of stillbirth or newborn death. There were 600 participants and 0 deaths. (35/39 trial). Therefore, there is not enough evidence to induce people early based solely on their age when they have otherwise uncomplicated singleton pregnancies. This is just ageist and not acceptable to be in the guidance.</p> <p>Black birthing people are 1.5-2 times more likely than white birthing people to have stillbirth at every week of pregnancy (Muglu et al, 2019). Racial health disparities are due to racism in all of its forms, including the effect of prejudice and institutional/systemic racism (Williams and Mohammed, 2013; Bailery at al. 2017). Evidence-based solutions to mitigate racial disparities in pregnancy outcome include doula support and midwife-led models of care (Bohren et al. 2017; Kozhimannil et al. 2016; Thoma et al. 2017; Sandall et al. 2016). In our opinion, this recommendation is treating racism with racism - Black and Brown bodies are not inferior and it is not ethical to induce healthy babies and women with uncomplicated pregnancies at 39 weeks based on the colour of their skin. We believe that inducing black and brown bodied people early will not end the disparities in outcomes.</p> <p>The ARRIVE trial stated that a policy of induction was linked to fewer perinatal deaths compared to expectant management, though absolute rates were small (0.4 versus 3 deaths per 1000, "high-certainty evidence"). Overall, the number needed to treat was 544 people with induction to prevent 1 perinatal death. This again is not ethical, practical, financially viable.</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|-----------|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | The difference in spontaneous birth for ART babies versus spontaneous conception is non-existent beyond 28 weeks so why is routine induction with no complications being suggested? Also, the increased risk of still birth is likely to be attributable to the factors that meant that people were not able to get pregnant in the first place, not the actual procedures themselves, so this would not be relevant for same sex couples, or surrogates, who have undergone Assisted Conception in order to have a baby so this is not individualised care but a blanket inclusion that does not make logical or ethical sense. (Risk of stillbirth and infant deaths after assisted reproductive technology: a Nordic study from the CoNARTas group A A Henningsen et al. Hum Reprod. 2014 May (Pubmed.gov)) | |
| The Doula Association | Guidance | 046 - 047 | Table 2 1.7.5 | We welcome the clearer wording of checking of foetal position before considering induction to improve safety of the procedure | Thank you for your comment. |
| The Doula Association | Guideline | 005 | 004 | <p>The reasons for induction being offered – This needs to have CLEAR medical reasons as to why an induction is being offered as birthing people are very often pressured into induction, do not know they have a choice to decline induction or are told their baby is at 50% increased risk of dying if they don't have an induction. This is not evidence-based information and is coercion and therefore can't be described as an informed decision that is being made.</p> <p><i>"Patient-perceived pressure from clinicians significantly predicts labour induction and caesarean delivery. Efforts to reduce provider-patient miscommunication and minimize potentially unnecessary procedures may be warranted."</i></p> <p>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4545342/</p> <p>Whilst it is clear that not all clinicians are statisticians, guidance needs to be given when asking clinicians to provide information on the increase in risk for pregnant people when considering whether or not to induce labour: the increase in risk should be provided in absolute NOT relative terms thereby giving the deciding family a clear</p> | Thank you for your comment. The guideline provides a number of clear medical reasons why induction should be offered, and for the sections that have been updated on timing of induction and induction in suspected fetal macrosomia, absolute risks have been given to aid discussions, However, a review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on these outcomes. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. We have also added further recommendations to emphasise that the decision to have an induction or not, rests with the woman and that decision must be respected. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>indication of what risks they will potentially expose themselves to.</p> <p>The right to refuse induction of labour must be clearly communicated <i>"Women feel unable to request anything other than what medical staff suggested"</i> Lou S, Hvidman L, Uldbjerg N et al (2018). Women's experiences of post term induction of labor: A systematic review of qualitative studies. Birth: Issues in Perinatal Care. https://doi.org/10.1111/birt.12412</p> | |
| The Doula Association | Guideline | 005 | 009 | <p>The alternative options need to be clearly laid out and explained in the guidelines so that all evidence-based information and choice are clearly stated. There are always pros and cons of all choices and this information should be balanced, not just stating negatives for one option and not the other.</p> <p>Long term impacts of Induction on Child and mother health and well-being also need to be considered and have not been in this guidance or evidence review</p> <p>The evidence in the latest research by Dahlen et al (2021) clearly indicates that "IOL for non-medical reasons was associated with higher birth interventions, particularly in primiparous women, and more adverse maternal, neonatal and child outcomes for most variables assessed." https://bmjopen.bmj.com/content/11/6/e047040</p> | <p>Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on these outcomes. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date.</p> |
| The Doula Association | Guideline | 005 | 018 | <p>The information on the NHS website needs to be evidence-based information that is accurate, true and up to date.</p> <p>NHS website <i>"If you're overdue Induction will be offered if you do not go into labour naturally by 42 weeks, as there will be a higher risk of stillbirth or problems for the baby."</i> This is not clear information and using terms such as 'higher risk' is not giving people enough detail to consider all their options. This information needs to be up to date and clear, showing the figures and actual risks and also include the pros and cons of each choice.</p> <p>NHS website <i>"If your waters break more than 24 hours before labour starts, there's an increased risk of infection to</i></p> | <p>Thank you very much for comment. We will address all your key points individually.</p> <p>1. Information on the NHS website is updated based on NICE guidelines, so once the induction of labour guideline has been updated, the NHS website will be updated. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. As detailed information on risks and benefits is best</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p><i>you and your baby.</i>" Where is the evidence to support this? If waters break before 37 weeks, expectant management is deemed appropriate. Why is this not the case after 37 weeks? What evidence is there for a 24 hour cut off period? This used to be 96 hours and many trusts had a 48 hour guideline.</p> <p>Some trusts are stating reasons for induction that have not been shown in research studies. E.g. NHS Isle of Wight Induction of Labour document states that <i>"there is an increased risk of a baby developing problems as the placenta becomes less efficient"</i> There is no evidence to support this statement, so the information is not evidence-based that is being given as a reason for induction. Birthing people are therefore, offering their consent based on FALSE information.</p> <p>One approach to limiting the unnecessary use of antimicrobials is to use the "sepsis calculator" developed by Puopolo et al ^[205] to estimate the probability of early-onset sepsis (EOS) using maternal risk factors in neonates born at 34 weeks of gestation or Later. Utilizing data from more than 600,000 infants at at least 34 weeks' gestation at birth, the investigators developed a model for EOS risk prediction based on objective maternal factors, then combined that model with findings from examination of the infants. ^[206] The model uses three categorical variables: group B <i>Streptococcus</i> (GBS) status (positive, negative, uncertain), maternal intrapartum antimicrobial treatment (GBS-specific or broad spectrum), and intrapartum prophylaxis or treatment given 4 hours or longer before delivery (yes, no) in addition to the following continuous variables: highest maternal intrapartum temperature (centigrade or Fahrenheit), gestational age (weeks and days), and duration of rupture of membranes (hours). A predicted probability per 1,000 live births can be estimated using the calculator (http://newbornsepsiscalculator.org). Several retrospective studies demonstrated that the use of the sepsis calculator in a population of well-appearing neonates (≥34 weeks'</p> | <p>discussed with a healthcare professional it is likely that this level of detail will be included only in the NICE guidelines, and not transferred to the website.</p> <p>2. Likewise, it is hoped that NHS organisations will update their local information resources based on the latest version of the NICE guideline when it is published.</p> <p>3. Guidance on the use of the sepsis calculator is included in the NICE guideline on neonatal infection (NG195) so has not been included in the induction of labour guideline.</p> <p>4. There is no mention or inference in the induction of labour guideline of the concept of an ageing or failing placenta, and the recommendations on timing of induction are based on a systematic review of evidence comparing earlier with later induction, and do not hypothesize on a causality.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>gestation) exposed to the clinical maternal diagnosis of chorioamnionitis would have substantially reduced the proportion of neonates undergoing laboratory tests and receiving antimicrobial agents. [202, 207, 208, 209] https://www.cochrane.org/CD005302/PREG_it-better-baby-be-born-immediately-or-wait-labour-start-spontaneously-when-waters-break-or-after-37 - Planned early birth (compared with expectant management) after PROM at term MAY help to reduce infection for women without increasing the need for a caesarean section, and neonatal infection may also be reduced. However, evidence about longer-term effects on children is needed. There is low quality evidence to suggest that planned early birth (with induction methods such as oxytocin or prostaglandins) reduces the risk of maternal infectious morbidity compared with expectant management for PROM at 37 weeks' gestation or later.</p> <p>A review of the available evidence indicates that the placenta does not undergo a true aging change during pregnancy. There is, in fact, no logical reason for believing that the placenta, which is a foetal organ, should age while the other foetal organs do not: the situation in which an individual organ ages within an organism that is not aged is one which does not occur in any biological system. The persisting belief in placental aging has been based on a confusion between morphological maturation and differentiation and aging, a failure to appreciate the functional resources of the organ, and an uncritical acceptance of the overly facile concept of "placental insufficiency" as a cause of increased perinatal mortality. https://fn.bmj.com/content/77/3/F171 https://www.ajog.org/article/S0002-9378(17)30756-1/pdf - MAY contribute to placental ageing and still birth but Not Conclusive evidence, just a hypothesis that certain factors were present in still birth and other placentas https://fn.bmj.com/content/77/3/F171 - Acidosis was attributed more to a reduction in amniotic fluid level than</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>placental degradation “The two most potent causes of increased morbidity in prolonged pregnancy are therefore clearly unrelated to any change in placental functional capacity. Examination of placentas from prolonged pregnancies shows no evidence of any increased incidence of gross placental abnormalities, such as infarcts, calcification, or massive perivillous fibrin deposition. The most characteristic histological abnormality, found in a proportion of cases but certainly not in all, is decreased fetal perfusion of the placental villi.¹³ The fetal villous vessels are normal in placentas from prolonged pregnancies⁴⁴ and Doppler flow velocimetry studies have, in general but not unanimously, indicated that there is no increased fetal vascular resistance in such placentas.⁴⁵⁻⁴⁷ The decreased fetal perfusion is therefore probably a consequence of oligohydramnios, because umbilical vein flow studies have shown that fetal blood flow to the placenta is often reduced in cases of oligohydramnios.⁴⁸ It has to be admitted that the pathophysiology of prolonged pregnancy has not been fully elucidated. It seems, however, quite clear that any ill effects which may befall the foetus in prolonged gestations can not be attributed to placental insufficiency or senescence.”</p> | |
| The Doula Association | Guideline | 005 | 022 | <p>“Support the woman in whatever decision she makes” We welcome this inclusion in the guidance. Especially in light of the evidence from https://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/s12884-020-03137-x</p> <p>“Clinicians counselling mothers concerning the need for labour induction should be aware of mothers’ perceptions about birth and engage in true shared decision making in order to avoid the maternal perception of being pressured into labour induction. Experience about people not knowing they had a choice, people being chastise for their decision etc”</p> <p>“One in six (16%) women who planned to have a vaginal birth reported feeling pressure from their provider to have an</p> | <p>Thank you for your comment. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline. We have also included that this decision must be recorded in the woman's notes.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | induction (Table 2), with more women who actually had an induction reporting pressure (27%) than those who did not (7%), Non-Latina white women who had an induction were most likely to report having felt pressured (36%). Other groups reporting significantly higher levels of perceived pressure included women 35 or older (21%), those with at least a college education (21%), those who were obese prior to starting their pregnancy (23%), first time mothers (20%) and women who had reached week 41 of their pregnancy (26%). We also found almost 1 in 4 mothers (24%) who experienced an induction prior to 39 weeks reporting feeling pressure to do so, though most of those cases involved a medical indication. Among mothers with an elective induction at less than 40 weeks, 17% reported feeling pressure to do so. | |
| The Doula Association | Guideline | 006 | 010 | <p>In uncomplicated singleton pregnancies, offer induction of labour at 41+0 10weeks, to take place then or as soon as possible afterwards. [2021] – We strongly object to this addition to the NICE guidance due to lack of evidence as to an appropriate time to offer induction as stated in the guidance.</p> <p>A due date is a construct from blanket recommendations of induction at 41 weeks are not appropriate, proportionate or individualised care. If there are not risk factors, there is not a strong enough body of evidence to recommend this in the guidance as there are mounting studies showing not only the short-term physical and mental negative impacts that induction can have but also the long-term impacts on maternal mental and child physical health. Dahlen et al (2021)</p> <p>Also, due dates are based on a German doctor from 1812 based on a theory that pregnancy lasts 10 lunar months, which was based on the bible. This is NOT evidence-based care. Different people have different cycle lengths, the lunar cycle is in fact 29.5 and not 28 days so the calculation is inaccurate, Parikh's formula takes cycle length into</p> | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion of the risks and benefits with the woman so she can make an informed decision. The committee agreed that dating scans are usually accurate to within a few days, and so for the majority of women discussions about their due date and their planned mode of birth will not lead to inappropriate interventions or the birth of preterm babies. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | consideration but doesn't allow for irregular cycles or differ from the average cycle length. Ultrasound dating may be accurate to within 3-5 days if performed before 12 weeks but the accuracy decreases as the baby grows, the margin for error in the 2 nd trimester being 8 days and in the 3 rd trimester being 14 days... This is NOT accurate data to be making life changing, sweeping guidelines on. Only 3-5% of babies are born on their estimated due date – This is NOT an accurate dating system. 80% of babies are born 2 weeks either side of the EDD so why not leave the guidelines at offering induction at 42 weeks as there is not sufficient evidence to move the recommended date earlier. It is not ethical or appropriate. | |
| The Doula Association | Guideline | 006 | 012 | <p>Explain to women that the risks associated with a pregnancy continuing beyond 41+0 weeks increase over time, and include:</p> <ul style="list-style-type: none"> •increased likelihood of caesarean birth •increased likelihood of the baby needing admission to a neonatal intensive care unit 16 •increased likelihood of stillbirth and neonatal death 17 •a possible increased likelihood of assisted vaginal birth (using forceps 18 or ventouse).[2021] <p>If these risks are stated in the NICE guidance, the risks of induction itself also need to be clearly stated. All risks should be given clear indication of their likelihood compared to other outcomes so informed decisions about care can be made. Best practice involves clearly stating numbers and comparisons so people can make an informed decision. Saying an increased risk of something tells you nothing because it could be an 0.1% increased risk or a 99% increased risk and that will change how people make informed decisions about their care</p> <p>If information is not clearly given at appointments and people are coerced into having an induction, this is directly contravening the Hippocratic oath as something that knowingly causes harm is being advocated for without a</p> | Thank you for your comment. Based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. We have added a cross-reference to this information from the recommendations on induction for prolonged pregnancy. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | balanced option of expectant management and the pros and cons for this being stated. | |
| The Doula Association | Guideline | 006 | 020 | <p>Consider induction of labour from 39+0 weeks in women with otherwise uncomplicated singleton pregnancies who are at a higher risk of complications associated with continued pregnancy (for example, BMI 2230kg/m² or above, age 35 years or above, with a black, Asian or minority ethnic family background, or after assisted conception).</p> <p>Why induce early at 39 weeks when trying to prevent continued pregnancy. Normal gestation is 37-42 weeks so offer induction past 42 weeks not before – in uncomplicated singleton pregnancies, why are guidelines suggesting introducing an intervention with known complications and side effects that in your own words can cause a negative experience for birthing people and their babies when you can leave them to birth naturally, which is known to be more beneficial physically and mentally for them. Induction can be offered when people reach continued pregnancy, not well before.</p> <p>Induction in people with increased BMI- Cesarean birth was more common among women with obesity compared with women of normal weight following labour induction (Mantel-Haenszel fixed-effect odds ratio, 1.82; 95% CI, 1.55-2.12; <i>P</i> < .001). Maternal obesity was associated with a longer time to birth, higher doses of prostaglandins, less frequent success of cervical ripening methods, and higher dose of synthetic oxytocin, as well as a longer time to birth after oxytocin use. Therefore why consider induction early when you know that it is more likely to cause problems and be unsuccessful thus wasting money, NHS time and causing upset and trauma to birthing people and their babies.</p> <p>Suggesting that the BMI is used as a standalone tool for measuring risk or as a risk indicator puts racial minorities at increased risk; it is well known that the BMI has a racial bias (NICE has produced research on the subject matter). It is generally weighted towards White people but also ignores variables such as lifestyle, bone density and muscle mass.</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>For instance, an active gym goer who regularly carries out weight bearing exercises is more likely to fall into the overweight/obese range on the index because of their healthy lifestyle will likely result in increased muscle mass and bone density. Using outdated tools such as the BMI as standalone risk indicators increases risk for minority races and people who actively exercise.</p> <p>35 years or above - "With people who are 35 or older, the care provider's perception that a person is "high-risk" because they are older might lead to a higher chance of them having an intervention, regardless of the actual need for the intervention. So there needs to be a lot of conclusive, good quality evidence before putting this recommendation in the guidelines as people are likely to be offered induction for no other reason than bias and that is not ethical.</p> <p>There has been one trial in induction of people aged over 35 and it indicated that induction of labour did not improve outcomes or cesarean rates, it was too small to determine if induction could reduce the risk of stillbirth or newborn death. There were 600 participants and 0 deaths. (35/39 trial). Therefore there is not enough evidence to induce people early based solely on their age when they have otherwise uncomplicated singleton pregnancies. This is just ageist and not acceptable to be in the guidance.</p> <p>Black birthing people are 1.5-2 times more likely than white birthing people to have stillbirth at every week of pregnancy (Muglu et al, 2019). Racial health disparities are due to racism in all of its forms, including the effect of prejudice and institutional/systemic racism (Williams and Mohammed, 2013; Bailery et al. 2017). Evidence-based solutions to mitigate racial disparities in pregnancy outcome include doula support and midwife-led models of care (Bohren et al. 2017; Kozhimannil et al. 2016; Thoma et al. 2017; Sandall et al. 2016). Race specific guidance on IOL reinforces racist idea that minority people's bodies are deficient and are at</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>issue rather than addressing the disparity in quality of care that causes the statistical divergence in risk. This specific guidance gives room for the healthcare system not to pick up mistreatment of monitory patients and allows room for preventable deaths to exist without being picked up. Where is the evidence that putting people from all of these "categories" on a highly medicalised induction pathway will close the disparity gap?</p> <p>This will lead to severely limited choices for these people (no birth centres / homebirths / midwifery-led care - all of which improve outcomes)</p> <p>This recommendation is treating racism with racism - black and brown bodies are not inferior and it is not ethical to induce healthy babies and women with uncomplicated pregnancies at 39 weeks based on the colour of their skin. Inducing black and brown bodied people early will not end the disparities in outcomes</p> <p>The ARRIVE trial stated that a policy of induction was linked to fewer perinatal deaths compared to expectant management, though absolute rates were small (0.4 versus 3 deaths per 1000, "high-certainty evidence"). Overall, the number needed to treat was 544 people with induction to prevent 1 perinatal death. This again is not ethical, practical, or financially viable.</p> <p>The difference in spontaneous birth for ART babies versus spontaneous conception is non-existent beyond 28 weeks so why is routine induction with no complications being suggested? Also the increased risk of still birth is likely to be attributable to the factors that meant that people were not able to get pregnant in the first place, not the actual procedures themselves, so this would not be relevant for same sex couples or surrogates who have undergone Assisted Conception in order to have a baby, so this is not individualised care but a blanket inclusion that does not make logical or ethical sense.</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | Risk of stillbirth and infant deaths after assisted reproductive technology: a Nordic study from the CoNARTas group A A Henningsen et al. Hum Reprod. 2014 May (Pubmed.gov) | |
| The Doula Association | Guidance | 008 | 005 - 006 | <p>"When making a shared decision, take into consideration the following factors"</p> <p>The decision is NOT shared. The discussion should include the birthing person, options should be presented clearly to them but the decision is their own and not anyone else's. This needs to be made clear in the guidance as bodily autonomy is very clear in human rights law and needs to be clear in the NICE guidance.</p> | <p>Thank you for your comment. The NICE definition of shared decision-making is a collaborative process, making sure the person understands the risks and benefits through discussion and we think this applies to decisions about maternity choices, although the final decision is ultimately the woman's. We have reviewed the use of the terminology 'shared decision-making' throughout the guideline and have amended it in a number of places. However, there are some circumstances where there may be factors that relate to the decision that are within the remit of the healthcare professional too - such as their professional responsibility to act in the woman's best interests, and in this example to determine if suitable neonatal facilities are available. In this case we think the decision would therefore be shared, and so have not amended it in this recommendation.</p> |
| The Doula Association | Guidance | 008 | 021 - 022 | <p>induction of labour as soon as possible or expectant management for up to 24 hours.</p> <p>The evidence for a 24 hour window when people who are not at term are offered expectant management sometimes for weeks seems to contradict your own evidence review and guidance which states: "1.1.10.3 Imprecision and clinical importance of effects Neonatal infections were lower in the immediate delivery group compared with expectant management. When the 2 included studies were meta-analysed, this effect had a high degree of imprecision, and was non-significant, with confidence intervals crossing the line of no effect." How can one low quality study be used to effect a nationwide policy?</p> <p>https://www.nice.org.uk/guidance/ng195/evidence/c-timing-of-delivery-to-reduce-the-risk-of-earlyonset-neonatal-infection-pdf-9078465712</p> | <p>Thank you for your comment. The evidence you are referring to is in the evidence review carried out as part of the development of the neonatal infection guideline (NG195), and relates to women with preterm prolonged rupture of the membranes between 34 and 37+6 weeks of pregnancy with urine or vaginal GBS detected during the current pregnancy, and so does not apply to the recommendations for women without GBS. However, the evidence goes on to say 'When the study that was only partially applicable (because not all women had prolonged rupture of membranes) was removed from the analysis, the size of the effect was much larger, and was statistically significant. There was less imprecision in the results, and the confidence intervals did not cross the line of no effect. The committee agreed that the point estimate for both the meta-analysed result and the result with the partially applicable study removed represented clinically very important effects as neonatal infection is such a serious</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | outcome'. The management of PROM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not made any changes to the recommendations on the length of time that expectant management is an option. |
| The Doula Association | Guidance | 008 | 002 | Expectant management until 37+0 weeks. [2008, updated 2021 Your own evidence review and guidance states: "1.1.10.3 Imprecision and clinical importance of effects Neonatal infections were lower in the immediate delivery group compared with expectant management. When the 2 included studies were meta-analysed, this effect had a high degree of imprecision, and was non-significant, with confidence intervals crossing the line of no effect." How can one low quality study be used to effect a nationwide policy? Why can expectant management not be continued as long as mother and baby are healthy? https://www.nice.org.uk/guidance/ng195/evidence/c-timing-of-delivery-to-reduce-the-risk-of-earlyonset-neonatal-infection-pdf-9078465712 | Thank you for your comment. The evidence you are referring to is in the evidence review carried out as part of the development of the neonatal infection guideline (NG195), and relates to women with preterm prolonged rupture of the membranes between 34 and 37+6 weeks of pregnancy with urine or vaginal GBS detected during the current pregnancy, and so does not apply to the recommendations for women without GBS. However, the evidence goes on to say 'When the study that was only partially applicable (because not all women had prolonged rupture of membranes) was removed from the analysis, the size of the effect was much larger, and was statistically significant. There was less imprecision in the results, and the confidence intervals did not cross the line of no effect. The committee agreed that the point estimate for both the meta-analysed result and the result with the partially applicable study removed represented clinically very important effects as neonatal infection is such a serious outcome'. The management of PPRM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not made any changes to the recommendations on the length of time that expectant management is an option. |
| The Doula Association | Guidance | 008 | 012 | Risks for induction also need to be included in this discussion in order to make a balanced point from which the birthing person can make an informed decision. Here only the risks of not inducing have been included. They need to be presented in the guidance as they will be presented in practice. Any <u>risk discussed should be provided in absolute NOT relative terms thereby giving the deciding family a clear</u> | Thank you for your comment. The management of PPRM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not reviewed the data on the risks and benefits of induction of labour compared to expectant management in preterm |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <u>indication of what risks they will potentially expose themselves to.</u> | prelabour rupture of the membranes, and so have not been able to make the changes you suggest. |
| The Doula Association | Guidance | 009 | 004 - 007 | a woman has prelabour rupture of membranes at term (at or over 37+04weeks) and has had a positive group B streptococcus test at any time in their current pregnancy, offer immediate induction of labour or caesarean birth.[2021] Surely they should also be offered expectant management, even though there is an increased risk, the choice is still that of the birthing person and is clear in human rights law that their decision should be respected even if it risks theirs or their baby's life | Thank you for your comment. The evidence for this recommendation comes from the new NICE guideline on neonatal infection and showed a higher rate of neonatal infection in the expectant management group. The guideline therefore recommends that healthcare professionals 'offer' immediate birth. As with all healthcare decisions it is the woman's choice whether or not to take up that offer, but it would not be evidence-based for healthcare professionals to offer expectant management as another equal alternative. |
| The Doula Association | Guidance | 009 | 021 - 024 | We welcome the inclusion of supporting the birthing person's decision in accordance with human rights law | Thank you for your comment. |
| The Doula Association | Guidance | 013 | 005 - 006 | <p>"That membrane sweeping might make it more likely that labour will start naturally, and so reduces the need for induction of labour" - We do not feel that offering more membrane sweeping is justified with the lack of evidence for effectiveness and the potential increased risk of infection https://www.cochrane.org/CD000451/PREG_membrane-sweeping-induction-labour "Membrane sweeping appears to be effective in promoting labour but current evidence suggests this did not, overall, follow-on to unassisted vaginal births. Membrane sweeping may reduce formal induction of labour. Only three studies reported on women's satisfaction with membrane sweeping. Women reported feeling positive about membrane sweeping. While acknowledging that it may be uncomfortable, they felt the benefits outweighed the harms and most would recommend it to other women. Further research is needed to confirm our review findings and to identify the ideal time for membrane sweep and whether having more than one sweep would be beneficial. Further information on women's views is also needed.</p> <p>Evidence Based Birth says: "However, in general, there was a high risk of bias for performance bias due to the fact that all 44 studies did not do any masking in the study. This is</p> | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps. However, we have now amended the recommendations on membrane-sweeping to reflect that it may be considered a method to induce labour, have clarified that it should be offered at antenatal appointments after 39 weeks, and expanded the recommendation on discussing it with women and obtaining their consent. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>sometimes called blinding. Masking would mean that clinicians and researchers did not know who was receiving which treatment, either the actual treatment or the no treatment or the placebo or sham. When no masking is used, as with all of these studies, this may lead to performance bias in which clinicians may be biased towards giving better care to the treatment group in hopes that the treatment will be shown to be effective. For example, if a provider knew someone was in the treatment group for membrane sweeping, they might delay scheduling a formal induction in hopes that the person in the treatment group will go into spontaneous labor on their own.</p> <p>https://evidencebasedbirth.com/updated-evidence-on-the-pros-and-cons-of-membrane-sweeping/</p> <p>Membrane sweeping IS a form of physical induction and intervention and should be clearly stated as such. We do not naturally or physiologically do this to ourselves so it is therefore an intervention that can disrupt the physiological process of labour. It IS and intervention</p> <p>"The aim of this Cochrane Review is to find out if membrane sweeping is a safe and effective way of inducing labour* at or near term and if it is more effective than the formal methods of induction."</p> <p>As you can see from this Cochrane review, a sweep is a way of inducing labour. It is a form of physical or mechanical induction</p> <p>Also, membrane sweeping is a medical procedure that requires informed consent so if this medical procedure is NOT to induce labour, what is it for?</p> <p>Sara Wickham makes these observations:</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>https://www.sarawickham.com/articles-2/what-is-a-stretch-and-sweep/ The stretch and sweep is a controversial procedure for a number of reasons. As above, it isn't as effective as some people would like you to think. it will only work for a few people and it doesn't bring labour forward by much anyway. It has potential downsides as well as potential benefits. There's another reason it's controversial. Some women have found that this procedure is offered or suggested during an antenatal visit without much prior discussion. And, shockingly, sometimes it is suggested while a midwife or doctor is in the middle of a vaginal examination. This is not OK. Neither is it OK for someone to do this without your full consent. A recent review of the literature on this has confirmed some of these things. Roberts et al (2020) found that, "There is a lack of evidence around women's information needs, decision-making and experiences of membrane sweeping. This is concerning, especially in the context of rising rates of formal induction of labour. Further research is needed to investigate how women are being offered membrane sweeping and what information women need to make informed choices about membrane sweeping to promote spontaneous labour." Therefore we object to more membrane sweeping being offered, at earlier appointments AND furthermore insist that it is a mechanical form of attempting to induce labour</p> | |
| The Doula Association | Guidance | 013 | 010 | We are encouraged by the inclusion of obtaining informed consent before performing a sweep. It is essential. | Thank you for your comment. |
| The Doula Association | Guidance | 013 | 014 | <p>At antenatal visits from 39+0weeks, offer women a vaginal examination for membrane sweeping. [2008, amended 2021 https://www.sarawickham.com/articles-2/what-is-a-stretch-and-sweep/ The stretch and sweep is a controversial procedure for a number of reasons. As above, it isn't as effective as some people would like you to think. it will only work for a few</p> | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps. However, we have now amended the recommendations on membrane-sweeping to reflect that it may be considered a method to induce labour, have clarified that it should be offered at |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>people and it doesn't bring labour forward by much anyway. It has potential downsides as well as potential benefits. There's another reason it's controversial. Some women have found that this procedure is offered or suggested during an antenatal visit without much prior discussion. And, shockingly, sometimes it is suggested while a midwife or doctor is in the middle of a vaginal examination. This is not OK. Neither is it OK for someone to do this without your full consent.</p> <p>A recent review of the literature on this has confirmed some of these things. Roberts et al (2020) found that, "There is a lack of evidence around women's information needs, decision-making and experiences of membrane sweeping. This is concerning, especially in the context of rising rates of formal induction of labour. Further research is needed to investigate how women are being offered membrane sweeping and what information women need to make informed choices about membrane sweeping to promote spontaneous labour."</p> <p>Therefore, we object to more membrane sweeping being offered, at earlier appointments AND furthermore insist that it is a mechanical form of attempting to induce labour</p> <p>How about increased risk of infection with 5+ vaginal exams – has this been considered alongside the effectiveness/lack thereof of vaginal sweeps? https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7183634/</p> | antenatal appointments after 39 weeks, and expanded the recommendation on discussing it with women and obtaining their consent. |
| The Doula Association | Guidance | 017 | 015 | "This can include simple analgesia, labour in water and epidural 15analgesia. [2008, amended 2021]" We welcome the inclusion of water as a pain management option and hope that it will actually be provided in trusts as it seems that it is often not offered or facilitated even when requested | Thank you for your comment. We hope that inclusion of water as pain management will encourage its availability. |
| The Doula Association | Guidance | 018 | 023 | Offering a rest period if clinically appropriate – We welcome the inclusion of this in the guidance | Thank you for your comment. |
| The Doula Association | Guidance | 020 | 028 | Why is membrane sweeping not considered a form of induction in this guidance when it is a form of physical | Thank you for your comment. We have amended the recommendations on membrane sweeping, so there is no |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|-----------|---------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | induction that would not occur naturally? We do not naturally separate our membranes with two fingers; therefore it is a form of physical induction. It is not physiological and is an intervention with associated risks. This should be made clear in the guidance for the reasons stated above. | longer an inference that membrane sweeping is not a method of induction, and also amended this in the 'terms used' section. |
| The Doula Association | Guidance | 021 | 018 | Changes to the recommended time for induction should not be made until there is evidence to show that it would be beneficial changing the recommendation from 42 to 41 weeks. If there is not enough evidence for appropriate timing of induction, which is stated there is not, the change to the guidance should not be made. This evidence is needed BEFORE the recommendation is made, not after, as induction is known to have negative consequences for everyone involved, including financially for the NHS, so this should not be introduced as a guideline until such a time as there is clear evidence. | Thank you for your comment. We have amended the recommendations on timing of induction to include more detail on the differences in risks between earlier and later induction and to advise that these risks should be discussed with women so they can make an individualised decision about whether to be induced for prolonged pregnancy or not. However, the data available only considers induction broken down by weeks of gestation and the committee considered that data broken down by shorter time intervals may provide useful information for women. |
| The Doula Association | Guidance | 022 | 017 | We welcome this research and feel that extra membrane sweeps from 39+0 weeks should not be introduced in the guidance until such a time as there is evidence showing the efficacy and highlighting possible increased risk of infection, risk of rupture of membranes and the further possible cascade of interventions, etc compared to the possible questionable benefits. | Thank you for your comment. Membrane-sweeping was not within the scope of this guideline update, and this research recommendation was carried forward from the previous version of the guideline as the committee were aware that there was still a lack of evidence for some of these aspects of membrane-sweeping. |
| The Doula Association | Guideline | 024 | 019 - 021 | “There was evidence that caesarean birth, perinatal mortality and neonatal intensive care unit admission are reduced by earlier induction of labour (at41+0weeks) compared to later induction (at 42+0weeks or after), and there may also be a reduction in assisted vaginal birth with earlier induction. However, there was not enough evidence to identify the optimal timing of induction more precisely and so the committee made a research recommendation.” Surely a recommendation that does not have enough evidence to determine the effective timing should not be introduced when there are known negative impacts on maternal and infant outcomes with induction. Especially when due dates are not proven to be accurate at all and a blanket approach is going to have a negative impact on a | Thank you for your comment. We will address your points in turn: 1. The optimal timing referred to in this sentence relates to the use of individual patient data to determine if there is a gestational age at which the risks of continuing with the pregnancy outweigh the benefits. This is explained in more detail in the research rationale in appendix L of evidence review C. 2. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>huge number of people's birth experiences. This is not individualised care. It is not ethical or appropriate to make a recommendation this far reaching and sweeping in nature. Especially considering the findings from Dahlen et al (2021) That showed those who had labour induced had higher rates of epidural/spinal analgesia, caesarean section (except for multiparous women induced between 37-40 weeks), instrumental birth, episiotomy and PPH than women with a similar risk profile who went into labour spontaneously. The children also had higher odds of birth asphyxia, birth trauma, respiratory disorders, major resuscitation at birth and hospitalisation for infection up to the age of 16" Surely this will cost birthing people, babies and the NHS far more than expectant management to 42 weeks.</p> <p>SWEPIS STUDY "It could be argued that the higher mortality in the expectant management group in our study is partly due to lack of routine foetal surveillance with cardiotocography or ultrasonography between 41 and 42 weeks unless there were clinical signs of complications. In general, however, the adverse perinatal outcomes were not higher in the expectant management group in our trial compared with the INDEX trial, and the median gestational age at delivery was higher in the expectant management group in our trial (292 days) than in the INDEX trial (289 days), which could augment mortality rates. No perinatal deaths occurred among women recruited in the Stockholm region, where all women are offered a routine ultrasound scan at 41 weeks (before randomisation), with the aim of identifying women with an increased risk for adverse outcomes.</p> <p>230 women would need to be induced to save one life. Is this ethical? Cost effective and taking into consideration the long-term health and mental wellbeing impacts that Induction has been shown to cause in several studies.</p> | <p>induction.</p> <p>3. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion of the risks of later versus earlier induction with the woman (and we have included tabulated details of absolute risks), so she can make an informed decision. Based on these changes to the guideline we have updated this rationale section.</p> |
| The Doula Association | Guidance | 025 | 001 - 024 | <p>In women who did not have a positive group B streptococcus test, but who had prelabour rupture of the membranes after 37+0 weeks, the committee were aware that expectant</p> | <p>Thank you for your comment. The evidence you are referring to is in the evidence review carried out as part of the development of the neonatal infection guideline</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|----------|---------|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>management for 24 hours was an option as the risk of infection to the baby was low. However, after that period, induction should be advised.</p> <p>Your own evidence review and guidance states: "1.1.10.3 Imprecision and clinical importance of effects Neonatal infections were lower in the immediate delivery group compared with expectant management. When the 2 included studies were meta-analysed, this effect had a high degree of imprecision, and was non-significant, with confidence intervals crossing the line of no effect." How can one low quality study be used to affect a nationwide policy? This is no logical or ethical.</p> <p>https://www.nice.org.uk/guidance/ng195/evidence/c-timing-of-delivery-to-reduce-the-risk-of-earlyonset-neonatal-infection-pdf-9078465712</p> | <p>(NG195), and relates to women with preterm prolonged rupture of the membranes between 34 and 37+6 weeks of pregnancy with urine or vaginal GBS detected during the current pregnancy, and so does not apply to the recommendations for women without GBS. However, the evidence goes on to say 'When the study that was only partially applicable (because not all women had prolonged rupture of membranes) was removed from the analysis, the size of the effect was much larger, and was statistically significant. There was less imprecision in the results, and the confidence intervals did not cross the line of no effect. The committee agreed that the point estimate for both the meta-analysed result and the result with the partially applicable study removed represented clinically very important effects as neonatal infection is such a serious outcome'.</p> <p>The management of PPRM was not within the scope of this guideline update, apart from ensuring the recommendations were in-line with the new neonatal infection guideline, so we have not made any changes to the recommendations on the length of time that expectant management is an option.</p> |
| The Doula Association | Guidance | 031 | Table 1 1.2.1.1 | <p>Women with uncomplicated pregnancies should be given every opportunity to go into spontaneous labour. This recommendation has been deleted because the next recommendation states which women with uncomplicated pregnancies should be offered induction, and so the committee agreed this recommendation was unnecessary.</p> <p>*We strongly disagree and believe this recommendation IS necessary and there is not enough evidence for the appropriate timing of induction for a sweeping statement of offering induction at 41 weeks to be made. This is not individualised care</p> <p>The evidence in the latest research by Dahlen et al (2021) clearly indicates that "IOL for non-medical reasons was</p> | <p>Thank you for your comment. We will address your points in turn.</p> <ol style="list-style-type: none"> 1. Based on stakeholder feedback we have reinstated this recommendation into the guideline. 2. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion of the risks of later versus earlier induction with the woman (and we have included tabulated details of absolute risks), so she can make an informed decision. 3. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|----------|---------|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | associated with higher birth interventions, particularly in primiparous women, and more adverse maternal, neonatal and child outcomes for most variables assessed." This includes long-term health implications for birthing person and children. https://bmjopen.bmj.com/content/11/6/e047040 | induction. 4. We have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report. |
| The Doula Association | Guidance | 031 | Table 1 1.2.1.2 | In uncomplicated singleton pregnancies, offer induction of labour at 41+0 weeks, to take place then or as soon as possible afterwards. 1.2.3Explain to women that the risks associated with a pregnancy continuing beyond 41+0 weeks increase over time, and include: increased likelihood of caesarean birth• increased likelihood of admission of the baby to a neonatal intensive care unit• increased likelihood of stillbirth and neonatal death• a possible increased likelihood of assisted vaginal birth (using forceps or ventouse). [2021] *No risks of induction are included here – this is hugely biased presentation of information and does not constitute evidence to make an informed decision about care. There are no relative risks mentioned here and these are often presented in a catastrophic way to coerce agreement into induction rather than offering evidence-based information upon which the birthing person can make an informed decision | Thank you for your comment. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based. It was not within the scope of this update to review the risks and benefits of induction compared to expectant management, but the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction. |
| The Doula Association | Guidance | 038 | Table 2 1.2.3.2 | Induction of labour is appropriate approximately 24 hours after prelabour rupture of the membranes at term. What evidence are you basing this sweeping statement on when your own reviews of the evidence were not conclusive: "1.1.10.3 Imprecision and clinical importance of effects Neonatal infections were lower in the immediate delivery group compared with expectant management. When the 2 included studies were meta-analysed, this effect had a high degree of imprecision, and was non-significant, with confidence intervals crossing the line of no effect." How can one low quality study be used to effect a nation wide policy? This is unethical and not logical | Thank you for your comment. The evidence you are referring to is in the evidence review carried out as part of the development of the neonatal infection guideline (NG195), and relates to women with preterm prolonged rupture of the membranes between 34 and 37+6 weeks of pregnancy with urine or vaginal GBS detected during the current pregnancy, and so does not apply to the recommendations for women without GBS. However, the evidence goes on to say "When the study that was only partially applicable (because not all women had prolonged rupture of membranes) was removed from the analysis, the size of the effect was much larger, and was statistically significant. There was less imprecision in the results, and the confidence intervals did not cross the line of no effect. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------|----------|---------|------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | https://www.nice.org.uk/guidance/ng195/evidence/c-timing-of-delivery-to-reduce-the-risk-of-earlyonset-neonatal-infection-pdf-9078465712 | The committee agreed that the point estimate for both the meta-analysed result and the result with the partially applicable study removed represented clinically very important effects as neonatal infection is such a serious outcome'. |
| The Doula Association | Guidance | 041 | Table 2 1.3.4 | <p>1.3.4At antenatal visits from 39+0 weeks, offer women a vaginal examination for membrane sweeping. [2008, amended 2021] https://www.sarawickham.com/articles-2/what-is-a-stretch-and-sweep/ The stretch and sweep is a controversial procedure for a number of reasons. As above, it isn't as effective as some people would like you to think. it will only work for a few people and it doesn't bring labour forward by much anyway. It has potential downsides as well as potential benefits. There's another reason it's controversial. Some women have found that this procedure is offered or suggested during an antenatal visit without much prior discussion. And, shockingly, sometimes it is suggested while a midwife or doctor is in the middle of a vaginal examination. This is not OK. Neither is it OK for someone to do this without your full consent. A recent review of the literature on this has confirmed some of these things. Roberts et al (2020) found that, "There is a lack of evidence around women's information needs, decision-making and experiences of membrane sweeping. This is concerning, especially in the context of rising rates of formal induction of labour. Further research is needed to investigate how women are being offered membrane sweeping and what information women need to make informed choices about membrane sweeping to promote spontaneous labour." Therefore we object to more membrane sweeping being offered, at earlier appointments AND furthermore insist that it is a mechanical form of attempting to induce labour</p> | <p>Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps. However, we have now amended the recommendations on membrane-sweeping to reflect that it may be considered a method to induce labour, have clarified that it should be offered at antenatal appointments after 39 weeks, and expanded the recommendation on discussing it with women and obtaining their consent.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------|-----------|---------|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | How about increased risk of infection with 5+ vaginal exams – has this been considered alongside the effectiveness/lack thereof of vaginal sweeps? https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7183634/ | |
| The Doula Association | Guidance | 046 | Table 2 1.7.2 | Welcome the change to unsuccessful induction | Thank you for your comment. |
| The Doula Association | Guidance | 046 | Table 2 1.7.2.4 | Welcome the offering of a rest period for more person-centred care | Thank you for your comment. |
| The Doula Association | Guidance | 046 | Table 2 1.7.3 | Welcome the more consultative nature of the process | Thank you for your comment. |
| The Empowering Birth School | Guideline | 006 | 023 | I am extremely concerned with the guidelines suggested here, this is stating that not only weight and age, but colour of skin should mean that a women is induced at 39 weeks. It is vital that where risks are discussed, benefits too are discussed. There is not enough evidence to justify induction at 39 weeks for these reasons. Perhaps we need to look at our treatment of these women affecting their pregnancies and labour, as opposed to solving the issue with unnecessary induction. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| The Pelvic Partnership | Guideline | General | General | The Pelvic Partnership offers support and information to women with pregnancy-related pelvic girdle pain (PGP), their families and carers. PGP affects around one in five women causing pain, immobility and associated mental health impacts. PGP is a biomechanical joint problem that can be successfully treated with manual therapy during pregnancy and postnatally. Many women are unable to access manual therapy on the NHS and are therefore left no option but to seek treatment privately from physiotherapists, osteopaths or chiropractors – if they can afford it. Unfortunately many women have reported being unable to be treated on the NHS and afford private manual therapy, leaving them in severe pain and immobility. | Thank you for your comment and for highlighting the issues relating to pelvic girdle pain (PGP) and induction. The role of induction in women with PGP was not included as a review question in this update so we have not been able to make any recommendations about induction specifically for women with PGP, but will pass this to the NICE surveillance team who ensure that guidelines are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>Many women with PGP report that they are offered or ask for an induction due to their PGP. There is no evidence that induction for PGP has an overall benefit for women. The decision to induce may be based on the assumption that PGP is hormonal and will stop after childbirth. However, our research suggests this is not the case¹; some women have reported having an induction as a "solution" to their PGP had gone on to have poor birth experiences and continued PGP postnatally.</p> <p>If PGP is the reason for induction, we need to ensure that manual therapy and other treatment options have been attempted. Induction is not and cannot be an alternative to manual therapy to treat PGP.</p> <p>As well as inductions being more expensive and riskier to the woman than manual therapy during pregnancy, we consider there is insufficient evidence supporting induction for women with PGP. If PGP can be sufficient medical cause for an induction, there needs to be evidence to support this and it needs to be applied universally across the UK for all women with PGP.</p> <p>¹ Over 50% of women we surveyed in June 2018 continued to experience PGP postnatally (Pelvic Partnership Survey, June 2018, Data available at www.pelvicpartnership.org.uk/womens-health-strategy/)</p> | |
| The Pelvic Partnership | Guideline | General | General | When discussing the risks and benefits of induction with women, it is important to focus on postnatal recovery as well as the short term impact on birth. For women with PGP who may also be experiencing severe pain postnatally, the impact of induction on recovery is more significant: | Thank you for your comment and for highlighting the issues relating to pelvic girdle pain (PGP) and induction. The role of induction in women with PGP was not included as a review question in this update so we have not been able to make any recommendations about induction specifically for women with PGP, but will pass this to the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------|-----------|-----------|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <ul style="list-style-type: none"> - Labour positions during a monitored birth following induction <p>Women with PGP may be unable to move their legs apart, as such their pain free gap is much smaller and there are fewer labour positions that may be comfortable. After an induction, women are usually monitored when lying on their back, one of the most challenging birthing positions for a woman with PGP, risking more strain on her pelvis</p> <ul style="list-style-type: none"> - An epidural reduces control over her pain-free gap <p>If the woman has an epidural she will no longer be aware of how far she can move her legs apart without putting too much strain on her pelvis, i.e. her pain-free gap. As such, she will likely cause further strain on her pelvis, lengthening her postnatal recovery.</p> <ul style="list-style-type: none"> - Impact of the cascade of intervention <p>Given the higher risk of a cascade of intervention with an induction, the recovery time of an instrumentalised birth, e.g. forceps, ventouse, episiotomy or a caesarean birth is significantly higher.</p> | NICE surveillance team who ensure that guidelines are up to date. |
| The Pelvic Partnership | Guideline | 006 - 010 | 001 004 1.2 - 1.2.18 | <p>We welcome clarity around the medical grounds for an induction and the process induction by maternal request.</p> <p>Many women with PGP report that they are offered or ask for an induction due to their PGP, although for some women and healthcare professionals this is based on the assumption that PGP is hormonal and will stop after childbirth. Furthermore, some women who have had an</p> | Thank you for your comment. The role of induction of labour in women with pelvic girdle pain was not included in the scope of this update, so we have not been able to make recommendations relating specifically to women with PGP. However, we have passed on the references you have supplied to the NICE surveillance team who ensure that guidelines are up to date. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------|-----------|------------|---------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>induction as a “solution” to their PGP had gone on to have poor birth experiences and continued PGP postnatally². If PGP is the reason for induction, we need to ensure that manual therapy and other treatment options have been attempted. Induction is not and cannot be an alternative to manual therapy to treat PGP.</p> <p>In addition, if PGP can be sufficient medical cause for an induction, there needs to be evidence to support this and it needs to be applied universally across the UK for all women with PGP.</p> <p>³ Over 50% of women we surveyed in June 2018 continued to experience PGP postnatally (Pelvic Partnership Survey, June 2018, Data available at www.pelvicpartnership.org.uk/womens-health-strategy/)</p> | |
| The Pelvic Partnership | Guideline | 004 005 | 006 008 003 015 1.1.1, 1.1.2, 1.1.3, 1.1.4 | <p>As a charity, the Pelvic Partnership is motivated to ensure women have the tools and confidence to make informed choices about all aspects of their health, including mode of birth. We welcome the continued focus on ensuring women have access to the appropriate information to make such important decisions, in consultation with their healthcare professionals, at all stages of their pregnancy.</p> <p>When discussing induction this needs to be timely, accessible, appropriate and respectful of the woman's wishes and include a full and thorough discussion including the risks and higher chances of a cascade of intervention or caesarean birth, both of which necessitate a longer postnatal recovery time.</p> <p>For women with PGP, this discussion also needs to consider the woman's access to manual therapy to treat her PGP; if she remains in pain and has not received manual therapy,</p> | <p>Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update and so we are unable to provide specific recommendations relating to women with pelvic girdle pain. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth, and this includes how mode of birth may impact on place of birth and considerations of likely pain. We have also added further recommendations to emphasise that the decision to have an induction or not, rests with the woman and that decision must be respected.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------|-----------|---------|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>decisions about induction may be made through a different lens, possibly being perceived as a solution to her PGP (see above).</p> <p>Induction is not and cannot be an alternative to manual therapy to treat PGP.</p> <p>It's also worth underlining the importance of the communication between healthcare professional and the woman being equal, balanced and fair so that the woman feels able to have a different opinion on her mode of birth. Consultation with our service users in 2018 showed that over 40% of women surveyed felt they weren't taken seriously in discussing their PGP with their healthcare professional³, implying that many women may feel unable to go against the suggestions of the team caring for them.</p> <p>² Pelvic Partnership survey, June 2018, Data available at www.pelvicpartnership.org.uk/womens-health-strategy/</p> | |
| The Pelvic Partnership | Guideline | 006 | 010 012 020 1.2.2, 1.2.3, 1.2.4 | <p>We are very concerned with the proposal to bring forward induction for all women.</p> <p>As the guideline states in 1.2.1, labour usually starts naturally by 42+0 weeks and discussing instrumental methods to start labour too early risks encouraging women to induce unnecessarily. We recognise that the committee stated there "was not enough evidence to identify the optimal timing of induction more precisely and so the committee made a research recommendation" (Page 24, Inducing labour DRAFT guideline).</p> <p>We would strongly encourage the recommendations to stay as for the 2008 guideline, pending the results of this research.</p> | <p>Thank you for your comment. The recommendations for induction at 41 weeks were based on evidence that certain risks may increase after this time. However, based on stakeholder feedback we have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. We have included tables of absolute risk and details of some of the limitations of the evidence upon which these tables are based.</p> <p>The optimal timing referred to in the research recommendation relates to the use of individual patient data to determine if there is a gestational age at which the risks of continuing with the pregnancy outweigh the</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | benefits. This is explained in more detail in the research rationale in appendix L of evidence review C. |
| The Pelvic Partnership | Guideline | 006 | 012 020 1.2.3, 1.2.4 | <p>As well as the recommendation for induction from 41+0 for general singleton pregnancies we are particularly concerned about the move to recommend induction for women who are 39+0 with uncomplicated singleton pregnancies due to their ethnicity, age, weight, and if they had support conceiving.</p> <p>By focusing on these factors during the pregnancy and underlining the perceived (see below) risk factors with these characteristics, additional stress and anxiety is placed upon the woman, encouraging her to make decisions regarding an instrumental birth and implying that this is due to her age, ethnicity and weight.</p> <p>We are very concerned about the statement in the guideline that "the committee noted that in their knowledge and experience women from the Black, Asian and minority ethnic family background, women with BMI of 30 or more, women aged 35 years or more and women who had assisted conception were at a higher risk of adverse events in a pregnancy that was prolonged beyond term" (our emphasis, Page 24, Inducing labour DRAFT guideline). As such, we consider there is insufficient scientific evidence and should not be included in the guidance.</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |
| The Women's Health and Maternal Wellbeing Initiative | Guideline | General | General | <p>The Women's Health and Maternal Well-being Initiative C.I.C. deem the recommendations included in this draft concerning Black, Asian and minority women to be unsupported and dangerous, as opposed to them being supported by a wide scope of strong evidence and research literature. Despite a general lack of research concerning the health narratives and experiences of Black women, much of the research that <i>has</i> been collected criticises race-based interventions and policies for perpetuating harmful untruths and stereotypes about the primary risk factors that put Black women at higher risk of complications. The proposed recommendations specific to Black, Asian and ethnically</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>diverse people in the updated NICE 'Inducing labour' clinical guideline reinforce the erroneous presumption that non-white women do not possess the ability to safely birth their babies without medical intervention. Offering induction of labour for uncomplicated pregnancies belies a systemic distrust in non-white birthing bodies, while failing to acknowledge how systemic racism within maternity systems contributes to poor pregnancy outcomes for Black, Asian and marginalised ethnic groups. The role, context, and risk factors of structural violence and institutionalised racism must be emphasised and not completely ignored. Moreover, this position has been shared by both lay and academic/professional Black women; who have been raising concerns long before the wider critical reflections on race, power, institutional racism, and health risks brought about by the resurgence of racial justice ethics.</p> <p>Regardless, the Committee has made the recommendation to consider offering induction of labour at 39+0 weeks in an effort to reduce poor maternal outcomes in uncomplicated pregnancies despite stating that there is no research evidence to support this recommendation (beyond their personal experiences and opinions). The overall recommendation of early induction of labour for Black women is, therefore, unfounded, irresponsible, insensitive, and will most likely directly contribute to greater racial disparities in maternal health including reduced maternal satisfaction with intrapartum experience, increased rates of assisted birth and operative birth, more birth injuries and a contested reduction in stillbirth rates. There is certainly a place (and need) for medical policies and practices which are tailored to ethnic minorities, with the aim of providing them with specialist, personalised care and support, and the long-term vision of reducing the health inequalities and disparities they face. However, these must be informed by:</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>1) Co-production: hard data collected and narratives shared by Black women (including those from smaller, grassroots organisations)</p> <p>2) Interdisciplinarity: research from outside of the medical sciences, like that from the social sciences (e.g. medical anthropology and sociology, etc)</p> <p>3) Black professionals: the centring of research conducted by Black women for (primarily) Black women and their health disparities.</p> <p>When tailored practices and policies do not follow these doctrines, they run the risk of (re)producing the power disparities that lead to Black women not only being failed by service providers/the wider healthcare system, but the very actions and mentalities that physically harm them and their babies.</p> <p>As the Committee will most likely know, Black women have been five times more likely to die in pregnancy, during childbirth, or six months postpartum than their white counterparts, according to the MBRRACE Report (Knight et al., 2018). This is despite England's overall decrease in maternal morbidity and mortality rates. The latest MBRRACE Report, however, shows that their risk is now four times more likely (Knight et al., 2020). This reduction has been acknowledged by many, but so has the fact that the decrease was not significant and Black women remain at the highest risk.</p> <p>Research conducted by Black academics, Black health professionals, and Black lay women alike have outlined the same probable reasons; major ones being (historical) institutionalised anti-Black racism in medical theory and policy and implicit racial bias in practice. In addition toxic working cultures exacerbate the poor outcomes experienced</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>by vulnerable groups. In sum, racism, misogynoir (sexist racism), and toxic cultures result in poorer maternal experiences and increased maternal morbidity and mortality risks, with Black women across the country and across generations consistently reporting discrimination and a lack of informed decision making. Service-users also report that they are less likely to receive pain relief- because staff assume they are "stronger", and/ or are lying about their pain levels, and/ or are simply being hysterical. Knowing this, a recommendation which increases Black women's likelihood of being offered early induced labour - which the Committee have noted is generally more painful than physiological birth – and at greater risk of an unsatisfactory maternity experience. This is in addition to the increased risk of maternal morbidity and adverse outcomes including severe perineal trauma, haemorrhage, birth trauma and uterine rupture. Black women's "near misses" have recently also been emphasised in discussions about how dire the Black maternal health crisis is, and the role of misguided, uninformed practices – thus, unless NICE recognises the deeply racial systemic issues in maternity care, these recommendations will only exacerbate the aforementioned.</p> <p>Furthermore, we do not believe that the committee have adequately made plain the interlinked relationship between infant health and wellbeing and maternal health and wellbeing. Black babies are already at increased risk of being stillborn, premature, and at a lower birth weight; institutional racism makes them equally as vulnerable to greater morbidity and mortality and maladaptive medical practices as their mothers are. There is also a lack of consideration given to the fact that induced births require more care of the mother and infant and, within the context of an NHS which is already over-stretched, under-staffed, and suffering from deeply-entrenched racism which affects both ethnic minority staff and patients. Public hospitals are simply not equipped to meet the increased demands of care</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>precipitated by mass labour induction. We make this assertion based upon feedback from midwives and clinicians currently working in maternity services, despite the Committee stating that offering inductions to more women will not overburden the already beleaguered NHS. Therefore, we believe such a recommendation is irresponsible and dangerous, especially if it is not accompanied by a standard of excellence and kindness for Black women and their babies.</p> <p>The Women's Health and Maternal Wellbeing Initiative urges that the Committee consults with us, and similar organisations, for a deep examination of the socio-medical, qualitative research that speaks to the issues raised.</p> <p>We believe that it would be unsafe and unethical for a midwife (or any qualified medical professional/student) to adopt these suggested guidelines, as they contradict their professional obligation to provide person-centred, culturally safe and evidence-based care. Nor do we believe that by masquerading as what racially-sensitive, tailored care looks like, these recommendations promote an understanding of the institutionalised role and responsibility of racism/misogynoir. There is strong evidence that asserts midwifery-led care and care in midwifery-led units have better outcomes than in other settings, we welcome an emphasis on increasing access to midwifery-led care and increased choice in place of birth. Consequently, we recommend that more emphasis should be placed on high quality training that is underpinned by cultural safety, human rights in childbirth and increasing choice and personalisation through informed decision-making.</p> | |
| The Women's Health and Maternal Wellbeing Initiative | Guideline | 004 | 001 | <p>The comment, "People have the right to be involved in discussions and make informed decisions about their care" is not in line with recent PCSP guidance and should be informed by the Montgomery principles outlined by Birthrights- "People have the right to be given the</p> | <p>Thank you for your comment. This is standard wording that is provided at the start of all NICE guidelines so we have not amended it here, but have ensured that the specific recommendations about induction of labour make clear</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | information that they need to make informed decisions about their care, and to have those decisions respected" (www.birthrights.org.uk) | that women should be provided with enough information and that the woman's decision should be respected. |
| The Women's Health and Maternal Wellbeing Initiative | Guideline | 005 | 016 - 023 | Should include that information should be provided in both written and oral format. Service-user should not only be referred to a web page. | Thank you for your comment. We have added another example of written information leaflets. |
| The Women's Health and Maternal Wellbeing Initiative | Guideline | 005 | 011 - 014 | This should be introduced into the conversation earlier. | Thank you for your comment. We have reordered the information and decision-making recommendations so this information comes earlier. |
| The Women's Health and Maternal Wellbeing Initiative | Guideline | 006 | 002 - 003 | <p>Explain what a prolonged pregnancy is and give evidenced-based information on why it has been deemed so. Starting at 40-43 weeks gestation explain the percentages of labour which start at each weekly interval.</p> <p>Black women as a group already a 4-5x higher risk of maternal morbidity and mortality, early induction has been recorded as a contributor to these risks (particularly in ethnographies and qualitative analyses).</p> <p>This was further evidenced recently at the Black Maternal Health Public Meeting (chaired by MP Bell Ribeiro-Addy). Here, the families of Black women who have passed away and women who had 'near misses' themselves, shared of how the idea of prolonged pregnancy led medical staff to take steps towards early induction of labour despite the women knowing that their bodies (and babies) were not ready; they were not listened to and the early inductions often led to emergency c-sections which were either fatal (and left surviving babies with lifelong disabilities) or led to post-partum morbidities.</p> | Thank you for your comment. We have added information into the guideline about the percentages of labour which start spontaneously at each week of gestation. Based on stakeholder feedback we have also replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report. |
| The Women's Health and Maternal Wellbeing Initiative | Guideline | 006 | 020 | Please provide evidence to support this recommendation. What evidence exists to support, "black, Asian and ethnic minority families" with uncomplicated pregnancies having better outcomes following an induction at 39 weeks? | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| The Women's Health and Maternal Wellbeing Initiative | Guideline | 008 | 006 | Please replace "shared decision" with informed decision, and ensure she is supported to make a decision with evidence-based and unbiased decision-making tools. Information should be provided that she is able understand. | Thank you for your comment. The NICE definition of shared decision-making is a collaborative process, making sure the person understands the risks and benefits through discussion and we think this applies to decisions about maternity choices, although the final decision is ultimately the woman's. We have reviewed the use of the terminology 'shared decision-making' throughout the guideline and have amended it in a number of places. However, there are some circumstances where there may be factors that relate to the decision that are within the remit of the healthcare professional too - such as their professional responsibility to act in the woman's best interests, and in this example to determine if suitable neonatal facilities are available. In this case we think the decision would therefore be shared, and so have not amended it in this recommendation. |
| The Women's Health and Maternal Wellbeing Initiative | Guideline | 013 | 014 | Why is this being suggested? Please provide clarification for stipulating 39 weeks. | Thank you for your comment. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, the likelihood of success, optimal timing or frequency, or the need for pain relief. However, the recommendations have now been clarified to state that membrane sweeps should be discussed after 39 weeks (as opposed to 'from 39 weeks') so sweeps will happen from week 40 onwards. |
| The Women's Health and Maternal Wellbeing Initiative | Guideline | 024 | 016 - 018 | Which group(s) of women have been evidenced to benefit from early induction of labour? Black women, who have the highest risk of maternal mortality, are most likely not included in these findings . In fact, there is evidence that early induction contributes to higher mortality and morbidity rates for them. This distinction must be made clear. | Thank you for your comment. We have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report. Based on this change to the guideline we have updated this rationale section. |
| The Women's Health and Maternal Wellbeing Initiative | Guideline | 024 | 023 | Medical staff will need to remember that early induction is a possible solution for some women, and not a rule of thumb for all prolonged pregnancies. The "may" needs to be | Thank you for your comment. The recommendations for women who may be at higher risk of stillbirth have been amended and revised substantially, and so we have |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|------------------------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | emphasised and remembered for this suggested guideline to be practiced ethically, responsibly, and with sensitivity. | updated this rationale section to reflect these changes to the recommendations. |
| The Women's Health and Maternal Wellbeing Initiative | Guideline | 024 | 029 | In relation to Black women, national audit data has been heavily scrutinised and challenged by Black lay women and Black women academics/ medical professionals alike. Therefore, it would be wise to look beyond it and include data gathered by independent thinktanks and academics. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the MBRRACE report. We have therefore updated this rationale section to reflect these changes to the recommendations. |
| The Women's Health and Maternal Wellbeing Initiative | Guideline | 029 | 012 - 013 | Context is crucial information. It would be wiser, and more effective, to place this at the beginning and reiterate it throughout. However, nuance also needs to be included in the context (i.e. racial disparities in outcomes). | Thank you for your comment. The standard format of the guideline is to include the context in this position as there are already several other pieces of over-arching information at the beginning of the guideline. |
| The Women's Health and Maternal Wellbeing Initiative | Guideline | 130 | 003 -009 | They should also be informed that infection could be introduced. | Thank you for your comment, which we think relates to page 13. Membrane-sweeping was not included in the scope of this guideline update, so we have not conducted an evidence review for its efficacy and so have been unable to revise the recommendations on the risks and benefits of membrane sweeps, including the risk of infections. |
| University Hospital Southampton NHS Foundation Trust | Evidence review C 3 | | Table 1 | Comparing induction of labour versus expectant management did not include longer term outcomes for neonatal and child health: this is an area of interest for our service users during consultations and should be included to support informed decision making. Evidence from large studies such as TIGAR (2020) by Coathup et al. would be relevant to include. A recent publication (although understandably outside the scope of review due to timing) Dahlen et al (2021) is an example of the data shared with us from women. | Thank you for your comment. The committee discussed the fact that there were a large number of outcomes which could be considered for this review, and agreed to prioritise 7 for women and babies as they believed these were the most direct indicators of safety for timing of induction of labour. Longer term outcomes were not included as the committee believed these would be reported sparsely, however they prioritised neonatal morbidity (meconium aspiration/HIE), as this has potentially long term implications for the baby. To encourage future studies to assess longer term outcomes, the committee have amended the research recommendation to include these. We have checked the references individually to ensure there is nothing we have missed that should have been included. The studies by Coathup 2020 and Dahlen 2021 are not eligible because they did not compare different timings of induction and were not RCTs. For further details |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|----------------------------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | regarding inclusion and exclusion criteria of studies, please see the review protocol in appendix A of evidence report C. |
| University Hospital Southampton NHS Foundation Trust | Equality impact assessment | 001 | 3.2 | In recognition of the potential scope of this recommendation was there consideration of diversity in the panel membership of the lay reviewers? | Thank you for your comment. The committee included 2 lay members with lived experience of induction of labour and wider experience of representing people using maternity services. The consultation process is the additional method we use to obtain input into the guideline from a wide range of stakeholders and individuals, and to ensure that the guideline is fit for purpose. This guideline received over 3000 comments in this way, many of which were from people who told us that they were non-white. Each comment was read and considered by the committee in order to amend and improve the guideline. |
| University Hospital Southampton NHS Foundation Trust | Guideline | 005 | 024 | A decision aid for women would be helpful to include in the resources that would be unbiased and nationally consistent | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data necessary for a decision aid. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth, and have included examples some of the problems babies may face due to an earlier birth. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| University Hospital Southampton NHS Foundation Trust | Guideline | 006 | 010 | This recommendation is largely based on discussion of the SWEPIs study. The study has a small sample size but it is acknowledged that there was a statistically significant difference in perinatal mortality between the two groups. The comparison is between 41-41+2 compared with 42-42+2; in the NICE discussion it suggests more detailed data on the exact timing of stillbirths occurred just after 41+2 and therefore justifies its recommendation to bring forward the recommended timing however we are unable to see this level of data to comment. Furthermore 100% of perinatal | Thank you for your comment. The committee specifically discussed the quality of the evidence from the SWEPIs study (Wennerholm 2019). The strengths of this study include its large size and relevance to this question. However, the fact that the study was terminated early due to ethical concerns and never reached the sample size intended to power its primary endpoint was a limitation, which may have led to an overestimation of the treatment effect in the intervention group and decrease the precision of the results. These limitations were acknowledged by the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>mortality outcomes occurred in nulliparous women, yet the recommendation by NICE based on these findings has been generalised to multiparous women. The study showed no statistical difference in outcomes for these women and this does not appear to have been discussed in the NICE review.</p> <p>The importance of this recommendation is the impact of increasing induction of labour capacity within any organisation including risks of increased length of stay, compounding delays and increased births in a high risk setting- the risks of this have not been broadly considered as part of the discussion. Busier labour wards may compromise the safety of women already in labour or needing to birth in that setting. Without an impact assessment of the change in capacity- unintended poor outcomes may occur as a result of increased acuity. This is based on a current estimation that around 18-20% of births occur in midwifery led settings and the increased induction rate as a result of this recommendation would then increase birth on labour ward as it is the uncomplicated pregnancy population directly impacted.</p> | <p>committee and were reflected in the overall quality of the evidence of this study. The detailed data on the exact timing of stillbirths is based on the full text study. We have now included the estimated risks associated with a pregnancy continuing beyond 41+0 weeks by parity to aid understanding of the evidence reviewed. The supporting information explains how this data was derived and how to interpret it.</p> <p>As a result of stakeholder feedback the guideline no longer recommends induction from 41+0 weeks. We have amended the recommendations on timing of induction for prolonged pregnancy to make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications.</p> |
| University Hospital Southampton NHS Foundation Trust | guideline | 006 | 012 | <p>From review it appears these outcomes within the better quality evidence (ARRIVE trial) relate to nulliparous women, the strength of the evidence supporting these recommendations for multiparous women seems low. Perhaps the two groups need separating as in place of birth recommendations in the NICE intrapartum care guideline. As a clinician it may be difficult to support an informed discussion with multiparous women based on the evidence underpinning this recommendation for them and in particular the impact it may then have on their birth choices as the majority of these women may choose to birth in midwifery led environments including home and freestanding midwifery led units.</p> | <p>Thank you for your comment. Based on stakeholder feedback, we have now included the estimated risks associated with a pregnancy continuing beyond 41+0 weeks by parity to aid understanding of the evidence reviewed. The supporting information explains how this data was derived and how to interpret it.</p> |
| University Hospital Southampton NHS Foundation Trust | Guideline | 006 | 020 | <p>Given the discussion presented on pg 20 in evidence review 3 presented there appears no evidence to support this broad recommendation considering the significant impact it may</p> | <p>Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|-----------|---------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>have- should this be a recommendation by NICE? NICE is there to provide evidence based guidance and advice. Further research is needed before such a significant change to practice in terms of timing of birth for such large populations. Again this does not separate the limited evidence within the sub groups such as parity and would present an extremely challenging conversation to inform women appropriately to make a decision given the lack of evidence. The adverse impact to women's anxiety may be considerable- evidence of this is already present in the social media discussions about this recommendation and the feedback that we have received for our maternity voices partnership.</p> <p>Furthermore what care is then recommended for women who do not wish to be induced at 39 weeks: will they be offered regular CTG's and scans and what is the impact of this within a maternity service where capacity impacts on safety.</p> | with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| University Hospital Southampton NHS Foundation Trust | Guideline | 009 | 004 | <p>Could we include other indications for immediate induction of labour or caesarean section such as HIV (BHIVA, 2020) this will support awareness of these recommendations.</p> <p>Please can we include advice if meconium stained liquor and timing for induction of labour</p> | Thank you for your comment. The recommendations on birth for women who are HIV positive mainly relate to the need to carry out Caesarean birth (or not) and so the BHIVA guidelines are cross-referenced from the Caesarean birth guideline (NG192). It was not part of the scope of this update to review the role of induction of labour in women with HIV or if there is meconium stained liquor and so we have not been able to add recommendations on these topics. However, we will pass this request to the NICE surveillance team who are responsible for ensuring that guidelines are up to date. |
| University Hospital Southampton NHS Foundation Trust | Guideline | 010 | 019 | <p>We are unable to access the hyperlink on page 11 below line 7 to see the rationale and impact section regarding this so apology if there is clarity regarding the following points.</p> <p>Here the 'limited evidence' is stated but the same level of detail is not conveyed in the points raised above with timing of induction despite the discussion within evidence 3:</p> | Thank you for your comment. Due to the uncertainty around the evidence for benefits and harms of induction of labour compared to expectant management for fetal macrosomia, the recommendation stated 'offer women...the choice of induction of labour or expectant management...'. It did not state that all women should be offered induction. However, we have now amended the |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|------------------------------------------------------|----------------------------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>however the terminology suggests a stronger level of evidence given the word 'offer' compared to 'consider'.</p> <p>What timing of induction is appropriate based on the evidence reviewed? The definition for fetal macrosomia in the document is defined at or after 36 weeks however evidence around early induction prior to 39 weeks may impact neonatal outcomes.</p> | <p>wording of this recommendation to make it clearer that this is a recommendation about having a discussion with the woman and that there is uncertainty around the evidence.</p> <p>The committee discussed whether it was possible to define the best time to induce labour in suspected fetal macrosomia but the evidence included induction at a range of gestational ages and it was not possible to identify the preferred gestational age. The committee also considered this would be an individualised decision based on the estimated size of the baby, the woman's clinical circumstances and her preferences.</p> <p>We have added an additional section to the recommendation to highlight that earlier induction may impact on the woman's experience of birth and on the baby's health.</p> |
| University Hospital Southampton NHS Foundation Trust | Guideline | 013 | 018 | Should there be specific guidance regarding methods of induction in the presence of ruptured membranes as some induction agents are not advised in this circumstance as highlighted on page 19 line 21. | Thank you for your comment. There are a number of cautions and contraindications for pharmacological methods of induction and it would not be possible to include them all in the guideline, so there is a separate recommendation advising reference to the manufacturers' guidance. |
| University Hospital Southampton NHS Foundation Trust | Evidence Review C 3 | 021 | 016 | <p>The resource impact considered may not be applicable: births after 42 weeks in England. The timing for comparison of impact is at 41 weeks not birth beyond 42 weeks. The previous NICE guidance recommended induction between 41 and 42 weeks. Experience within the region and nationally suggests that this would normally be offered around 41+5. Therefore the resource impact should quantify births between 41 and 42 weeks.</p> <p>There is no impact of resource use for considering induction of labour at 39 weeks using comparable ONS data.</p> | Thank you for your comment. As a result of stakeholder feedback the guideline recommendations on the timing of induction have been amended so that they make the focus a discussion with the woman about the risks of earlier or later induction. Based on the revised recommendations there may be an increase in inductions in some units but it will depend on current rates of induction at 40 and 41 weeks and variations in populations giving birth in the unit and this may have resource implications. The recommendation relating to induction from 39 weeks in high-risk women has been removed based on stakeholder feedback so there will no longer be any resource impact relating to this recommendation. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------|-------------------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| University of Birmingham Clinical Trials Unit | Evidence Review B | 008 | | Definition of intervention (page 8) in the PICO table suggests osmotic cervical dilators also included devices known as laminaria. Laminaria rods are the plant stem of a Japanese seaweed, which is dried and sized. Dilapan-S is a synthetic hydrogel, which has a consistent action and is supplied in sterile packaging. The pooling of the two methods is questionable in relation to efficacy and adverse effects, particularly genital tract infection. The two types cannot be mixed into one group. | Thank you for your comment. The committee agreed that osmotic cervical dilators was the over-arching term that included all devices that worked by absorbing fluid and swelling in the cervix, and were also aware that there were both naturally-derived and synthetic products included in this category. However, the committee agreed these were sufficiently similar that they could be analysed under the grouping of osmotic cervical dilators. Based on stakeholder feedback, the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour. |
| University of Birmingham Clinical Trials Unit | Guideline | 010 | 020 | 1.2.22 - The statement regarding offering women with suspected fetal macrosomia and without diabetes, the choice of induction of labour or expectant management should <u>also</u> include caesarean section. The evidence behind the current statement is outdated and does not account for Montgomery principles. If a customised GROW chart indicates that there is suspected fetal macrosomia with a persistent growth above the 95th centile, with no gestational diabetes, then the choice should also include <u>to offer</u> caesarean section at 39 weeks gestation, as well as induction of labour or expectant management. It is important that NICE recognises the principles of Montgomery in their recommendations. NHS Improvement has a significant number of cases where the option of caesarean section has not been offered in these circumstances and this is likely to lead to successful litigation for breaching Montgomery principles. | Thank you for your comment. We have added caesarean birth into this recommendation as an option for birth. |
| University of Birmingham Clinical Trials Unit | Guideline | 015 | 020 | 1.4.2 - This section on 'Non-pharmacological methods' specifically mentions not to use osmotic cervical dilators for induction of labour. This is an incorrect recommendation. This indicates a flaw in NICE's ability to do a scoping search, which should have identified, within trial registries, 3 randomised control trials that were ongoing or published. The DILAFOL study is a randomised control trial comparing Foley's catheter with Dilapan osmotic dilators. This has now | Thank you for your comment. The DILAFOL trial was included in the evidence review but there was no data on vaginal delivery in 24 hours. We are also aware that the COMRED and SOLVE trials have been completed but has not been fully published yet. We will pass this information on the NICE surveillance team who monitor guidelines to make sure they are up to date. However, based on stakeholder feedback the committee has reconsidered the evidence for osmotic cervical dilators and included them |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| | | | | <p>been published (https://pubmed.ncbi.nlm.nih.gov/30790569/) and concluding 'Dilapan-S is not inferior to the Foley balloon for preinduction cervical ripening at term. Advantages of Dilapan-S over Foley include Food and Drug Administration approval, safe profile, no protrusion from the introitus, no need to keep under tension, and better patient satisfaction'.</p> <p>The US Trials Registry should have identified the COMRED study (https://clinicaltrials.gov/ct2/show/NCT03670836), which is a randomised control trial between oral 25 mcg misoprostol and Dilapan osmotic dilators. This has now been accepted for publication in AJOG and awaiting full publication. The conclusions are that Dilapan is non inferior to oral misoprostol for pre induction cervical ripening at term. The advantages of Dilapan over misoprostol include better safety profile, FDA approval, better patient satisfaction and pain scores. There was reduced frequency of uterine tachysystole with or without abnormal fetal heart rate changes in the Dilapan group.</p> <p>The third randomised control trial is the SOLVE study, which is a randomised control trial between Dilapan and dinoprostone (PGE2) slow release (https://clinicaltrials.gov/ct2/show/NCT03001661). As dinoprostone is the first-choice pharmacological method in the revised guidelines, this trial is particularly pertinent. The results are currently available but not published. We are happy to share these results with NICE. The conclusions are that there is little evidence of a difference between the groups with regard failure to achieve vaginal delivery (i.e. caesarean section rates are similar) but there is reduced frequency of uterine tachysystole and hyperstimulation with better maternal satisfaction and pain scores. With 3 randomised control trial data this would indicate that the use of osmotic dilators is an important addition to offering women this choice for induction of labour. Therefore, NICE needs to reconsider the statements in line with current</p> | <p>as an option for the mechanical induction of labour, so they have been removed from this list.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | evidence for this latest update, otherwise it could be seen that the latest update is already outdated even before it is published. | |
| University of Birmingham Clinical Trials Unit | Guideline | 028 | 001 - 030 | <p>The evidence supporting the use of prostaglandins (PGE1 and PGE2) is currently based on promoting vaginal birth within 24 hour for women with a Bishop score of 6 or less. It is now well established that induction of labour should not be associated with speed of achieving a vaginal delivery (G Justus Hofmeyr commentary: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)01042-9/fulltext). The fast and furious approach using prostaglandins should be outweighed with the slow and steady approach in terms of safety and maternal satisfaction, which has now been consistently shown by randomised control trials that mechanical dilators such as balloon catheters and osmotic dilators are associated with better safety profiles and maternal satisfaction rates (PROBAAT (https://pubmed.ncbi.nlm.nih.gov/22030144/), PROBAAT-II (https://pubmed.ncbi.nlm.nih.gov/26850983/) and DILAFOL, COMRED and SOLVE studies).</p> <p>Therefore, NICE needs to reconsider the recommendations based on vaginal birth within 24 hours when it has clearly been shown that the slow and steady approach of vaginal delivery at 36 and up to 48 hours, or indeed vaginal delivery whenever, is associated with better safety outcomes i.e. lower risk of hyperstimulation which is usually associated with fetal heart rate changes and better maternal satisfaction rates i.e. less painful cervical ripening process.</p> | <p>Thank you for your comment. The committee agreed that the main aim of induction of labour is to achieve a vaginal birth without adverse effects for the woman or her baby, therefore the outcomes relating to mode of birth (no vaginal birth within 24 hours and caesarean birth) were deemed critical. While the 24 hour limit may appear artificial, the committee agreed that this is a well-established outcome measure for assessing efficacy when inducing labour, and would provide a good indication of the relative efficacy of different methods. The committee focused primarily on the outcome of no vaginal birth within 24 hours, but also balanced this with the evidence for hyperstimulation as this is one of the main concerns when inducing labour. Much of the data for the other outcomes did not provide much clear evidence of benefit or harm on which the committee could base decisions. For example, there were few clear differences between placebo and any of the interventions for the outcomes of caesarean birth, instrumental birth, NICU admission, use of epidural, maternal mortality or serious morbidity, perinatal mortality, or maternal satisfaction (in either the whole population or the subgroups with higher or lower Bishop score).</p> |
| University of Birmingham Clinical Trials Unit | Guideline | 028 | 026 - 028 | <p>Regarding the statement 'there was no evidence for the effectiveness of osmotic cervical dilators at promoting vaginal birth within 24 hours, but they too did not appear to markedly increase the risk of other adverse outcomes'. This statement needs revision as there is RCT evidence for the effectiveness of osmotic cervical dilators promoting vaginal birth within 36 and 48 hours.</p> | <p>Thank you for your comment. Based on stakeholder feedback, the committee has reconsidered the evidence for osmotic cervical dilators and included them as an option for the mechanical induction of labour.</p> |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-----------------------------------------------|-----------|---------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| University of Birmingham Clinical Trials Unit | Guideline | 029 | 011 - 021 | NICE is urgently required to review its current recommendations to be updated in line with very recent RCT evidence regarding osmotic cervical dilators. The statement that 'it is generally more painful than spontaneous labour' is not correct when considering mechanical methods, especially Dilapan for the reasons given above. | Thank you for your comment. The evidence on methods of induction showed there was no significant difference between need for an epidural for any of the methods of induction (mechanical or pharmacological) so we have not amended this text. |
| White Ribbon Alliance UK | Guidance | General | | <p>There is clearly a disregard and lack of engagement from the committee with the Surrogacy community in relation to the latest NICE recommendations. UK surrogacy births are steadily increasing, and with a lack of education already around the care of surrogates and intended parents this may only confuse matters more, or at worst but Surrogates and Babies at risk.</p> <p>Surrogacy births may have come through a route of assisted conception and we are concerned that the committee are suggesting that all surrogacy births will now be encouraged to consider induction of labour at 39 weeks – the guidelines do not provide specific evidence or insight into the needs and requirements of individuals or families coming to maternity care through a surrogacy pathway.</p> | Thank you for your comment. The committee did not disregard the surrogacy community, and based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women with who have had assisted conception. |
| White Ribbon Alliance UK | Guideline | General | | <p>White Ribbon Alliance and our alliance members/ individuals aligning with this response, consider that recommendations in this draft guideline relating to women from Black, Asian and ethnic minority family backgrounds are unsupported by robust research evidence. Within these draft guidelines there are assumptions and a lack of evidence to support recommendations specific to people from particular ethnic backgrounds.</p> <p>At present, we are deeply concerned that the committee alludes to non-white pregnant people requiring different care pathways for uncomplicated pregnancies than their white counterparts without demonstrating that they have reviewed evidence that highlights why the needs of these racial groups differ. The current draft recommendations point to ethnicity as a standalone risk factor for poor pregnancy</p> | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|-------------|----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| | | | | <p>outcomes and do not refer to issues of systemic racism within the maternity care system as a contributing factor to disproportionate adverse outcomes for specific ethnic groups. It is our recommendation that the committee re-examine their recommendations with the consideration that ethnicity alone is not a risk factor that puts women at risk of complications if their pregnancies advance beyond 39+0 weeks.</p> <p>The committee do not make it clear if the new recommendations are intended for white ethnic minority women as well as for women of colour, although the way that language and context has been used implies that you are recommending specific changes for women from ethnic minority groups, who are also women of colour. This requires clarification, although we are actively seeking a total removal rather than an adaptation of clarity of any recommendations related specifically to ethnicity rather than presentation of medical condition/ concern/ need.</p> <p>The committee cite their 'knowledge and experience' and the MBRRACE reports as evidence that non-white women experience poorer outcomes, but it remains unclear how inducing labour at 39+0 weeks will improve this group's pregnancy outcomes. At all points throughout the new recommendations, where specific ethnic groups are mentioned or identified as requiring specific care, the committee's recommendations should be underpinned by research evidence specific to each ethnicity. Highlighting particular groups by race/ethnicity, especially without evidence, only further perpetuates the idea that particular groups are at risks due to race and alienates people.</p> <p>It is deeply flawed and unethical to suggest recommendations, unfounded and without evidence, that can have grave immediate and long-term impact on women, birthing people, their babies and families. Notwithstanding,</p> | |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------|-----------|---------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|
| | | | | <p>there is strong evidence that induction can lead to avoidable harm. Induction of labour limits choice of birth place as service users are more likely to require monitoring and interventions resulting in birth injury, no reduction in stillbirth and increased hospital admission of neonates and children due to birth at early gestational age.</p> <p>Robust evidence demonstrates that women and babies who receive care in midwifery led settings (e.g. home births and midwifery- led units) have better outcomes and greater efforts should be channelled to increase accessibility to midwifery-led care, continuity of carer and plausible place of birth.</p> <p>We highlight this as our first response and wish to emphasise our belief that the recommended guidelines are thoroughly re-examined in consultation with obstetricians, midwives, doulas, maternity service users and members of the multidisciplinary team that are representative of Black, Asian and ethnic minority communities.</p> <p>White Ribbon Alliance recommend that the committee consult with us on a deep examination of the NMC's Standards in Proficiency for Midwives 2019 to comprehensively address the many contradictions between these new recommended guidelines for women from specific ethnic groups, and the expected standards of practice outlined by the NMC. We consider that it would be contradictory for a midwife to practice using these new guidelines, whilst also upholding their requirement to act within the standards of proficiency.</p> <p>It is our opinion that these guidelines present recommendations, when considering the needs of women from ethnic minority groups, which are harmful and racist.</p> | |
| White Ribbon Alliance UK | Guideline | General | | The quality of evidence associated with any identifiable risk should be high and included. | Thank you for your comment. The quality of evidence for each outcome is included in the evidence statements in |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------|-----------|---------|---------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | | each evidence review, and in the GRADE tables in Appendix F of each evidence review. |
| White Ribbon Alliance UK | Guideline | General | | We draw the committee's attention to the second right within the Universal Charter for Respectful Maternity Care which states that 'Everyone has the right to information, informed consent, and respect for their choices and preferences, including companion of choice during maternity care and refusal of medical procedures.' We urge the committee to integrate language which is demonstrative of this right, with particular focus on informed consent and respect for choices and preferences. We ask the committee to review the guidelines to ensure that informed consent and autonomy is prioritised, rather than focusing on the care provider 'explaining' this could be changed to 'explore' or 'offer' throughout the paper. Explaining illudes to making facts clear, many of the recommendations within these guidelines are not facts, but rather mitigations of potentials, therefore explaining is the wrong terminology and is not empowering for the woman | Thank you for your comment. We always try to ensure NICE guidelines strike a balance between providing clear guidance to healthcare professionals on the course of action that is likely to lead to the best outcomes for their patients, while ensuring that the people in receipt of that care have the opportunity to make decisions about their care. We also try to use clear verbs that specify an action so there is no confusion, and 'explain' lets the healthcare professional know that they must describe options, benefits or risks, whereas 'explore' is more nebulous and may not lead to the desired information being shared. We have added an additional recommendation to the information and decision-making section of the guideline to clarify that whether to have labour induced or not is a woman's decision, and that this decision must be respected. We have reiterated this message at several other points in the guideline. |
| White Ribbon Alliance UK | Guideline | General | | The committee have opted not to refer to women and birthing people but rather to keep only the use of the word women throughout the guidance. WRA UK encourage the committee to reconsider the safety of guidelines for the LGBTQ+ community and urge an integration of the use of the words birthing person in addition to the term woman, to ensure safety and inclusivity of the trans community. | Thank you for your comment. To ensure consistency between NICE guidelines the NICE editorial team have developed a more inclusive description and rationale for the use of the terminology relating to the intended population for maternity and obstetric guidelines, and this is included in the introductory information at the beginning of the guideline. |
| White Ribbon Alliance UK | Guideline | General | | WRA UK, request that the committee takes the traction and deep concern of the many individuals who have presented concerns on the new recommendations into consideration and revisits the process of guideline proposals through an integrative process which includes and embeds the voices and perspectives of service users, particularly from all service users for whom induction of labour is being presented a consideration. | Thank you for your comment. We have fully considered all the comments, edits and suggestions made by the WRA and many other stakeholders and have substantially amended the guideline. The committee includes service users or lay people who are involved throughout the development process and the consultation process has taken into account the views of a large number of stakeholders and several hundred individuals, many of whom were service users. |
| White Ribbon Alliance UK | Guideline | 004 | 001 | The committee have stated 'People have the right to be involved in discussions and make informed decisions about | Thank you for your comment. This is standard wording that is provided at the start of all NICE guidelines so we have |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------|-----------|---------|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | their care' this requires considerable changes to ensure that Women and birthing people are empowered to make the decisions about their care and to have agency in how they reach decisions, based on evidence and dignified care. | not amended it here, but have ensured that the specific recommendations about induction of labour make clear that women should be provided with enough information and that the woman's decision should be respected. |
| White Ribbon Alliance UK | Guideline | 005 | 003 | Women and birthing people should be given full and detailed information about the procedures involved in induction, including vaginal examinations and foetal monitoring. This information should include the risks associated and discomfort/ potential trauma associated with regular VE's and foetal monitoring. | Thank you for your comment. A review of the comparative risks and benefits of induction of labour compared to other modes of birth was not included in the scope of this update, therefore we are not able to provide more detailed data on these outcomes. However, the committee have expanded the recommendations on information and decision-making to clarify the factors that healthcare professionals and women will need to take into account when discussing mode of birth, and this includes vaginal examinations and the possible need for continuous fetal monitoring. We have also passed on your suggestion to the NICE surveillance team which monitors guidelines to ensure that they are up to date. |
| White Ribbon Alliance UK | Guideline | 006 | 024 - 026 | There is a lack of recognition of autonomy within this section. The committee should revisit this section taking into consideration the decisions, dignity and right to choice of the women or birthing person. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from these groups. |
| White Ribbon Alliance UK | Guidance | 006 | 020 | Remove 'with a black, Asian or minority ethnic family background' from the given examples of women with otherwise uncomplicated singleton pregnancies recommended for consideration of induction of labour. Ethnicity is not a stand-alone risk factor and portraying it as such is harmful and racist. Whilst evidence from within the MBRRACE-UK collaboration's <i>Stillbirths and Neonatal Deaths in Twin Pregnancies 2020</i> highlights that <ul style="list-style-type: none"> Maternal death rates were almost four times higher for women from Black ethnic backgrounds | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from certain ethnic family groups. We have also provided additional information on the proportion of women who go into spontaneous labour at different gestational ages, to support discussions with women about term and prolonged pregnancies. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

Consultation on draft guideline - Stakeholder comments table 25 May – 06 July 2021

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------|-----------|---------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | <p>and almost two times higher for women from Asian ethnic backgrounds, compared to white women. We urge the committee to also consider the MBRRACE-UK report is based on women with high-risk and/or complicated pregnancies which does not necessarily translate to women and birthing people with low-risk pregnancies. This recognition has been ignored by the committee in the recommendation to cite ethnicity as an example reason for the consideration of induction.</p> <p>Additionally, we advise the committee to revisit and define terms (by gestational week): term, full-term and prolonged pregnancy.</p> | |
| White Ribbon Alliance UK | Guideline | 006 | 020 | <p>WRA recognise the risks associated with prolonged pregnancies but feel that this section requires the inclusion of evidence of the benefits of physiological birth. The committee are presenting a very one sided view of risk, which is not inclusive of the benefits, to both women and birthing people and their babies, when a supported physiological and spontaneous birth are achieved.</p> <p>The committee do not present any evidence of the associated trauma that many women and birthing people have experienced as a result of induction, it has been presented by the committee only in relation to the point of birth and no evidence or consideration has been given to the postpartum recovery and the likelihood of induction related trauma.</p> | Thank you for your comment. The review carried out for this update compared earlier induction with later induction and it was not within the scope of this update to review the risks and benefits of induction compared to expectant management. However, the committee updated the section of the guideline on information and decision-making to include the factors that should be taken into consideration by women when deciding whether or not to have an induction |
| White Ribbon Alliance UK | Guideline | 029 | 023 - 024 | <p>As per the World Health organisation guidelines on Induction of labour, we request that the committed brings these recommendations in line with the recognition of a need for clear medical indications- <i>'Induction of labour should be performed only when there is a clear medical indication for it and the expected benefits outweigh its potential harms.'</i> WHO</p> | Thank you for your comment. We have amended the opening sentence of the context section to state that induction should only be carried out when the benefits appear to outweigh the risks. The context section does not define any groups at increased risk as this is included as part of the recommendations. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Inducing labour (update)

**Consultation on draft guideline - Stakeholder comments table
25 May – 06 July 2021**

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder | Document | Page No | Line No | Comments | Developer's response |
|--------------------------|----------|---------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | | | The committee should detail the medical risks associated, not the characteristics of particular groups of people in this line of the report- age, ethnicity, and assisted conception are not medical risks – they are identities, characteristics, heritage and conception pathways. We recommend that the committee undertakes the due diligence of using language that details medical risk, as opposed to generalisations on the likelihood of risk associated on characteristics | |
| White Ribbon Alliance UK | Guidance | 029 | 024 | We request that the committee informs us of how, and which specific national audit data, evidence that 'women from the Black, Asian and minority ethnic family background' (sic) are at higher risk of adverse events in pregnancy, when presented as in this combined ethnicity grouping. If national audit data can be highlighted to specific increased risk for Black women and Asian women, we urge for these to be presented separately and with reference to the specific increased risks identified to each separately stated ethnic group. | Thank you for your comment. Based on stakeholder feedback we have replaced the recommendation on earlier induction for groups of women who may be at higher risk with the information from the most recent MBRRACE report, and there is therefore no longer a recommendation to consider earlier induction in women from certain ethnic family groups. |

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees