Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Association for Improvements in Maternity Services	Guideline	General		We were surprised and concerned that no recommendations have been made about optimal cord clamping at a caesarean birth. This issue has a serious impact on the health of babies, particularly those whose health is already compromised. The issue is one that is of great concern to many parents and we request that it is addressed in this guideline.	Thank you for your comment. Cord-clamping was not within the scope of this update, no evidence was reviewed and therefore we are unable to make any recommendations. However, the NICE guideline on Intrapartum care is being updated in 2021 and it is anticipated that this topic will be covered in that guideline (including after caesarean birth).
Association for Improvements in Maternity Services	Guideline	General		We are disappointed to see no acknowledgement of the issue of the effect of caesarean birth on babies' gut flora and the potential effect of this. This is an issue of great concern to many parents. If there is currently not adequate research on this issue, then we would have hoped to see a research recommendation.	Thank you for your comment. We agree that there may be interest in this topic but the committee chose to prioritise 28 other outcomes and did not prioritise the effect of caesarean birth on babies' gut flora as an outcome in our review on the risks and benefits of caesarean birth, and so did not search for evidence on this. We are therefore unable to make a research recommendation.
Association for Improvements in Maternity Services	Guideline			If a woman wishes to plan a vaginal breech birth, particularly a physiological breech birth, the guideline should make it clear that this should be supported. If the Trust does not have staff with the appropriate skills and experience available to provide this, there should be a recommendation that the woman is referred to another service which is able to do so.	Thank you for your comment. The section of the guideline relating to breech birth was not included in this update, and the committee did not therefore look at the recommendations relating to staffing for physiological breech births. However, the committee amended the order of the existing recommendations to make it clear that a discussion about external cephalic version, vaginal birth and caesarean birth is held with all women, so vaginal birth is available as an option for all women.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Association for Improvements in Maternity Services	Guideline	004	018	Saying "around 25% to 35% of women will have a caesarean birth" is likely to be read by some as this being a suitable rate or a rate that is intentional.This needs to be a statement of fact that **currently** around 25 - 35% of women have a caesarean, but that the rates vary between maternity services. We would like to see a recommendation that the information given to individuals should include the local rate, as well as an indication of how this rate compares to the national average, and the range of rates nationally.	Thank you for your comment. We have amended the wording about the percentage of women who have a caesarean birth to state that this is the number who currently have a caesarean birth nationally. The committee were aware there are differences across the country but did not agree to include this level of detail in the recommendation.
Association for Improvements in Maternity Services	Guideline	004	019-020	Please can the examples here be expanded, so that the focus is not just on personal characteristics, for example include in the list planning to birth in an OU, or having continuous fetal monitoring.	Thank you for your comment. A bullet point later in the same recommendation already addresses the fact that choice of place of birth may impact on mode of birth and having continuous fetal monitoring would only happen in certain places of birth, so we have not expanded the list of personal characteristics to include these.
Association for Improvements in Maternity Services	Guideline	005	006-007	Between the "what the caesarean birth procedure involves" and "implications for future pregnancies…." please add "how a caesarean birth may impact the postnatal period (for example need for pain relief, additional challenges for caring for or feeding her baby, longer recovery period)	Thank you for your comment. We have amended this recommendation as you suggested and included pain relief as an example. With support, the committee did not think that caring for or feeding a baby should be different, and the longer recovery period is already covered in the benefits and risks section of the recommendations.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Association for Improvements in Maternity Services	Guideline	005	010	Please include uterine rupture in the examples in brackets	Thank you for your comment. The examples in brackets were designed to capture implications that had not been captured in the benefits and risks tables, and these tables do include information on uterine rupture, so these risks have not been duplicated in the recommendations.
Association for Improvements in Maternity Services	Guideline	005	010	Please include a subsequent bullet point about outcomes for the baby (including longer term outcomes for the baby).	Thank you for your comment. The examples in brackets were designed to capture implications that had not been captured in the benefits and risks tables, and these tables do include information on longer term outcomes for the baby, so these risks have not been duplicated in the recommendations.
Association for Improvements in Maternity Services	Guideline	007	003	We appreciate how using 100,000 as the denominator in all the cases aids the comparison of risks. We would like to also see these figures given as a 1 in 1500, or 1 in 5000, etc. This would help people to comprehend these risks better. We appreciate that it is difficult to produce infographics for such rare outcomes, but it would be good if the practicality of this could be considered.	Thank you for your comment. The committee agreed that the most appropriate denominator for the number of events such as those reported in the benefits and risks table is per 100,000, and that inclusion of other denominators as well would make the table more confusing. An infographic was considered but due to the small risk differences for many outcomes per 100,000 women, it was agreed this may not be useful for women and healthcare professionals. Instead, the tables and boxes that provide the estimates of benefits and risks have been revised and additional explanatory information has been

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					included alongside and we hope this will include the clarity of the information, rather than using an infographic.
Association for Improvements in Maternity Services	Guideline	010	011	Please can section 1.2.2 be moved before section 1.2.1. This then means it first addresses the discussion of the risk, benefits and options, which should include in this discussion the option of ECV, along with the risk and benefits of ECV, so that in the following section when an offer of ECV is made, it will allow an informed decision as to whether to accept or not, to be made.	Thank you for your comment. The order of these 2 recommendations has been switched so the discussion of benefits and risks of vaginal birth, caesarean birth and external cephalic version are all discussed before the offer of external cephalic version.
Association for Improvements in Maternity Services	Guideline	013	011	We are concerned by the use of the term **shared decision making.** This phrase fails to recognise that decisions are always for the woman to make and that it is not legal for any health care professional to be making decisions (except in the rare situation where a woman genuinely lacks capacity). Doctors and midwives have a legal duty to provide information and support maternity service users to make informed decisions, and then to respect and support the decisions made. Please could the heading of this section be changed to reflect this clearly, we would suggest that it be retitled **Supporting informed decision making**.	Thank you for your comment. Shared decision-making is the agreed NICE terminology and is defined by NICE as: 'Shared decision making is when health professionals and patients work together. This puts people at the centre of decisions about their own treatment and care.' We think this encompasses the process you have described so we have not changed this heading.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Association for Improvements in Maternity Services	Guideline	015	024	Please can it be made clear that the collection of items in brackets define the package of care also called 'active management of labour. Perhaps actually saying in the brackets (a package of care comprising of …..then list)	Thank you for your comment. The wording in the brackets has been amended as you suggested to clarify that this is what is meant by active management of labour.
Association for Improvements in Maternity Services	Guideline	016	012	We are concerned by the reappearance of the word emergency in this guideline. This is a source of confusion and misinformation when communicating with women and lay people in general, and many people interpret the term to mean what medical staff would consider to be a category 1 caesarean. As an emergency caesarean is just one that is unplanned, please can we ask for the term emergency to be removed from the guideline text and replaced by the term unplanned. (On the other hand, we are pleased to see that the word 'elective' has not been included in your text.).	Thank you for your comment. We have removed the wording 'unplanned and emergency' to make it clear that these recommendations apply to all caesarean births.
Association for Improvements in Maternity Services	Guideline	016	012	We are unclear as to why the classifications are being considered here only in relation to unplanned caesareans, as surely all caesareans should be classified in this way. We appreciate that most planned caesareans would fall into category 4	Thank you for your comment. We have removed the wording 'unplanned and emergency' to make it clear that these recommendations apply to all caesarean births.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Association for Improvements in Maternity Services	Guideline	019	009	We were pleased to see recommendations around the prevention and management of hypothermia and shivering.	Thank you for your comment
Association for Improvements in Maternity Services	Guideline	022	015	Please can the uncertainty over the cosmetic impact of closure/non closure be included. It is shocking - 16 years on from this being commented on with the publication of the First NICE Caesarean Guideline in 2004 - that you have no comment about the availability of research on this issue, despite much anecdotal evidence from women and some relevant studies, e.g. Suture Closure versus Non-Closure of Subcutaneous Fat and Cosmetic Outcome after Cesarean Section: A Randomized Controlled Trial (plos.org).	Thank you for your comment. This section of the guideline was not included in the scope of this update and so the committee did not look for or review evidence on closure of subcutaneous fat. However, we will pass your comment and the evidence you have identified to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
Association for Improvements in Maternity Services	Guideline	023	009	Please can something be added about the discussion of whether antibiotics reach the baby and the option of them being given later. Without this information women are not enabled to provide informed consent.	Thank you for your comment. The recommendation already specifies that there is no known effect of antibiotics before skin incision on the baby, and as this section was not updated, the committee did not review the evidence for the timing of antibiotic administration and so are unable to recommend the option of them being given later.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Association for Improvements in Maternity Services	Guideline	023	023	We are confused by the text saying "offer these interventions if there is uncertainty about whether there is an increased risk of thromboembolic disease". Can this be explained?	Thank you for your comment. We have clarified the recommendation to state that thromboprophylaxis should be offered to all women after caesarean birth.
Association for Improvements in Maternity Services	Guideline	028	028	Surely this should say "in some babies" and not 'some women'?	Thank you for your comment. The words 'in some women' has been removed from the recommendation to make it clear. It is women who are the rapid metabolizers of codeine, but we agree this could have been confusing.
Association for Improvements in Maternity Services	Guideline	029	006	We would like to see this include a recommendation to include a discussion with the woman of when to have her catheter removed, and for the timing to be agreed with her. We know that some women will want the catheter removed earlier, and for others it would be better to leave it longer, and that there are likely to be a variety of reasons for this.	Thank you for your comment. We have amended the wording of the recommendation to state 'Offer removal…' as this indicates the removal (or not) should be discussed with the woman.
Association for Improvements in Maternity Services	Guideline	031	021	We are confused that it says 'may be' when women are being given interventions following a caesarean to reduce the risk of thromboembolic disease.	Thank you for your comment. We have clarified the recommendation to state that thromboprophylaxis should be offered to all women after caesarean birth.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Association for Improvements in Maternity Services	Guideline	031	027	We are concerned by the wording of this recommendation for a number of reasons. Firstly, we think it is inappropriate to use the wording **"encourage** women…" women should be free to make their own decisions about when they are ready to resume these activities, particularly sexual intercourse. Secondly, it needs to be made clear that for some activities, such as driving, to be safe, women need to be able to do this without being affected by any pain (eg to allow them to carry out urgent manoeuvres such as an emergency stop). Finally, many women still get some pain for many months or even years after surgery, and to suggest that they should not be yet resuming any of these activities could be dismissive of individuals' recoveries. Currently the wording of this recommendation doesn't seem supportive of different people's circumstances and needs.	Thank you for your comment. The wording of this recommendation has been changed as you suggest, to make it clear that resuming activities should be discussed with women but they can resume such activities when they feel ready to do so.
Association for Improveme	Guideline	032	005	We are pleased to see the word dyspareunia put into plain english	Thank you for your comment.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
nts in Maternity Services					
Birth Trauma Association	General	General	General	Thank you for the opportunity to respond to this consultation. We would have liked to have taken part in the scope consultation and applied for the guideline development group but did not get notification even though we were one of the organisations actually quoted in the last Caesarean Update. We have very direct contact with a wide audience of service users (over 9,000) many of whom are affected by the recommendations. We are investigating this with NICE to identify the problem which hopefully will prevent this happening in future.	Thank you for your comment. This guideline update was a small update of a number of questions which had been identified by the NICE surveillance team as requiring amendment due to the emergence of new evidence. As this was a small update, the original scope for the guideline remained unchanged, no scoping phase was carried out and no scope was issued for public consultation. This update was carried out by a committee who were appointed in late 2017 and early 2018 to carry out a number of smaller updates to obstetrics and gynaecology guidelines, including caesarean birth, and vacancies were advertised on the NICE website in the usual way.
Birth Trauma Association	Guideline	006-008 Overall	Outcomes	I think the evidence needs to be separated into definite risks (e.g. placenta accreta in subsequent pregnancy/injury to the vagina) and those where the evidence may be higher but where the evidence is weak. Also, choice of outcomes should include factors such as pelvic floor prolapse, levator ani and PTSD.	Thank you for your comment. The committee decided to report outcomes separately, categorising these by outcomes that may be more likely with caesarean birth, with vaginal birth, and outcomes that have conflicting or limited evidence. In this latter group, the committee

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					included studies in which the evidence was of insufficient quality or contradictory. PTSD was prioritised as an outcome, but no relevant studies were identified for inclusion. Pelvic floor prolapse and levator ani were not prioritised as outcomes but the outcome bladder/bowel/ureteric injury was included as a short-term outcome, and urinary and faecal incontinence as long-term outcomes, so the committee agreed these would give an indication of how the pelvic area is affected. The committee discussed the fact that there were a large number of outcomes which could be considered as potential benefits or risks of either caesarean birth or vaginal birth. The committee agreed to prioritise 28 outcomes as they believed these were the most direct indicators of safety for mode of birth and would be the most informative ones for women's decision making. However, they acknowledged that there could be more outcomes relevant for decision-making. This is reflected in the committee discussions of the evidence under 'the outcomes that matter most'.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Birth Trauma Association	Guideline	005	012	There is a general problem with the research around c/s and planned vaginal birth which often conflates the higher risk profiles of women planning c/s and the different and usually lower risk profiles of those planning vaginal birth. Additionally, planned elective c/s outcomes cannot be compared with unassisted or spontaneous vaginal birth as several of the included studies in this NICE guideline have done. Nor is planned c/s after first breech a proxy for low risk; women who have had a first breech birth have ongoing higher risk factors. *(Recurrence of breech presentation in consecutive pregnancies* *June 2010BJOG An International Journal of Obstetrics & Gynaecology 117(7):830-6)* Maternal request caesareans are relatively rare; nearly all planned caesareans are because of risk factors. Moreover, risks are non-generalisable. A small, older woman with a large, first baby and IVF conception could be seriously misled unless this is addressed. Risks need to be individualised to have any degree of accuracy, even within the broad spectrum called 'low risk women.'	Thank you for your comment. The review aimed to look at differences in outcomes between planned caesarean birth and planned vaginal birth, but due to a lack of evidence for some outcomes, evidence based on actual mode of birth was used. The benefits and risks tables have been clarified to include details of the exact populations of women for each outcome. The committee agrees that the ideal control group would have been women undergoing any type of planned vaginal birth (including assisted and spontaneous), however this type of evidence was not always available. Please note that studies including women with babies in breech presentation have not been included as this was considered a possible medical or obstetric indication for caesarean birth. The committee agrees that there may be other risks not included in the benefits and risks tables, and there is an existing recommendation in the section of benefits and risks of caesarean and vaginal birth about explaining to women that there are other risks relevant to the woman's individual circumstances.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Birth Trauma Association	Guideline	006	Box 1 Faecal incontinence	Separating the risks for faecal incontinence into two parts – risks after spontaneous vaginal birth where risks are similar and in a separate section listing the risks as lower for caesarean - goes against good practice in the communication of risk to patients. Patients/women should have explained to them the risks and options they face. Women do not have a choice of spontaneous birth – that is largely luck. They have a risk of planned caesarean versus planned vaginal birth. There is an enormous amount of evidence that faecal incontinence is increased in planned vaginal birth – mainly operative vaginal birth The study quoted in NICE C/S guideline certainly isn't supportive of 'no difference' between planned vaginal and planned c/s. It only compares planned c/s with spontaneous vaginal delivery. Anal sphincter injuries only occur when the anal sphincter has been damaged. Unless the obstetrician is slightly squiffy, his knife will not – hopefully - slip that far off target! While OASI is not the cause of all faecal incontinence, it causes around 50%. Planned	Thank you for your comment. Unfortunately, no studies were identified that provided comparisons of planned caesarean birth with planned vaginal birth (including those that both went on to have assisted and unassisted vaginal birth in a composite group) for this outcome. The only evidence available reported the two comparisons (caesarean birth versus unassisted vaginal birth and caesarean birth versus assisted vaginal birth) separately and therefore they are reported separately here. Full information on the evidence underlying these statements is available in evidence report A and we have also provided additional information alongside the tables to explain why this evidence has been presented in this way. To ensure we have not missed any evidence we have checked the references you mention in your comment. Please see below our response to each reference: 1. Lunniss 2004: this study did not adjust for confounders, therefore is not relevant for inclusion. 2. Kargın 2017: this study did not adjust for confounders, therefore is not relevant for inclusion.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				vaginal birth leads to an increase in both urinary and faecal incontinence. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1079318/ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5558316/ https://pubmed.ncbi.nlm.nih.gov/17885465/ https://pubmed.ncbi.nlm.nih.gov/16941639/ https://pubmed.ncbi.nlm.nih.gov/31213053/ https://pubmed.ncbi.nlm.nih.gov/30478651/ etc. etc. etc. We would request the reference to lower faecal incontinence in Box 1 be removed.	3. Wheeler 2007: narrative review; some of the studies included any type of caesarean birth (including emergency), therefore this review is not relevant for inclusion. 4. Wietek 2007: functional asymmetry is not within the scope of this guideline's update, therefore this study is not eligible for inclusion. 5. Lincová 2019: this study reported OASI, which is not a relevant outcome in the review protocol. 6. Murad-Regadas 2018: this study did not have a relevant intervention group (caesarean birth).
Birth Trauma Association	Guideline	007	Table 1 Peripartum hysterectomy	NICE has used a Canadian birth records study. These can be very unreliable as described later. We have very good risk assessment based on UKOSS data in the UK. This is what it concludes: 'On the basis of an analysis of risk of hysterectomy, the authors suggested that ERCS should be the strategy of choice for women planning one additional pregnancy, but for women who desire two or more subsequent pregnancies, VBAC should be attempted to minimise morbidity associated with multiple caesarean	Thank you for your comment. We appreciate the reference provided to the UKOSS reporting system. We have checked the study by Nair 2015 you mention in your comment. However, this is not relevant for inclusion because the reported outcomes were not prioritised by the committee and included in the protocol. The studies report on peripartum hysterectomy, severe sepsis, peripartum haemorrhage, and failed tracheal intubation (all in women with a previous caesarean or vaginal birth). In terms of outcomes in any future pregnancy, the committee prioritised

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				sections. *(BMJ Open 2015;5:e007434 doi:10.1136/bmjopen-2014-007434 Selected maternal morbidities in women with a prior caesarean delivery planning vaginal birth or elective repeat caesarean section: a retrospective cohort analysis using data from the UK Obstetric Surveillance System Manisha Nair1, Kate Soffer2, Nudrat Noor1, Marian Knight1, Malcolm Griffiths)* This is really helpful to women when deciding on birth options - it provides much more of the granular detail that is needed for women to make informed decisions although more emphasis on respect for the woman's decision would be appropriate.	placenta accreta/morbidly adherent placenta/abnormally invasive placenta, uterine rupture and stillbirth. For further details about the review protocol, please see appendix A in Evidence review A. We have already included in the recommendations that implications for future pregnancies and birth after caesarean birth should be considered as part of the decision-making process when deciding on mode of birth.
Birth Trauma Association	Guideline	007	Table 1 Maternal death	This is misleading. In-labour caesarean section does indeed have a higher risk but this is an outcome of planned vaginal birth. Women reading this guidance are women planning caesarean section not an intrapartum emergency one. As for maternal deaths being 6 times higher, this is completely wrong. The confidential enquiries collected very accurate data on planned caesarean for six years (see below) and there was no difference. Indeed, given the higher risk factors for women planning	Thank you for your comment. The data provided by MacDorman 2008 was from an 'intention to treat' type analysis, so women in the planned caesarean birth group may have ended up with a vaginal birth, or an emergency caesarean without labour, and women in the planned vaginal birth group may have had either a caesarean birth (if there were labour complications) or a vaginal birth. Therefore, this study reflects the relevant risks during the antenatal period when a woman

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				caesarean, the risks seem relatively lower. The study this guideline has used refers to caesarean without recorded labour as the comparator cohort. This is not a proxy for planned c/s because it excludes the 'in extremis' emergency admissions to A&E with fatal – usually cardiovascular -conditions. The readers of this leaflet are not planning to choose this sort of section so the information is grossly misleading. We have accurate UK data on this from the years 2003-2008 covering millions of UK births from two CEMACH reports. There were 7 direct deaths (early or late) involving women who had planned c-section. There were a total of 185 direct deaths across these triennium. Given planned c/s is around 11-13% of total births, 7 planned c/s deaths out of 4 million births clearly does not indicate a six fold increase in maternal deaths. The detail of CEMACH and MBRRACE data show that most deaths are complex in cause and relate primarily to NHS resourcing, skill training and maternal risk factors .	is planning mode of birth and we therefore believe these data are an accurate representation. Thank you for the reference provided. The confidential enquiry reports provide descriptive data about maternal health, and although the committee acknowledges that these are important sources of data, these cannot be included because only peer-reviewed published full text studies were considered for inclusion under the protocol for this review.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				(Only 2006-8 report seems to be online) *P.39 for 2006-8 https://www.oaa-anaes.ac.uk/assets/_managed/editor/File/Reports/2006-2008%20CEMD.pdf* **Strongly urge NICE to re-examine the evidence. We have robust evidence for maternal deaths which does not support the information it is currently providing.**	
Birth Trauma Association	Guideline	008	Outcomes for babies.	There are multiple studies on asthma and mode of delivery including a recent metaanalysis of all studies showing a 20% increase in asthma https://aacijournal.biomedcentral.com/articles/10.1186/s13223-019-0367-9 What we still don't know is whether caesarean section is a result of conditions that also lead to asthma (e.g. low gestational age) or obesity or whether they are causal. Ditto obesity; although some extremely large long term recent studies show no link https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002996 I think it is reasonable to say there may be a link – more so for asthma than obesity but it does not belong in the same category as placenta accreta, , uterine rupture, faecal incontinence	Thank you for your comment and the references provided. We have checked the references and they cannot be included in the current review because they were published after our search dates (August 2019). However, the reported results are consistent with the review findings for both asthma and childhood obesity. A causal link between the reported results and mode of birth cannot be established for any outcome. This has been highlighted in the discussion section of Evidence review A and in the introductory text that has now been added alongside the benefits and risks tables.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				or injury to the vagina where the evidence is incontrovertible and robust.	
Birth Trauma Association	Guideline	008	Table 1 Uterine rupture	There is a huge difference in risk of rupture between women planning a second vaginal birth versus those planning a repeat c/s. Without this crucial information this will make women anxious about spontaneous rupture in late pregnancy which is extremely rare. Furthermore it will mislead women deciding between VBAC or second C/S. The risks are overwhelming for the group choosing VBAC. Hence it could cause women to make a choice that would increase the risk of the very outcome they fear. *(LoS Med. 2012;9(3):e1001184.* doi: 10.1371/journal.pmed.1001184. *Epub 2012 Mar 13.* *Uterine rupture by intended mode of delivery in the UK: a national case-control stud**y*** "The estimated incidence of uterine rupture was 0.2 per 1,000 maternities overall; 2.1 and 0.3 per 1,000 maternities in women with a previous caesarean delivery planning vaginal or elective caesarean delivery, respectively.")	Thank you for your comment. The risk of uterine rupture in a subsequent pregnancy is increased following a caesarean birth, but as you highlight this will be affected by the mode of birth in that subsequent pregnancy, and other factors. Although this is not addressed in detail in the benefits and risks table, the guideline does include a later section specifically on pregnancy and childbirth after caesarean birth and this section includes recommendations on discussing these risks with woman. The reference you have supplied (Fitzpatrick 2012) was excluded from the review because the population did not match the protocol criteria, as the study included women with uterine rupture versus women without a uterine rupture.
Birth Trauma Association	Guideline	008	Table 1	It is important that guidance adheres to good practice in communication of risk to the public. When women are deciding between	Thank you for your comment. We agree that women wish to know the likely outcome based on their planned mode of birth and the aim of this

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
			Neonatal mortality	planned caesarean or planned vaginal birth, the question they are asking, in this context, is whether either one of these increase the risk of their baby dying as a consequence of their choice. The question is not an academic one of whether more babies with complications are born one way or the other – unfortunately and misleadingly this is the one that the McDorman study answers. The evidence on whether prior c/s leads to stillbirth is conflicting as correctly stated elsewhere. If we then ask the correct question, i.e. does the intervention 'planned c/s at 39 weeks + (as recommended) lead to more intrapartum or early neonatal death as compared with a planned vaginal birth?', we can answer the question women are asking. There is ample evidence: This study analyses the main causes of unexpected intrapartum and neonatal death. 1. https://pubmed.ncbi.nlm.nih.gov/29301489/ Nearly all intrapartum or early neonatal deaths are caused by congenital malformation, asphyxia, chorioamnionitis or placental abruption. None of these are	review was to identify evidence that compared outcomes with planned caesarean compared to planned vaginal birth. To ensure we have not missed any evidence we have checked the references provided in your comment. Please see below our response to each reference: 1. McNamara 2018: study did not adjust for confounders, therefore it does not meet inclusion criteria. 2. NIH State-of-the-Science Conference Statement on caesarean delivery on maternal request: this is a statement prepared by a committee. Only peer-reviewed published full texts papers were eligible for inclusion, therefore it does not meet inclusion criteria. 3. Pasupathy 2011: reports adjusted ORs by maternal age and not by mode of birth. Only descriptive data are provided by mode of birth. 4. Lawn 2009: narrative and systematic review, focused on global trends of intrapartum related outcomes for women and neonates, focusing on variations per country and possible strategies. No

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				caused by the caesarean operative procedure. 2. An international symposium organised by the US National Institute of Health in 2006 reviewed the evidence on maternal choice planned C-section and concluded : *"Fetal mortality. Based on epidemiologic modeling, there is an increased risk of stillbirth in the planned vaginal delivery group, because planned caesarean delivery would result in delivery by 40 weeks of gestation, and planned vaginal delivery could occur up to 42 weeks of gestation.* *Intracranial haemorrhage, neonatal asphyxia, and encephalopathy. Consistently higher rates of intracranial haemorrhage are observed in operative vaginal delivery and caesarean delivery in labor, suggesting caesarean delivery on maternal request should be associated with lower risk of intracranial haemorrhage than the aggregate of spontaneous and assisted vaginal deliveries that comprise planned vaginal delivery. Evidence indicates a lower risk of neonatal asphyxia and encephalopathy with*	data are provided to assess whether there are any differences of intrapartum or early neonatal death by mode of birth, therefore this study does not meet criteria for inclusion. 5. Pasupathy 2009: reports adjusted ORs by causes of death, however only descriptive data are provided by mode of birth, therefore this study does not meet inclusion criteria. In response to your comments relating to the McDorman study: McDorman 2008 is a retrospective cohort, population based study including above 7 million births in low-risk women with no risk factors (such as cardiac disease, chronic hypertension, pregnancy associated hypertension or eclampsia). The committee agreed that birth registers can be inaccurate and interpreted the results of this study with this limitation in mind. However, the data provided by the study were by intention to treat, so women in the elective caesarean birth group may have ended up with a vaginal birth, or an emergency caesarean without labour, and women in the planned vaginal birth group may have had either a caesarean birth with labour complications or a vaginal birth.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				elective caesarean delivery compared to operative and spontaneous vaginal deliveries plus emergency or laboured caesareans, which comprise planned vaginal delivery." https://consensus.nih.gov/2006/cesareanstatement.htm 3. The main risk of death in babies that relates to the actual birth process is hypoxia. Virtually all the other causes are factors that lead to the caesarean not a result of the intervention itself. The only possible cause of death of a baby by the caesarean operation would seem to be laceration or respiratory distress syndrome. I am unable to identify a single case anywhere in the literature of a term baby born at 39 weeks plus and with no other abnormalities dying of either of these conditions. https://pubmed.ncbi.nlm.nih.gov/20719805/ (relates only to advanced maternal age and hypoxia). https://obgyn.onlinelibrary.wiley.com/doi/full/10.1016/j.ijgo.2009.07.016 1. The most enlightening study of all is the huge Scottish study of factors	Therefore, this study reflects the relevant risks during the antenatal period when a woman is planning mode of birth.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				related to perinatal death in Scotland where outcomes for planned caesarean versus vaginal are separated. (Note some of the vaginal births -1-2% may have been planned c/s but the difference between the two outcomes is so large it would not make a significant difference). The lower death rate from hypoxia, arising from planned caesarean is substantial. https://jamanetwork.com/journals/jama/fullarticle/184382 Pasupathy D, Wood AM, Pell JP, Fleming M, Smith GCS. Rates of and Factors Associated With Delivery-Related Perinatal Death Among Term Infants in Scotland. *JAMA.* 2009;302(6):660–668. doi:10.1001/jama.2009.1111 We then come to the problems with the McDorman Study which NICE uses and has been widely criticised. This study used birth certification data and made the assumption that the absence of any record of labour was a proxy for a planned C-section. There are two significant flaws. Firstly, there is a study warning not to use birth certification data for	

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				research because it is highly inaccurate. (Rydon-Rochelle MT, Holt VL, Nelson JC, Cárdenas V, Gardella C, Easterling TR, Callaghan WM. Accuracy of reporting maternal in-hospital diagnoses and intrapartum procedures in Washington State linked birth records. Paediatric Perinat Epidemiol. 2005 Nov;19(6):460-71. doi: 10.1111/j.1365-3016.2005.00682.x. PMID: 16269074).Secondly, there are a multiplicity of reasons why an emergency caesarean would be carried out without labour e.g. foetal compromise after the mother has reported reduced foetal movements, severe eclampsia etc. So this study is not answering the question women are asking. In conclusion, please use higher quality UK data that is available and clearly shows lower neonatal mortality.	
Birth Trauma Association	Guideline	008	Table 1 Placenta Accreta	Without doubt there is an increase in placenta accreta with increasing numbers of C-sections. However, I do think the framing of this risk in this way is not helpful because it does not address the exponential increase in risk with sequential caesareans. For a woman who has had a single (most likely	Thank you for your comment. The committee prioritised the outcome placenta accreta in any future pregnancy, therefore they were unable to make specific recommendations by number of previous pregnancies. However, in the recommendations, the committee outlined that there may be risks relevant to women's individual

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				emergency caesarean) she does not increase the risk of accreta by choosing planned caesarean for the next birth. The risk occurs antenatally and at the time of birth the risk is the same whatever mode of birth is chosen. The risk increases if she chooses to have a larger family i.e. this is not her last planned c-s pregnancy. Multiple repeat caesareans are risky – and caesarean birth is highly inadvisable for anyone planning a large family. Tahir Mahood et al did a very good analysis of the risk after a single caesarean birth which was increased but by a very small margin. Given that the overwhelming majority of women plan only two children and most first c/s are emergency in-labour sections, it would be useful to include this reassuring information and strengthen the recommendations around the higher risk arising from multiple c/s. *Risk of placenta previa in second birth after first birth cesarean section: a population-based study and meta-analysis BMC Pregnancy and Childbirth2011**11**:95*	circumstances, and provided placental adherence problems from multiple caesarean births in their example. Although this is not addressed in detail in the benefits and risks table, the guideline does include a later section specifically on pregnancy and childbirth after caesarean birth and this section includes recommendations on discussing these risks with woman. Thank you for the reference provided. We have reviewed it, but it is not eligible for inclusion because the outcome of interest in that study is placenta previa, and the outcome prioritised by the committee was placenta accreta/morbidly adherent placenta/abnormally invasive placenta.
Birth Trauma Association	Guideline	009	Table 2	Injury to the vagina appears to exclude episiotomy.	Thank you for your comment. The committee did not prioritise this outcome for inclusion in this review and the outcome 'injury to the vagina' was

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					carried through from the previous guideline and this was the terminology used, but we have looked at the evidence upon which this was based and it refers to vaginal tears, so we amended this to 'vaginal tears' to better reflect the meaning of the outcome reported by the study. It does not include episiotomy.
Birth Trauma Association	Guideline	050	1.1.1.2	Evidence based antenatal discussion of c/s is welcome. However, it is important that the health care professionals imparting the information understand the risks themselves and have training on the latest evidence.	Thank you for your comment. It is useful to know that you are aware of potential implementation issues with this NICE guidelines and your comments will be considered by NICE where relevant support activity is being planned
Birth Trauma Association	Guideline	051	1.1.2.4	Excellent change: "The recommendation has been amended to make it clear that it is the woman's decision, not something that is decided for her."	Thank you for your comment.
Birth Trauma Association	Guideline	052	1.2.1	Whilst welcoming the inclusion of the word declined, it should be made clear to women that ECV does not improve outcomes. It only reduces breech births. The woman and baby suffer the same high risk of complications as if the birth were still breech. 'Labor following successful ECV is more likely to result in increased intrapartum intervention rates and poorer neonatal outcomes'. *J Perinatol. 2016 Jun;36(6):439-42. doi: 10.1038/jp.2015.220. Epub 2016 Jan*	Thank you for your comment. The section of the guideline on caesarean for breech was not included in the scope of this update, the evidence was not reviewed, and so the committee were not able to make this change. However, we will pass the evidence you have identified to the NICE surveillance team who ensure that guidelines are up to date.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				21.'Intrapartum intervention rates and perinatal outcomes following successful external cephalic version. Women are not being given full information and it is leading to litigation.	
Birth Trauma Association	Guideline	055	1.2.9.2	Very strongly disagree with this. There should be no team opt out of offering caesarean. Women are currently being psychologically and often (as in the case of Montgomery v Lanarkshire) physically harmed along with their babies because of failure to listen to women's voices, understand reasons for choices or even understand the complexity of the evidence. The sheer level of cruelty that this inflicts on women – particularly those with severe tokophobia – is unacceptable. As a user group, overwhelming the best outcomes occur when women feel in control of how they give birth. Taking away control by making them jump through a series of hoops to get their choices respected causes enormous distress and risks harm to both the baby and the woman. Where teams are more focused on their own beliefs than on the avoidance of harm to women and are unable to respect individual autonomy then they should not be working in the NHS. That said, there are very	Thank you for your comment. The recommendation to which you refer relates to the maternal request section of the guideline. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				few teams who hold such views – the overwhelming direction of travel is in understanding the central role of patient autonomy.	
Birth Trauma Association	Guideline	055	1.2.9.3	Mental health support should be equally available to women requesting any birth choice. Many women with severe obstetric problems (i.e. morbidly adherent placenta) can suffer extreme anxiety about a caesarean birth. Mental health support should be offered on the basis of need.	Thank you for your comment. The recommendation to which you refer relates to the maternal request section of the guideline. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
Birth Trauma Association	Guideline	064	1.5.4.1.	Please amend the wording to women who have had a c/s should be offered additional support with holding the baby and feeding including breastfeeding.	Thank you for your comment. The recommendation you refer to (1.5.4.1) is from the previous version of the guideline and has been amended to make to clear it applies to women who wish to breastfeed.
Birth Trauma Association	Research Question			Research is urgently required into the different outcomes of planned vaginal versus planned caesarean for a variety of risk strata in women and babies so that women can be given more granular information based on their individual risk factors.	Thank you for your comment. The committee agreed that more research was needed to determine the short and long-term outcomes of caesarean birth and have made a research recommendation.
Birthrights	Guideline	General	General	As an organisation, we don't generally comment on clinical matters. However we absolutely promote an individual's legal right to be given up to date, balanced, evidence	Thank you for your comment. The boxes and tables relating to the benefits and risks of caesarean birth and vaginal birth have been amended to clarify the population on which the

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				based information. There is a longstanding concern in relation to planned caesarean birth, that the information used to counsel women is drawn from studies that use mixed caesarean data ie outcomes from both planned and unplanned caesareans which is not directly applicable to a woman who is choosing a planned caesarean birth with no other health or pregnancy concerns. In addition even when planned caesarean data only is used, a distinction is not made between those who were advised to have a caesarean because of other factors that made them "high risk" and those who have no such risk factors. Jonathan West (FRCS FRCOG) has recommended the following statement to be made before the tables and boxes that start on page 6 ***' Evidence on which the list of comparative risks of CB and VB are presented will of necessity be historic and in some cases derived from studies of populations and healthcare systems that differ from the UK. Changes and improvements may have improved current practice and modified these risks. Healthcare professionals advising women on their choice of mode of birth should be***	risk figures have been based, and this is discussed in more detail in Evidence review A. In addition, introductory text providing more information about this and the outcomes which the committee agreed were most likely to demonstrate actual differences due to the mode of birth has now been added before the tables. The committee agreed that including data by planned mode of birth ("intention to treat", ITT, which is synonymous with 'choice of method of delivery') would be the ideal scenario. Unfortunately, this type of evidence was rarely available and so the committee took a hierarchical approach to the evidence in their analyses preferentially including ITT type analysis, but if none was available they then included analyses conducted by the actual mode of birth women had, but excluding emergency caesareans. However, there was not always evidence available of this type and so for some outcomes the committee accepted evidence from a third category where emergency caesarean births were included in the caesarean birth arm. This does not mean that in those studies the caesarean birth group was exclusively emergency caesareans, just that in those studies the caesarean birth

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				as up to date as possible about the latest available data. Figures quoted should also be interpreted in the light of the possibility that the evidence from studies may be influenced in the case of both planned and emergency CB in particular that the procedure may have been recommended because of special risk factors affecting the mother's or baby's health'. We would wholeheartedly support this addition and would welcome clarity throughout the document (particularly pages 6 to 9) when comparisons are made between vaginal birth and caesarean birth, whether the comparison is between planned vaginal birth (which may result in a straightforward vaginal birth, an instrumental birth or an unplanned caesarean) and planned caesarean birth or whether any distinction is uncertain. We are aware that others are submitting comments about the reliability of the statistics set out in the tables and boxes. T is essential that these are considered carefully to ensure that the information being given to women and birthing people to enable them to make an informed decision is as up to date and accurate as possible.	group may have included both emergency and non-emergency caesarean births.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Birthrights	Guideline	009	Table 2	Although we appreciate the guideline is aimed at healthcare professionals, it will also be read by women and birthing people and the description of the reduction in pain scores was particularly difficult to understand. It would be helpful if the description of the pain scores could be explained more clearly.	Thank you for your comment. We have added more detail to the benefits and risks table to clarify the scoring system used. We have also added a new appendix to the evidence report that supports this table. It includes additional details about the outcomes in this table that are derived from the previous version of the guideline.
Birthrights	Guideline	011	016-024	As NHSE is in the process of commissioning specialist centres for placenta accreta spectrum disorders, it would be good to see this guideline recommend that ideally the woman should have her caesarean birth at a specialist centre commissioned to care for women with placenta accreta spectrum conditions.	Thank you for your comment. The committee were aware that commissioning of specialist centres was being planned, but they were not in place everywhere and would be subject to commissioning arrangements and so did not agree this should be included in the guideline.
Birthrights	Guideline	013	011	Strong preference for the term "supported decision making" or "informed decision making". "Shared decision making" suggests that the healthcare professional makes a decision jointly with the woman whereas in law the decision is the patient's and the patient's only.	Thank you for your comment. Shared decision-making is the agreed NICE terminology and is defined by NICE as: 'Shared decision making is when health professionals and patients work together. This puts people at the centre of decisions about their own treatment and care.' We think this encompasses the process you have described so we have not changed this heading.
Birthrights	Guideline	013	019	Welcome this clarification that the decision is the woman's.	Thank you for your comment.
Birthrights	Guideline	013	023	Please remove the wording "with no medical indication". The current phrase suggests a	Thank you for your comment. This part of the guideline is outside the scope of the current

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				black and white distinction between when a caesarean is medically warranted (including for psychological reasons) and when it is not, and that that boundary needs to be policed by a medical professional rather than relying on an individual's own judgement of what is right for her. We believe the notion is inherently discriminatory against women. Our analysis of our advice service enquiries set out in our maternal request caesarean report published in 2018, found that 28% of women wanted a caesarean because they were concerned about a vaginal birth aggravating another medical condition such as vaginismus, symphysis pubis dysfunction or fibroids. The Montgomery vs Lanarkshire judgement implies that the decision about whether a woman is prepared to take this risk, even if the risk is small, belongs to the individual patient. The medical professional may not agree with her but it is still her decision. Similarly, women have described to us being put through gruelling psychological assessments to assess whether they warrant a caesarean on psychological grounds, when the woman is already clear that this is what would be best for her psychologically. Finally,	committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out..

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				even when a woman wants a caesarean to avoid an outcome such as a severe tear even if the chance of this happening is small, this could still be regarded as a "medical" outcome she strongly wishes to avoid.	
Birthrights	Guideline	013	028	Please change to "If the woman decides after this conversation that she would like a caesarean, her decision and the reasons for her decision should be recorded." Recording not only that the discussion took place but what the woman/birthing person's decision was shows respect and that she/they have been listened to.	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
Birthrights	Guideline	014	001	Please phrase this as "offer meetings with…". It should be clear that where the woman already feels she has enough information to make an informed decision the woman is not obliged to have a range of meetings and this should not affect whether a caesarean is offered.	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Birthrights	Guideline	014	008	Pleased to see this phrased as "offer". However we would like to see it made explicit that it is not mandatory to accept the offer or perinatal mental health support, and that it should not be assumed that anyone asking for a maternal request caesarean has a mental health issue. Our maternal request caesarean report (see above) rated Trusts as amber that required a compulsory mental health assessment in order to access caesarean. Our research suggested that in practice there is confusion about whether a referral to a mental health professional is genuinely an offer of support or whether it is about ascertaining whether a woman is "anxious enough" to offer a caesarean on psychological grounds. We found that many Trusts guidelines were based on the assumption that anyone requesting a maternal request caesarean must have anxiety issues around birth and did not really know how to treat anyone requesting a caesarean for any other reason.	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
Birthrights	Guideline	014	014	This feels more appropriate in a guideline for healthcare professionals treating tokophobia. Mental health support should be available to	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				all those requiring it regardless of whether they are requesting a caesarean.	that a review of this section of the guideline is required and has asked NICE to carry this out.
Birthrights	Guideline	014	017	Change to "If after discussion of the benefits and risks a woman opts for a caesarean birth, offer a planned caesarean birth" – the current wording very much suggests that a vaginal birth is preferable. The guideline should be unbiased.	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
Birthrights	Guideline	014	017	Would like to see the guideline indicate that these discussions should be held and a caesarean offered as soon as possible. One of the main themes of the enquiries to our advice line on this issue is the anxiety caused to women by the final decision being taken around 36 weeks in many Trusts which means women go through the whole of their pregnancy not knowing if their request is going to be honoured. Even worse some women find themselves having to contemplate a change of Trust at this very late stage if the Trust says no. Birmingham Women's guideline which we have on our website as an example of best practice says the decision should be made between 24-28 weeks. We would argue that where women/birthing people are aware of all the relevant evidence and are clear in their	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				decision there is no reason for this not to be offered even earlier. Where the process may take a number of weeks, women should be reassured from the outset that once a conversation on the risks and the benefits has taken place, their decision (whatever it is) will be respected.	
Birthrights	Guideline	014	019-020	Would like to see it explicitly stated that the caesarean should be offered at 39 weeks. We are aware of Trusts who schedule a maternal request caesarean for 40 weeks – again increasing anxiety for women for no good reason.	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
Birthrights	Guideline	014	022-024	Strongly disagree with the change from "obstetrician" to "current healthcare team". Individual obstetricians may theoretically have the right to opt out of a caesarean if they really believe this will harm the patient (although this is very debatable on the basis that any woman who has her decision overridden will suffer psychological harm and caesareans are routine procedures for obstetricians)– but there is no basis for a team opting out. We strongly disagree that whole teams within Trusts should be able to opt out of offering maternal request caesareans leaving women with no option but	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out..

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				to travel longer distances for appointments and in labour, with all the expense/ time/childcare issues associated with this, and another Trust having to take these women on when there is no benefit to either party. These women are often very concerned about what would happen if they went into labour before their given c-section date, leaving them with the choices of travelling a considerable distance in labour or going to a hospital they know will not honour their request. In addition, some women, who cannot drive for example, have no choice when it comes to changing hospital. Given the impact on women and their families, we believe there is a strong case for arguing that it is unlawful for a Trust not to offer a caesarean to a particular group of women who are making an informed choice to undergo a routine procedure. Trusts need to ensure that they have obstetricians within their workforce who are happy to perform maternal request caesareans.	
Birthrights	Research question 3	035	019	Once again this perpetuates the view that women only ask for a caesarean due to anxiety. There are more urgent research questions here which would help women and	Thank you for your comment. This research recommendation was carried forward from the previous version of the guideline and was not included in this update. The maternal choice

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				birthing people make an informed choice in particular around the real expected outcomes for individuals at low risk of complications undergoing planned caesarean (separated from individuals at high risk of complications undergoing planned caesarean and women and birthing people undergoing unplanned caesarean). In addition, when Birthrights undertakes training with healthcare professionals, the additional cost of a caesarean is often raised as an objection to offering CS . You will be aware that the economic modelling undertaken in 2011 only costed treatment of urinary incontinence as a possible outcome of planned vaginal birth. This analysis could be made significantly more sophisticated. You will be aware of analysis by Jonathan West, Myles Taylor and Michael Magro which shows that where the costs of litigation are taken into account planned caesarean birth looks to be very cost effective. We would welcome an explicit restatement of the 2011 finding that cost is not a reason for not offering a planned caesarean and that the 2011 modelling did not take into account the costs of litigation. Furthermore we would welcome further	section of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out. The exclusion of litigation costs in the cost-effectiveness analysis has been clarified in section 13.3 of the previous version of the guideline.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				modelling/research into the costs of caesarean.	
British Intrapartum Care Society	Guideline	Overall	Overall	BICS considers further clarity would help regarding; Are the quoted risks for women who were aiming for a vaginal birth and ultimately may have birthed their baby by CB? Or are the risks for women who had a vaginal birth / CB?	Thank you for your comment. The benefits and risks tables have been clarified to include details of the exact populations of women for each outcome.
British Intrapartum Care Society	Guideline	007 008 009	General	Is it possible to present these data in an infographic?	Thank you for your comment. An infographic was considered but due to the small risk differences for many outcomes per 100,000 women, it was agreed this may not be useful for women and healthcare professionals. Instead, the tables and boxes that provide the estimates of benefits and risks have been revised and additional explanatory information has been included alongside and we hope this will include the clarity of the information, rather than using an infographic.
British Intrapartum Care Society	Guideline	009	Table 2	BICS is unsure of the source of the data for the 'injury to the vagina' row of table 2. The data quoted is around 0.5%. BICS is unclear what is included in the term injury to the vagina. The RCOG perineal hub suggests up to 90% of first time mothers will experience some	Thank you for your comment. The committee did not prioritise these outcomes for inclusion in this review. The outcome 'injury to the vagina' was carried through from the previous guideline and this was the terminology used, but we have looked at the evidence upon which this was based and it refers to vaginal tears, so we

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				form of tear, graze or episiotomy following a vaginal birth. In addition, the risk of 3rd or 4th degree tear is in the order of 3.5% [NMPA 2016/17]. A rate of 0.5% of injury to the vagina following a vaginal birth seems improbably low.	amended this to 'vaginal tears' to better reflect the meaning of the outcome reported by the study, and can confirm that this was the rate reported. We have also added a new appendix to the evidence report that supports this table. It includes additional details about the outcomes in this table that are derived from the previous version of the guideline, and the reference to the relevant reference has been added to appendix P in Evidence review A.
British Intrapartum Care Society	Guideline	030	007-012	BICS members have expressed concern over the cost of implementing this recommendation	Thank you for your comment. Based on new evidence identified by another stakeholder we have updated the search for this intervention within the guideline and incorporated 2 new studies into Evidence report B (Tuuli 2020 and Hussamy 2019). Having reviewed this updated evidence the committee agreed that the basis for recommending NPWT is now weaker and have removed the recommendation for the BMI 30-35 kg/m^2 group and retained the recommendation for the BMI >35 kg/m^2 group but downgraded it to a weaker 'consider recommendation. A revised economic' analysis suggests that NPWT is only likely to be cost-effective in women with a BMI over 35 kg/m^2, and as this is now a weaker 'consider' recommendation, the resource

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					implications of implementing it are likely to be much lower.
British Intrapartum Care Society	Guideline	030	007-012	BICS considers this recent publication should be considered by NICE with regards to this recommendation - https://jamanetwork.com/journals/jama/article-abstract/2770848?resultClick=3 Effect of Prophylactic Negative Pressure Wound Therapy vs Standard Wound Dressing on Surgical-Site Infection in Obese Women After Cesarean Delivery A Randomized Clinical Trial, Tuuli et al. JAMA 2020 'Conclusions and Relevance. **Among obese women undergoing cesarean delivery, prophylactic negative pressure wound therapy, compared with standard wound dressing, did not significantly reduce the risk of surgical-site infection. These findings do not support routine use of prophylactic negative pressure wound therapy in obese women after cesarean delivery'**.	Thank you for your comment and highlighting this new evidence. We have updated the search for this intervention within the guideline and incorporated 2 new studies into Evidence report B (Tuuli 2020 and Hussamy 2019). Having reviewed this updated evidence we agree that the basis for recommending NPWT is now weaker and have removed the recommendation for the BMI 30-35 kg/m^2 group and retained the recommendation for the BMI >35 kg/m^2 group but downgraded it to a weaker 'consider' recommendation.
British Intrapartum	Guideline	019, 020	General	BICS welcomes the guidance regarding skin and vaginal preparation prior to CB	Thank you for your comment

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Care Society					
British Maternal and Fetal Medicine Society	Evidence Review G			The costs of planned vaginal delivery versus planned Caesarean section are not fairly represented. The former attracts enormous costs from litigation, the latter almost none. To ignore litigation costs pertinent to each is to ignore the elephant in the room.	Thank you for your comment. We think you are referring to Evidence review A as there was no Evidence review G. Evidence review A was a systematic review undertaken so that the committee could make recommendations about the advice that should be given to women concerning the risks and benefits associated with different modes of birth. Therefore, as the focus is not a decision between alternative courses of action (the committee were not recommending caesarean birth or vaginal birth), a health economic analysis was not pertinent to this review. However, we recognise that there is the view that litigation costs should be included in any consideration of the costs of caesarean birth and vaginal birth. In the previous version of the guideline (2011) a cost-effectiveness analysis was carried out as part of the review of maternal request for caesarean birth. This was not within the scope of this update and therefore we are unable to revise it. However, we have added the following text to Section 13.3 of the 2011

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					guideline to clarify the position with regard to litigation costs: "In line with standard NICE methods, the 'downstream' costs do not include litigation costs or compensation for harm. Maternity claims feature prominently amongst the clinical negligence claims made to the NHS Litigation Authority (https://resolution.nhs.uk/wp-content/uploads/2018/11/Ten-yearsof-Maternity-Claims-Final-Report-final-2.pdf) and so are an important issue for funding healthcare. However, economic evaluation in NICE guidelines is based on care being provided according to NICE guidelines and NHS best practice, rather than care that is sometimes negligent or sub-standard in some respect.
British Maternal and Fetal Medicine Society	Guideline	General		As it stands, the NICE information on the costs and risks of Caesarean section could be regarded as institutional paternalism, with a strong bias against planned Caesarean section. With the Montgomery ruling steering modern obstetric practice, NICE has to be seen as being impartial, and present its findings on mode of delivery in an unbiased academically robust manner.	Thank you for your comment. The guideline makes clear recommendations that mode of birth should be discussed with all women, and that they should be supported to make an informed decision. The maternal request section of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
British Maternal and Fetal Medicine Society	Guideline	General		NICE is world renowned for its rigour in reviewing subjects in the light of the best evidence available. On the issue of Caesarean section, however, NICE appears to have fallen short of its normal high standards. This update is an opportunity to rectify matters.	Thank you for your comment. This guideline has been updated in accordance with all NICE processes, and after conducting a systematic review of the evidence for all the questions that were updated.
British Maternal and Fetal Medicine Society	Guideline	General		Was the administration and timing of antenatal corticosteroids included within the scope of the guideline for the current update? There is new evidence of potential harm with later pregnancy steroid administration and current clinical practice is variable.	Thank you for your comment. The administration and timing of antenatal corticosteroids is not included in the scope of this guideline. This topic is covered in the NICE guideline on preterm labour and birth.
British Maternal and Fetal Medicine Society	Guideline	013	005 1.2.19	Do not routinely offer pregnant women with recurrent HSV infection a planned caesarean birth outside of the context of research. [2004, amended 2020] The inclusion of the word "routine" is important. We 've discussed use of elective CS for recurrent active HSV internally several times with our neonatal colleagues. We do use prophylactic acyclovir antenatally. Whilst we concur that avoiding 'routine elective CS' is appropriate, we also feel that an 8% risk of neonatal infection in recurrent active HSV is not insignificant. We cannot predict severe cases of neonatal encephalitis. In our discussions, we don't	Thank you for your comment. We understand your comment to mean that you agree with our recommendation as it includes the word 'routinely', and therefore allows some individualisation of care. However, this section of the guideline was not included in the scope of this update, so no evidence was reviewed and so the committee were unable to update this recommendation.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				even try 'to talk women out of having an elective CS' when discussing the possibility of recurrent HSV near delivery.	
British Maternal and Fetal Medicine Society	Guideline	030	008-011 1.7.2, 1.7.3	Offer negative pressure wound therapy after caesarean birth for women with a BMI of 35kg/m2 or more to reduce the risk of wound infections. [2020] Consider negative pressure wound therapy after caesarean birth for women with a BMI of 30kg/m2or more, but less than 35 kg/m2. [2020] Most units would require a business case to support the practice of negative pressure wound therapy for a significant cohort of women. The guideline states 'there was some evidence. Some units have actively demonstrated a significant fall in CS SSIs by using '7day dressings' for women with BMI>35 compared to 'standard dressings' (observational local data - presented at BMFMS. Also one US paper showing no advantage for expensive negative pressure dressings in the obese and another showing advantage.	Thank you for your comment and highlighting this new evidence. We have updated the search for this intervention within the guideline and incorporated 2 new studies into Evidence report B (Tuuli 2020 and Hussamy 2019). Having reviewed this updated evidence we agree that the basis for recommending NPWT is now weaker and have removed the recommendation for the BMI 30-35 kg/m^2 group and retained the recommendation for the BMI >35 kg/m^2 group but downgraded it to a weaker 'consider' recommendation. A revised economic analysis suggests that NPWT is only likely to be cost-effective in women with a BMI over 35 kg/m^2, and as this is now a weaker 'consider' recommendation, the resource implications of implementing it are likely to be much lower.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
British Maternal and Fetal Medicine Society	Guideline Table 4 Evidence Review E	017, 034		The BMFMS is concerned that NICE has misrepresented the true maternal and fetal risks of planned Caesarean Section Vs planned vaginal delivery. It is simply incorrect to present the outcomes in terms of the eventual mode of delivery. You cannot choose a normal vaginal delivery, just plan for one. Instead, outcomes should be described on an "intention to treat" basis. Thus if a low risk mother is considering whether to have a planned CS or planned vaginal delivery, the risks and benefits of each choice should be outlined. For the former, almost all mothers end up having a CS. For the latter, a significant number end up having an emergency Caesarean, which, like all emergency unplanned surgery, carries more risks, or an instrumental delivery, which has its own attendant complications including increased risks of anal sphincter injury.	Thank you for your comment. We believe your comment refers to Evidence review A, not E. The committee agreed that including data by planned mode of birth ("intention to treat", ITT) would be the ideal scenario. Unfortunately, this type of evidence was rarely available and so the committee took a hierarchical approach to the evidence in their analyses preferentially including ITT type analysis, if none was available they then included analyses done by the actual mode of birth women had. However, there was not always evidence available of this type and so for some outcomes the committee accepted evidence from a third category where emergency caesarean births were included in the caesarean birth arm. This does not mean that in those studies the caesarean birth group was exclusively emergency caesareans, just that in those studies the caesarean birth group may have included both emergency and non-emergency caesarean births. The benefits and risks tables have been clarified to include details of the exact populations of women for each outcome.
British Maternal and Fetal	Guideline	010, 014, 019, 025		The neonatal risks of planned Caesarean section versus planned vaginal delivery are simply wrong and need to be reviewed, and	Thank you for your comment. The neonatal mortality outcome has now been reviewed to reflect the risk of neonatal mortality excluding congenital anomalies. The committee agreed that

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Medicine Society				more modern studies reflecting modern practice represented.	there was limited evidence informing maternal and infant short-term outcomes and added a research recommendation.
British Society of Urogynaecology	Guideline	General	General	On behalf of the British Society of Urogynaecology, a stakeholder for the Caesarean Birth NICE Guideline (draft), we would like to make the following comments. Firstly, we feel this is a comprehensive and helpful guideline. However, there are some areas where we would like to make comment and hope the GDG will give these due consideration as they are intended to help women make informed decisions. References are numbered throughout and the full bibliography is provided in comment 12.	Thank you for your comment. We have responded to your individual comments.
British Society of Urogynaecology	Guideline	General	General	Finally with regards costs, in the previous guidance it is stated that planned CS is approximately £700 GBP more expensive than vaginal delivery (https://www.nice.org.uk/guidance/cg132/resources/costing-report-pdf-184766797). However, in a sensitivity analysis of this guidance when litigation and 'compensation	Thank you for your comment. Evidence Review A was a systematic review undertaken so that the committee could make recommendations about the advice that should be given to women concerning the risks and benefits associated with different modes of birth. Therefore, as the focus is not a decision between alternative courses of action (the committee were not recommending

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				for harm' costs are included, planned CS is £439 GBP *less* expensive than vaginal delivery (21). In addition, costs for the treatment of adverse events, mental health support for PTSD (both more common after vaginal delivery than planned CS), and the long-term cost avoidance for POP surgery (9) have not been included. Therefore, for women at high risk of PFD particularly pelvic organ prolapse, planned CS is likely to be cost-effective. Again, this should be reviewed, and the data presented in this updated guideline. Women should be risk assessed, provided with evidence and be given the choice of planned caesarean section where they regard a risk as 'material' (as per the Montgomery Ruling (2)).	caesarean birth or vaginal birth), a health economic analysis was not pertinent to this review, and so the costs of PTSD or POP surgery could not be included in this update. We recognise that there is the view that litigation costs should be included in any consideration of the costs of caesarean birth and vaginal birth. In the previous version of the guideline (2011) a cost-effectiveness analysis was carried out as part of the review of maternal request for caesarean birth. This was not within the scope of this update and therefore we are unable to revise it. However, we have added the following text to Section 13.3 of the 2011 guideline to clarify the position with regard to litigation costs: "In line with standard NICE methods, the 'downstream' costs do not include litigation costs or compensation for harm. Maternity claims feature prominently amongst the clinical negligence claims made to the NHS Litigation Authority (https://resolution.nhs.uk/wp-content/uploads/2018/11/Ten-yearsof-Maternity-Claims-Final-Report-final-2.pdf) and so are an important issue for funding healthcare. However, economic evaluation in NICE guidelines is based

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					on care being provided according to NICE guidelines and NHS best practice, rather than care that is sometimes negligent or sub-standard in some respect. The maternal choice section of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
British Society of Urogynaecology	Guideline	General	General	References 1. Stinson LF, Payne MS, Keelan JA. A Critical Review of the Bacterial Baptism Hypothesis and the Impact of Cesarean Delivery on the Infant Microbiome. Front Med (Lausanne). 2018 May 4;5:135. doi: 10.3389/fmed.2018.00135. eCollection 2018. 2. Montgomery v Lanarkshire Health Board, S. Court 2013- 0136-Judgment, 2015. 3. Silver RM, Landon MB, Rouse DJ et al. Maternal morbidity associated with multiple repeat cesarean deliveries. Obstet Gynecol. 2006;107(6):1226-32.	Thank you for your comment. We have responded to your comments that cite these references but have also 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: 1. Stinson 2018: infant microbiome in the context of caesarean birth was not an outcome included in the benefits and risks of caesarean birth therefore this study is not eligible for inclusion. 2. Montgomery versus Lanarkshire 2015: this document outlines the judgement details of the Montgomery versus Lanarkshire Health Board case. It does not meet inclusion criteria because only peer-reviewed, full-text studies are eligible for inclusion, but the committee were aware of it

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				4. Jelovsek JE, Chagin K, Gyhagen M, et al. Predicting risk of pelvic floor disorders 12 and 20 years after delivery. Am J Obstet Gynecol. 2018;218:222 e221-222 e219. 5. Glazener C, Elders A, MacArthur C et al. Childbirth and prolapse: long-term associations with the symptoms and objective measurement of pelvic organ prolapse. BJOG 2013;120:161–168. 6. Gyhagen M, Bullarbo, M, Nielson,TF, I Milsom (2013) - Prevalence and risk factors for pelvic organ prolapse 20 years after childbirth: a national cohort study in singleton primiparae after vaginal or caesarean delivery. http://onlinelibrary.wiley.com/doi/10.1111/1471-0528.12020/pdf 7. Friedman T, Eslick GD, Dietz HP. Delivery mode and the risk of levator muscle avulsion: a meta-analysis. Int Urogynecol J. 2019;30:901-907. 8. Keag OE, Norman JE, Stock SJ. Long-term risks and benefits associated with	and amended the recommendations on provision of advice on benefits and risks and on obtaining consent, based on their expertise and knowledge of this ruling. 3. Silver 2006: the comparison used to obtain the adjusted effect estimate was first caesarean birth, therefore this study was not relevant for inclusion according to the review protocol. Note that, in order to be eligible, studies should have compared caesarean birth with vaginal birth. For further details about inclusion criteria, please see appendix A in Evidence review A. 4. Jelovsek 2018: prognostic models did not meet the criteria in the review protocol for inclusion in this update and therefore this study is not eligible for inclusion. 5. Glazener 2013: this study included any type of caesarean birth (including emergency) and did not assess any outcome relevant for the review protocol, therefore is not eligible for inclusion.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. *PLoS Med.* 2018;15:e1002494. 9. Leijonhufvud A, Lundholm C, Cnattingius S, et al. Risks of stress urinary incontinence and pelvic organ prolapse surgery in relation to mode of childbirth. Am J Obstet Gynecol 2011;204:70.e1-6. 10. Gleason RL, Jr., Yigeremu M, Debebe T et al. A safe, low-cost, easy-to-use 3D camera platform to assess risk of obstructed labor due to cephalopelvic disproportion. PLoS ONE 2018;13(9): e0203865. https://doi.org/10.1371/journal.pone.0203865 11. Yi-Ge Li · Chun-Lin Chen· Ke-Dan Liao et al. Study on the cephalopelvic relationship with cephalic presentation in nulliparous full-term Chinese pregnant Archives of Gynecology and Obstetrics (2018) 298:433–441	6. Gyhagen 2013: this study was excluded from the review because did not assess any outcome relevant for the review protocol. 7. Friedman 2019: this systematic review and meta-analysis did not assess any outcome relevant for the review protocol, therefore is not eligible for inclusion. 8. Keag 2018: this systematic review and meta-analysis was included in the review for the following outcomes: stillbirth, placenta accreta and uterine rupture in any future pregnancy. Please note that it was not included for the outcomes urinary incontinence and fecal incontinence as other studies including direct population (i.e. excluding unplanned caesarean birth) relevant for inclusion were found. 9. Leijonhufvud 2011: this study was excluded from the review because it included any type of caesarean birth (including emergency). 10, 11 and 16. Gleason 2018, Li 2018, and Toh-Adam 2012: cephalopelvic disproportion was not an outcome included in the review protocol,

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				12. Zaretsky MV, Alexander JM, McIntyre DD et al. Magnetic Resonance Imaging Pelvimetry and the Prediction of Labor Dystocia. Obstet Gynecol 2005;106:919–26) 13. G. Stulp, S. Verhulst, T. V. Pollet, D. Nettle, and A. P. Buunk. Parental height differences predict the need for an emergency caesarean section. *PLoS One.* 2011; **6**: e20497 14. K. M. Merchant, J. Villar, and E. Kestler.Maternal height and newborn size relative to risk of intrapartum caesarean delivery and perinatal distress. *BJOG.* 2001*;* **108**:689-96, 15. N. Wongcharoenkiat and D. Boriboonhirunsarn.Maternal height and the risk of cesarean delivery in nulliparous women. *J Med Assoc Thai.*2006*;***89** : S65-9. 16. R. Toh-Adam, K. Srisupundit, and T. Tongsong. Short stature as an independent risk factor for cephalopelvic disproportion in a	therefore these studies are not eligible for inclusion. 12. Zaretsky 2005: MRI pelvimetry disproportion was not an outcome included in the review protocol and therefore this study is not eligible for inclusion. 13, 14, 15, and 17. Stulp 2011, Merchant 2001, Wongcharoenkiat 2006, and Sheiner 2005: prediction of emergency caesarean birth based on parental features is out of the scope of this update, therefore this study is not eligible for inclusion. 18. Gudmundsson 2005: fetal macrosomia is out of the scope of this update, therefore this study is not eligible for inclusion. 19. Gyhagen 2013: this study was excluded from the review because did not assess any outcome relevant for the review protocol. 20. Raisanen 2013: this study did not assess any outcome relevant for the review protocol, therefore is not eligible for inclusion.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				country of relatively small-sized mothers.*Arch Gynecol Obstet.*2012;**285**:1513-6. 17. Sheiner E, Levy A Katz M; Moshe M. Short stature--an independent risk factor for Cesarean delivery. European journal of obstetrics, gynecology, and reproductive biology 2005; 120 (2):175-178. 18. S. Gudmundsson, A. C. Henningsson, and P. Lindqvist. Correlation of birth injury with maternal height and birthweight. BJOG 2005; **112**: 764-7. 19. M. Gyhagen, M. Bullarbo, T. F. Nielsen, and I. Milsom. Prevalence and risk factors for pelvic organ prolapse 20 years after childbirth: a national cohort study in singleton primiparae after: a national cohort study in singleton primiparae after vaginal or caesarean delivery.BJOG 2013; **120**:152-160. 20. S. Raisanen, K. Vehvilainen-Julkunen, R. Cartwright, M. Gissler, and S. Heinonen.A prior cesarean section and incidence of	21. West 2019: the section "maternal request for caesarean birth" was not within the scope of this update and it was not appropriate to conduct a health economic analysis for the risks and benefits of caesarean compared to vaginal birth as this was a review aimed at providing information and not recommending one intervention over another, therefore this study is not eligible for inclusion.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				obstetric anal sphincter injury.Int Urogynecol J 2013;**24**:1331-9. 21. West JH, Taylor MJ, Magro M. The true relative financial costs of Planned Caesarean Section (PCS) versus Planned Vaginal Birth (PVB) in England taking into account litigation and compensation for harm. F1000 Research 2019,8:518 (https://doi.org/10.7490/f1000research.1116508.1)	
British Society of Urogynaecology	Guideline	007-008	Table 1	The risks of planned vs in-labour CS are different and should be presented separately. For example in Table 1 (Outcomes for women and babies that may be more likely with caesarean birth). The evidence shows that maternal death with CS occurs more commonly in developing countries where access to safe caesarean delivery is different to that of more developed countries. This could cause anxiety and fear for women in the UK reading this guideline and should be clarified.	Thank you for your comment. The benefits and risks tables have been clarified to include details of the exact populations of women for each outcome. Only studies from high income countries have been included in the review as this was agreed to be the population applicable to the UK population.
British Society of	Guideline	004	005	Informing Women of the Evidence 1.1.1: we agree entirely that women should be offered evidence-based information.	Thank you for your comment. The committee discussions, detailed in the discussion section of evidence review A, make clear the limitations of

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Urogynaecology				However as presented, much of the evidence is of low quality e.g. in the case of outcomes for babies/children after delivery by caesarean section (CS) e.g. obesity, asthma, mortality, and stillbirth in subsequent pregnancies. These are statistical associations, in many cases weak ones, with no evidence of causality or evidence for the pathophysiology. For example, the evidence regarding the fetal microbiome is conflicting with few large studies of CS vs vaginal delivery matched for BMI, intrapartum antibiotic use, and breastfeeding patterns. While an association has been found no studies have confirmed causality (1). It is not clear if women are to be informed of these associations. For example, would this be mentioned only to those women requesting CS for 'no medical indication' or to all women having either planned or in-labour CS?	the evidence base that you have noted. Some of the limitations outlined in this section include the quality of the evidence, which was based on observational studies. As you suggest, reported findings represent associations between mode of birth and the different outcomes, therefore a causal link between these cannot be inferred. The committee discussed this limitation, which is also included in the discussion section. The evidence related to fetal microbiome was not reviewed, and therefore the committee could not discuss it. However, as outlined in the Evidence review A protocol (appendix A), only data which adjusted for relevant confounders (as identified by study authors) was included in the review, and most of the included studies adjust for the factors outlined in the publication by Stinson 2018, such as use of antibiotics or maternal obesity. For further details about the confounders each of the studies adjusted for, please see Table 2 and Table 3 in the Evidence review. The overall benefits and risks of caesarean birth compared with vaginal birth will allow women with no medical indication for caesarean birth to make informed decisions about their preferred mode of birth. We have checked the reference provided (Stinson 2018) and this is not eligible for inclusion because infant

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					microbiome in the context of caesarean birth was not prioritised as an outcome for this review.
British Society of Urogynaecology	Guideline	005	026	1.1.4 It is stated that: these tables give summary estimates only and are intended to help discussions, but personal risk estimates cannot be given for individual women. **[2020]** For pelvic floor dysfunction ie urinary and faecal incontinence, and pelvic organ prolapse the UR-CHOICE risk calculator provides such personal risk estimates (4). This is based on 2 long-term studies at 12 and 20 years after vaginal delivery and CS (5,6).	Thank you for your comment. Use of risk calculators were not within the scope of this update and therefore the committee was unable to review evidence or make recommendations on this topic but thank you for letting us know about the availability of these calculators for pelvic floor dysfunction. A separate NICE guideline on pelvic floor dysfunction is currently in development and we will pass this information to the team working on that guideline. The committee did not prioritise pelvic organ prolapse as an outcome, but included bladder/bowel/ureteric injury as a short-term outcome, and urinary and faecal incontinence as long-term outcomes, so the committee agreed these would give an indication of how the pelvic area is affected. We have checked the references to ensure we have not missed any evidence and Jelovsek 2018 is not eligible for inclusion because prognostic models did not meet the protocol criteria for this review. We have checked the references by Glazener 2013 and Gyhagen 2013. Glazener

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					2013 is not relevant for inclusion because it included any type of caesarean birth (including emergency) and did not assess any outcome relevant for the review protocol. Gyhagen 2013 was excluded from the review because it did not assess any outcome relevant for the review protocol.
British Society of Urogynaecology	Guideline	008	Table 1	Placenta accreta occurs with multiple CS's but World Population statistics (2015) show that in developed countries the fertility rate is 2-3 babies per woman. Should they all be delivered by planned CS, the risk of accreta with the 2nd and 3rd is 0.24%, 0.31% respectively (3). For the individual woman the risk is therefore low and that evidence should be provided during counselling	Thank you for your comment. The committee prioritised the outcome placenta accreta in any future pregnancy, therefore they were unable to make specific recommendations by number of previous pregnancies. However, in the recommendations, the committee outlined that there may be risks relevant to women's individual circumstances, and provided placental adherence problems from multiple caesarean births in their example. Although this is not addressed in detail in the benefits and risks table, the guideline does include a later section specifically on pregnancy and childbirth after caesarean birth and this section includes recommendations on discussing these risks with woman. We have checked the reference provided by Silver 2006 and it does not meet the protocol criteria for inclusion because the comparison used to obtain the adjusted effect estimate was

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					first caesarean birth compared with subsequent caesarean births. In order to be eligible, studies should have compared caesarean birth with vaginal birth. For further details about inclusion criteria, please see appendix A in Evidence review A.
British Society of Urogynaecology	Guideline	009	Table 2	Table 2 The draft guideline fails to mention pelvic organ prolapse where there is good evidence for the pathophysiology ie levator trauma/avulsion (7). Studies show that CS has a consistent protective effect for pelvic organ prolapse unlike urinary and faecal incontinence (8). The most likely explanation for this difference is that the causes of anal/faecal incontinence are multifactorial including irritable bowel syndrome, constipation with overflow etc. which are unlikely to be affected by planned CS; this is not controlled for in most studies. The same applies to the high prevalence of UI after CS with non-pregnancy-related confounders e.g. overactive bladder, UTI. Pelvic Organ Prolapse (POP) The one condition that is caused almost entirely by childbirth (with the exception of a	Thank you for your comment. The committee did not prioritise pelvic organ prolapse as an outcome, but included bladder/bowel/ureteric injury as a short-term outcome, and urinary and faecal incontinence as long-term outcomes, so the committee agreed these would give an indication of how the pelvic area is affected. To ensure we have not missed any evidence we have checked the references you mention in your comment. Please see below our response to each reference: 1. Glazener 2013: this study included any type of caesarean birth (including emergency) and did not assess any outcome relevant to the review protocol, therefore is not eligible for inclusion. 2. Gyhagen 2013: this study was excluded from the review because did not assess any outcome relevant for the review protocol.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				connective tissue abnormality) is pelvic organ prolapse. In the SWEPOP study, 20years after one delivery only, the risk of POP symptoms was reduced in those delivered by CS (VD 14.8%, CS 6.3%) (6). In the ProLONG study at 12 years the incidence of prolapse at or beyond the hymen was likewise reduced (VD 29%, CS 5%). (5). In addition, a reduction in POP surgery long-term has been reported for a protective effect of CS (VD vs CS Hazard Ratio 9.2 and Forceps vs CS Hazard Ratio 20.9) (9). Evidence relating to Pelvic organ prolapse should therefore be included in the guideline.	3. Friedman 2019: this systematic review and meta-analysis did not assess any outcome relevant for the review protocol, therefore is not eligible for inclusion. 4. Keag 2018: this systematic review and meta-analysis was included in the review for the following outcomes: stillbirth, placenta accreta and uterine rupture in any future pregnancy. Note that it was not included for the outcomes urinary incontinence and fecal. incontinence as studies including direct population (i.e. excluding unplanned caesarean birth) relevant for inclusion were found. 5. Leijonhufvud 2011: this study was excluded from the review because it included any type of caesarean birth (including emergency).
British Society of Urogynaecology	Guideline	012	005	1.2.13 and 1.2.7.1 Amended recommendation wording (change to intent) without an evidence review <u>Do not use pelvimetry for decision making about mode of birth.</u> **[2004]**	Thank you for your comment. This section of the guideline was not included in the scope of this update, so no evidence was reviewed and so the committee were unable to update these recommendations. However, as you state there may be new evidence and we have passed this on to the NICE surveillance team which monitors guidelines to ensure that they are up to date.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				1.2.7.1 Pelvimetry is not useful in predicting 'failure to progress' in labour and should not be used in decision making about mode of birth. [2004] 1.2.12 Do not use pelvimetry for decision making about mode of birth [2004, amended 2020] This recommendation, based on studies performed 20 years ago has been repeated without an evidence review. The rationale for this is unclear and has been 'removed on the advice of the NICE editor'. Several studies have been undertaken in recent years showing an association between pelvic size and labour dystocia/CPD (e.g. 10-12). We strongly recommend that this recommendation be reviewed in the light of the evidence.	The rationale for why pelvimetry should not be used is not needed in the recommendation so has been removed on the advice of the NICE editor.
British Society of Urogynaecology	Guideline	012	009	Maternal Height	Thank you for your comment. This section of the guideline was not included in the scope of this update, so no evidence was reviewed and so the committee were unable to update these recommendations. However, as you state there may be new evidence and we have passed this

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				1.2.7.2 Shoe size, **maternal height** and estimations of fetal size (ultrasound or clinical examination) do not accurately predict cephalopelvic disproportion and should not be used to predict 'failure to progress' during labour. [2004] 1.2.13 Do not use the following for decision-making about mode of birth as they do not accurately predict cephalopelvic disproportion: • maternal shoe size • **maternal height** • estimations of fetal size (ultrasound or clinical examination) [2004, amended 2020] Again this has not been reviewed despite evidence showing that short stature is a known risk factor for intrapartum caesarean section [13-17], shoulder dystocia [18] and pelvic floor trauma resulting in long-term urinary incontinence and pelvic organ prolapse, and obstetric anal sphincter injury (OASI) [19, 20]. Again, this recommendation should be reviewed.	on to the NICE sh[illegible] Shoe size has been clarified in some of the guidelines to ensure that they are up to date. recommendation was clarified to indicate that these features should not be used to decide mode of birth.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
British Society of Urogynaecology	Guideline	013	023	1.2.24: what is the definition of 'no medical indication for caesarean birth'? Please add to the guideline.	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
British Society of Urogynaecology	Guideline	013	026	1.2.25: the benefits and risk of both CS (presumably planned/elective?) should be compared with those of vaginal birth in keeping with the Supreme Court Ruling: (Montgomery vs Lanarkshire (2)). The wording states that: "Where either mother or child is at heightened risk from vaginal delivery, doctors should volunteer the pros and cons of that option compared to a caesarean". In the case of pelvic floor dysfunction as a result of maternal birth trauma, risk groups have been identified (see below: 1.1.4).	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out..
Caesarean Birth	Equality impact assessment	001	3.2	Re: "Have any other potential equality issues (in addition to those identified during the scoping process) been identified, and, if so, how has the Committee addressed them? The committee were aware that there may be variation in access to maternal request CB, and that choice of mode of birth should be supported, appropriate to a woman's clinical needs and the decisions they have made	Thank you for your comment. We have noted your concerns that women whose caesarean birth request is refused, and who are referred to another obstetrician may have to travel further and that this may be difficult for some women. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				about mode of birth, regardless of service configuration in their local area." It is unclear what the action is? Women without adequate access to transport, family support and/or financial means to arrange transport and overnight accommodation cannot easily manage transfer of hospital maternity care (and even Trust) when their caesarean birth request is refused. NICE has acknowledged 'lack of support' for maternal request in some areas, but there is no substantial change in the recommendations to help protect all women, and certainly women for whom equality issues will exacerbate the situation.	the guideline is required and has asked NICE to carry this out.
Caesarean Birth	Equality impact assessment	002	3.4	Re: "Do the preliminary recommendations make it more difficult in practice for a specific group to access services compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?" See #86, above.	Thank you for your comment. We have noted your concerns that women whose caesarean birth request is refused, and who are referred to another obstetrician may have to travel further and that this may be difficult for some women. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
Caesarean Birth	Equality impact	002	3.5	Re: "Is there potential for the preliminary recommendations to have an adverse impact	Thank you for your comment. We have noted your concerns that women whose caesarean birth

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
	assessment			on people with disabilities because of something that is a consequence of the disability?" See #86, above.	request is refused, and who are referred to another obstetrician may have to travel further and that this may be difficult for some women. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
Caesarean Birth	Evidence review A	006	010-012	Re: "Planned caesarean birth (CB) is an alternative to planned vaginal birth (VB) for women with a number of conditions diagnosed antenatally, or on request for women with no specific medical indication. Planned caesarean birth is an alternative birth to planned vaginal birth for all women, and my organisation is concerned that caesarean birth should not be reserved only for when there is aa antenatal (or intrapartum) clinical diagnosis of a specific condition. Informed decision making can only happen if women are presented with all birth choices (place and mode). There are numerous cases of low risk pregnancies, with no diagnosed conditions, resulting in adverse outcomes for mothers and/or babies. Re: "there is also the potential for the mode of birth to lead to longer-term risks for the	Thank you for your comment. This introduction is in line with the current recommendations on maternal request for caesarean birth which are recommendations for women with no specific medical indication for caesarean birth. Caesarean birth is not reserved for women with an antenatal (or intrapartum) clinical diagnosis only, and is available on request to women with no specific medical indication, as the first paragraph in the introduction describes. The maternal choice section of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.We have amended the last sentence of the first paragraph in the introduction as you have suggested to say: "However, (…) there is also the potential for both modes of birth

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				woman and her child." Suggest: also the potential for **both [or either]** modes of birth	to lead to longer-term risks for the woman and her child".
Caesarean Birth	Evidence review A	007	010	Table 1 'Outcomes for women and babies that may be more likely with caesarean birth' p7 of the guideline lists a 'risk difference' for CB as ***'About 20 more women per 100,000 who had caesarean birth would be expected to die'***. Leaving aside that this does not distinguish between planned CB, emergency CB or whether the women had particular risk factors this appears from the accompanying documents (Evidence review A, p19 line10) to be based on evidence that is described as of 'low quality' from a single observational study in Canada on women of 'advanced maternal age' who delivered between 1991 and 2005. This study thus includes data from thirty years ago up until the most recent fifteen years ago. There have been many advances since that time, including adjuvant antibiotics, thromboprophylaxis, labour ward staffing and protocols. Should this really be the basis for our information provision in the UK in 2021?	Thank you for your comment. As described in the protocol, (appendix A), Table 1, and included studies section in evidence review A, maternal and infant short-term outcomes included women with pregnancies at lower obstetric/medical risk (no absolute medical/obstetric indication for caesarean birth), analysed according to planned mode of birth. Therefore, women included in Lavecchia 2016 (study which reported maternal death) did not have specific risk factors and results were analysed by "intention to treat". The committee discussions, detailed in the discussion section of the evidence review, make clear the limitations of the evidence base that you have noted. Some of the limitations outlined in that section include the quality of the evidence, which was based on observational studies, or the fact that some studies were conducted in countries where healthcare is mainly accessible through private funding. As you note, the committee also discussed the fact that some studies included only women above 35 years old and also that some of these collected their data between 25 and 30 years ago. The committee interpreted the

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					evidence taking these limitations into account. However, they 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.
Caesarean Birth	Evidence review A	008	021-022	Re: "The main aim of this review was to provide information for women requesting a caesarean birth in the absence of a clinical indication." Qu.: Was this really the main aim of the review? The review question states: "What are the benefits and risks (short and long-term) of planned caesarean birth compared with planned vaginal birth at term for women and neonates/infants/children?" Qu.: This is an important distinction in NICE's research methods; can you please confirm which is correct? My organisation would suggest that this question is of importance and relevance to all pregnant women, and the healthcare team who are caring from them. The information and evidence about comparative risks and benefits of each birth mode should not be	Thank you for your comment. The objective of the review was to assess the possible benefits and harms for the mother and infant of a planned caesarean birth, compared to planned vaginal birth, in order to provide information for women and healthcare professionals. The committee agreed that this question is of importance and relevance to all pregnant women, and the healthcare team who are taking care of them. However, if a woman has an antenatal condition or risk factor that indicates that a caesarean birth may be more appropriate or safer option, then healthcare professionals would include this in the discussion, and so the balance of risks and benefits may change for that woman. The recommendations make it clear that the risks and benefits of different modes of birth should be discussed with all women.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				reserved for maternal request discussions exclusively (Montgomery).	
Caesarean Birth	Evidence review A	008	022-025	Re: "Therefore, studies including pregnant women with breech presentations, multi-fetal pregnancies, preterm births, babies who are small for gestational age, placenta praevia, and maternal infections have been excluded." With this said, NICE selected the MacDorman 2008 study as one of its key studies for review. Planned caesarean births here are defined as: "singleton, term (37–41 weeks' gestation) …cesareans with no labor complications or procedures, which is the closest approximation to a "planned cesarean delivery" category possible, given data limitations", in a country where caesarean birth data is recorded as primary and repeat. In England, planned caesarean births are not usually scheduled prior to 39 weeks' EGA, yet this study included births at 37 weeks' EGA. As such, can NICE confirm what definition it used for "preterm births" in its exclusion criteria please?	Thank you for your comment. The eligibility criteria for this review question included pregnant women giving birth near/at term (defined as >34 weeks), as defined in the review protocol in appendix A of Evidence review A. Based on this, MacDorman 2008 meets criteria for inclusion.
Caesarean Birth	Evidence review A	008	027-030	If only four studies could be identified for informing maternal and infant short-term outcomes, this is an overwhelming	Thank you for your comment. The committee agreed that there was limited evidence informing maternal and infant short-term outcomes and

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				justification for a new research recommendation.	have added a research recommendation relating to this.
Caesarean Birth	Evidence review A	008	029	Imagine a situation where a pregnant mother and midwife or obstetrician may sit down together in the antenatal clinic to discuss birth choices for when, hopefully, she reaches term without complications. Let us suppose that the mother has conceived after many years of infertility and requests a Caesarean Birth (CB) because she believes it may be her best and only ever chance to have a healthy baby. Clearly she should be counselled about the implications of her choice and there is a risk that the data presented in the guideline could be used to inform that choice. The problem is that the guideline relates to and describes the risks in terms of the 'method of delivery' (as it does throughout Table 1) rather than the *choice* of method of delivery and should therefore not be used in this way. Quite apart from that the evidence itself is deeply flawed as the basis for such counselling. On the face of it our mother may	Thank you for your comment. The committee agreed that including data by planned mode of birth ("intention to treat", ITT, which is synonymous with 'choice of method of delivery') would be the ideal scenario. Unfortunately, this type of evidence was rarely available and so the committee took a hierarchical approach to the evidence in their analyses preferentially including ITT type analysis, but if none was available they then included analyses conducted by the actual mode of birth women had, but excluding emergency caesareans. However, there was not always evidence available of this type and so for some outcomes the committee accepted evidence from a third category where emergency caesarean births were included in the caesarean birth arm. This does not mean that in those studies the caesarean birth group was exclusively emergency caesareans, just that in those studies the caesarean birth group may have included both emergency and non-emergency caesarean births. The benefits and risks tables have been

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				be told that NICE has evaluated the risk to her baby of dying in the neonatal period from choosing PCB to be '*About 80 more babies per 100,000 whose mothers had caesarean birth would be expected to die*'. This seems so strongly at odds with normal experience that closer examination of the evidence is required. It is based on a publication: 'Infant and Neonatal Mortality for Primary Cesarean and Vaginal Births to Women with ‘‘No Indicated Risk,’’ United States, 1998–2001 Birth Cohorts. Marian F. MacDorman, BIRTH 33:3 September 2006. Table 3. of this publication lists the causes of the neonatal deaths according to CB or VB, and it is immediately apparent where the problem lies. By far and away the greatest reason for neonatal deaths in this study was congenital malformations. I hope the committee would agree that it would not make any sense to include any difference in the risk of congenital abnormalities in the scenario outlined (leaving aside the impact that advances in ultrasound and antenatal	clarified to include details of the exact populations of women for each outcome. The committee welcomed your suggestion to include the outcome neonatal mortality excluding congenital anomalies, so the risk difference outlined in the tables has now been amended to reflect this. Please note that the publication included is not MacDorman MF, Declercq E, Menacker F, Malloy MH. Infant and neonatal mortality for primary cesarean and vaginal births to women with "no indicated risk," United States, 1998-2001 birth cohorts. Birth. 2006 Sep;33(3):175-82 referred to in your comment. The publication included in the systematic review is posterior and included ITT type analysis: MacDorman MF, Declercq E, Menacker F, Malloy MH. Neonatal mortality for primary cesarean and vaginal births to low-risk women: application of an "intention-to-treat" model. Birth. 2008 Mar;35(1):3-8.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				diagnosis since 1999-2001 would have on the overall figures). Just as misleading are the figures presented for 'Intrauterine hypoxia' and 'birth asphyxia', which are listed as being seven times higher with CB than with VB! I believe that even a non-medical person would detect that this must be an error of some sort and certainly not the basis on which the mother should make her choice in the scenario outlined. A further problem in presenting data on 'method of delivery' rather than 'choice of method of delivery' is highlighted by some risks may be overlooked. For example the risk of stillbirth in the current pregnancy. This risk would be virtually zero for PCB once the woman has reached term and PCB is performed at 39 weeks gestation. Although low, however, it may be significant for the mother in our scenario should she choose PVB as the pregnancy continues unless she chooses planned induction of labour (with its own attendant drawbacks and risks) to forestall this possible complication.	

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Caesarean Birth	Evidence review A	009	013-016	Again, the inability of NICE to identify evidence for the outcomes in this list is deeply concerning.	Thank you for your comment. The committee agreed that there was limited evidence informing maternal and infant short and long-term outcomes and added a research recommendation.
Caesarean Birth	Evidence review A	009	018-032	The Birth Trauma Organisation would be a good source of information for evidence on post-traumatic stress disorder (PTSD) in women.	Thank you for your comment. We appreciate the reference to the Birth Trauma association. As per the protocol in appendix A of Evidence review A, we included only published full text papers found through a systematic search of the evidence.
Caesarean Birth	Evidence review A	018	008-009	Re: "Economic evidence… A systematic review of the economic literature was conducted but no economic studies were identified which were applicable to this review question." Did NICE consider reviewing evidence from NHS Resolution? Given the level of litigation claims in obstetrics, is NICE willing to reconsider its 2011 decision not to incorporate this as part of its economic evidence review? It remains concerning that maternity care recommendations have such a blind spot on litigation.	Thank you for your comment. Evidence Review A was a systematic review undertaken so that the committee could make recommendations about the advice that should be given to women concerning the risks and benefits associated with different modes of birth. Therefore, as the focus is not a decision between alternative courses of action (the committee were not recommending caesarean birth or vaginal birth), a health economic analysis was not pertinent to this review. However, we recognise that there is the view that litigation costs should be included in any consideration of the costs of caesarean birth and vaginal birth. In the previous version of the guideline (2011) a cost-effectiveness analysis was carried out as part of the review of maternal

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					request for caesarean birth. This was not within the scope of this update and therefore we are unable to revise it. However, we have added the following text to Section 13.3 of the 2011 guideline to clarify the position with regard to litigation costs: "In line with standard NICE methods, the 'downstream' costs do not include litigation costs or compensation for harm. Maternity claims feature prominently amongst the clinical negligence claims made to the NHS Litigation Authority (https://resolution.nhs.uk/wp-content/uploads/2018/11/Ten-yearsof-Maternity-Claims-Final-Report-final-2.pdf) and so are an important issue for funding healthcare. However, economic evaluation in NICE guidelines is based on care being provided according to NICE guidelines and NHS best practice, rather than care that is sometimes negligent or sub-standard in some respect.
Caesarean Birth	Evidence review A	019	028	Where is evidence on stillbirth in first pregnancy/birth? Particularly at late gestational age. Also, perinatal mortality?	Thank you for your comment. Perinatal mortality was prioritised for inclusion as a composite outcome of stillbirth and mortality during first 7 days of life. Please see Table 1 and appendix A in evidence review A. One study meeting eligibility criteria reporting on neonatal mortality was

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					included, but no relevant studies were found reporting on the composite outcome perinatal mortality or stillbirth in first pregnancy/birth.
Caesarean Birth	Evidence review A	020	011-012	Re: "Moderate or severe hypoxic ischaemic encephalopathy" This is an important outcome for this review question, and research should address it.	Thank you for your comment. The committee agreed that there was limited evidence informing maternal and infant short-term outcomes and added a research recommendation aimed at identifying the short and long-term outcomes of planned caesarean birth compared with planned vaginal birth. Please note that one of the short-term outcomes included is hypoxic ischaemic encephalopathy.
Caesarean Birth	Evidence review A	020	013-015	Re: "Nerve injury (including brachial plexus injury, phrenic nerve injury or facial nerve injury)" There is evidence on this, but perhaps in smaller studies and/or HES data that were not reviewed.	Thank you for your comment. No evidence meeting inclusion criteria was found for nerve injury (including brachial plexus injury, phrenic nerve injury or facial nerve injury). However, the committee agreed that there was limited evidence informing maternal and infant outcomes and added a research recommendation aimed at identifying the short and long- term outcomes of planned caesarean birth compared with planned vaginal birth. Please, note that one of the outcomes included in the research recommendation is nerve injury (including brachial plexus injury, phrenic nerve injury or facial nerve injury).

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Caesarean Birth	Evidence review A	028	003-010	Re: "studies included women above 35 years old only… appropriate to extrapolate to the general population" Many would argue this was not appropriate given that advanced maternal age increases likelihood of adverse outcomes with a planned vaginal birth, and could bias outcomes in favour of planned caesarean birth.	Thank you for your comment. The committee agreed that this was a limitation of the evidence. The 2 studies including women above 35 years old (Herstad 2016, Lavecchia 2016) had low risk pregnancies, however the committee acknowledged that maternal age may be a key factor significantly influencing planned caesarean birth in women. The committee agreed that it was nonetheless appropriate to extrapolate the results from these 2 studies because these were population based and had adjusted for relevant confounders, such as maternal age. These additional details about the discussion have now been added to the 'other factors the committee took into account' section in Evidence review A.
Caesarean Birth	Evidence review A	028	042-047	Re: "The committee were aware that there may be variation in access to maternal request caesarean birth, and that choice of mode of birth should be supported, appropriate to a woman's clinical needs and the decisions they have made about mode of birth, regardless of service configuration in their local area. They noted that the guideline already contained a recommendation to this effect on the later section on maternal request caesarean birth." As per comment #2, the recommendations	Thank you for your comment. The maternal choice section of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				need to be strengthened further to avoid blanket policies.	
Caesarean Birth	Evidence review A	130	n/a	Hankins 2006 was excluded from the systematic review because "no relevant outcomes were reported". Extract: "Overall, the frequency of significant fetal injury is significantly greater with vaginal delivery, especially operative vaginal delivery, than with cesarean section for the nonlaboring woman at 39 weeks EGA or near term when early labor has been established." Can NICE explain further why these outcomes (and others, including stillbirth) were not considered relevant to its review question?	Thank you for your comment. The study by Hankins 2006 reports fetal injury, which is a term the study authors used to encompass multiple outcomes, such as brachial plexus injury or subdural haemorrhage. The committee prioritised some outcomes related to fetal injury, such as nerve injury or hypoxic ischaemic encephalopathy, however the authors by Hankins 2006 did not report these outcomes prioritised for inclusion in the review (or the outcome stillbirth itself) with summary statistics adjusted for relevant confounders. More specifically, in Table 3 of Hankins 2006, study authors report the incidence of birth-associated injuries per type of birth, however no adjusted odd ratios (ORs) were reported. In Table 4 and Table 8 of Hankins 2006, the reported ORs do not appear to have been adjusted for relevant confounders. In Table 6 of Hankins 2006, authors report outcomes providing adjusted ORs for some of the outcomes. However, caesarean birth does not appear to have been included as a relevant comparison. In this case, the adjusted OR reports the association between vaginal mode of birth

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					and neonatal morbidity using assisted vaginal birth (forceps) as the reference category. We agree that the original reason for exclusion may not reflect these factors, so it has been amended accordingly.
Caesarean Birth	Evidence review A	148	n/a	Dahlgren 2009 was excluded because it "included women with medical/obstetric indication for caesarean birth". It is correct that the planned caesarean birth group in this study were breech presentation, but the comparison planned vaginal birth group were deemed low risk at full term. The researchers found that even a breech planned caesarean birth "decreased the risk of life-threatening neonatal morbidity compared with spontaneous labour with anticipated vaginal delivery."	Thank you for your comment. In order for a study to be eligible for inclusion, both the caesarean and vaginal birth arms had to be relevant. This is because studies report an adjusted effect estimate reflecting the likelihood of certain outcomes happening in women having caesarean birth compared to vaginal birth. Therefore, for Dahlgren 2009, women in the caesarean birth arm should have included babies in cephalic presentation in order to be eligible for inclusion.
Caesarean Birth	Final scope	General	General	The NICE guidelines manual (1.4.1 Process and methods) states, "Prepares the draft scope and revises the scope after consultation". Could NICE please advise why there was no Stakeholder consultation on this draft guideline Final scope (as there was for CG132 in 2010/2011)? In particular, my organisation would have liked the opportunity to comment prior to this decision being made: Maternal request for	Thank you for your comment. This guideline update was a small update of a number of questions which had been identified by the NICE surveillance team as requiring amendment due to the emergence of new evidence. As this was a small update, the original scope for the guideline remained unchanged, no scoping phase was

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				CS: "No evidence review: retain recommendations from existing guideline" (p.3). It would also have provided an important opportunity for all Stakeholders to suggest research studies/evidence that would have been valuable in informing the boxes and tables here. Thank you	carried out and no scope was issued for public consultation. The maternal request section of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
Caesarean Birth	General	General	General	Thank you very much for this opportunity to comment; it is much appreciated.	Thank you for your comment and for reviewing the draft guideline.
Caesarean Birth	Guideline	General	General	A sincere thank you to NICE for revising the name of this guideline, "Caesarean birth". My organisation welcomes this important change, which was agreed at the January 24th 2020 NICE obstetric guidelines committee meeting.	Thank you for your comment. We are pleased your approve of the name change to caesarean birth.
Caesarean Birth	Guideline	General	General	When NICE publishes this guideline in 2021, almost a decade will have passed since it first recommended support for maternal request caesarean birth. However, despite NICE CG132, QS32, the 2015 Montgomery Supreme Court judgment on autonomy, and the CQC's 2018 promise to stop focusing on birth mode targets during maternity inspections (https://caesareanbirth.org/2018/09/07/the-cqc-will-no-longer-inspect-against-targets-and-says-trusts-should-not-be-encouraged-	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				to-reduce-caesarean-rates/), my organisation is still contacted by women whose requests are refused in NHS Trusts, and evidence of pressure to reduce caesarean birth rates remains. Therefore, I would urge NICE to strengthen its recommendations on maternal request, and further protect women from the anxiety and stress related to delayed confirmation during their pregnancy, and/or having to seek alternative care at a hospital outside their local NHS Trust. Clearer emphasis, including a requirement for every NHS Trust to employ a minimal rotation of obstetricians who **are** willing to support maternal request, is essential if we are to remove the postcode lottery women experience, and reduce litigation costs. It should simply never be the case that an entire hospital "healthcare team are unwilling to offer this" (so far deemed acceptable in 1.2.30). This provides support to an ideological position or nonmedical judgment regarding vaginal versus caesarean birth (see Montgomery #114: https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf), and is directly at	

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				odds with 1.2.29: "If a vaginal birth is still not an acceptable option… offer a planned caesarean birth". Certainly, there are individual obstetricians who view maternal request in the absence of immediate clinical or obstetric indication as inappropriate, and the law affords them this view (see Montgomery #115: "The medical profession must respect her choice, [but]… She cannot force her doctor to offer treatment which he or she considers futile or inappropriate."). However, there is a serious problem if **all** members of a healthcare team (including management) in any single NHS maternity hospital or Trust hold this view, or if there is a culture/environment in which (especially junior) staff fear expressing a different view. In 2018, a report on maternal request by the charity Birthrights echoed unpublished findings by electivecesarean.com and c-sections.org in 2012 (following CG132's publication) that inconsistent support for maternal request caesarean birth exists in NHS Trusts. My organisation has received numerous examples of antenatal communication (including letters, and even a	

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				poster in the room where one discussion took place) informing women that their hospital does not agree to caesarean birth requests. There are evidently whole NHS healthcare teams who will not provide women with unbiased information and support when it comes to mode (though not place) of birth choice, and this is unacceptable. NICE is in one of the strongest positions to change this situation, and I would urge the committee to please do so. As NICE is aware, my organisation strongly disagreed with the November 2011 decision to remove the word "all" from its Stakeholder agreed maternal request recommendation in the final version of CG132 (at a stage in development when only factual errors were to be changed): "For all women requesting a CS,…offer a planned CS." The subsequent action (and inaction) by some NHS Trusts highlights the importance of language in controversial guideline recommendations. This last minute decision to reduce the strength of the NICE maternal request recommendation led to continued	

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				debate around which women, and in which particular circumstances, the offer of caesarean birth should apply (e.g. 'NICE says caesarean section is not available on demand unless clinically indicated' 2013: https://www.bmj.com/content/347/bmj.f4649/rr/656733). Hospitals even set up clinics with the specific aim of discouraging such requests, and changing women's minds, for fear their caesarean birth rate might increase. Therefore, if NICE is wholly committed to patient autonomy, informed decisions, and its stated guideline aim "to improve the consistency and quality of care for women who are considering a caesarean birth", it needs to ensure that in 2021, there is no room for misinterpretation or avoidance of each NHS Trust's responsibility to respect a woman's individual decision, and to "offer a planned caesarean birth". This is one of the key areas that would have the biggest impact on practice for women, as it would remove the uncertainty, trepidation and fear (of being refused) that can often exist when trying to schedule their preferred birth plan.	

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Caesarean Birth	Guideline	General	General	These comments were shared with me by women who have chosen or plan to choose a caesarean birth, and who read the new guideline draft. They are included with permission. Maternal satisfaction and long-term maternal trauma aren't mentioned… I would like to know how rates of trauma relate to mode of delivery when making my decision. Section 1.2.30 still confuses and angers me,…"If you don't think a woman having a choice as to how she gives birth is a good idea, refer." Why are they allowed to ignore what is recommended by NICE? Their personal opinion should be irrelevant, shouldn't it? This is generally very positive, and I'd welcome this model, but it is laughably far from my experience, either time. And who is checking the information that's given to women? Leaflets [my hospital is] giving out are extremely biased and deliberately misleading. Likewise, I believe, are the stats here on incontinence.	Thank you for sharing these comments from women with us. We note that these comments relate to 3 topics - maternal satisfaction and long-term maternal trauma, maternal request for caesarean birth, and the different categories of caesarean and vaginal birth included in the tables outlining benefits and risks and we have responded to these 3 points: 1) Maternal satisfaction and trauma - maternal satisfaction and health-related quality of life were included as short-term outcomes in the review of the benefits and risks of caesarean birth compared to vaginal birth but no evidence was found for these outcomes. Postnatal depression and post-traumatic stress disorder were included as long-term outcomes in this review. One systematic review of 13,221 women provided very low quality evidence to show that there was no clinically important difference in the occurrence of postnatal depression between those who had an elective caesarean birth or a planned vaginal birth. No evidence was found for post-traumatic stress disorder. This evidence is discussed in Evidence review A. 2) The maternal choice section of the guideline is outside the scope of the current committee's work. However, the committee agree that a

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				The figures all conflate EMCS and ELCS, without any explanation. This is very misleading. I see this mishandling of data all the time, especially when it comes to pregnancy and childbirth. I think it is much much clearer than before. Only bit that jars with me is: 1.2.29 If a vaginal birth is still not an acceptable option after discussion of the benefits and risks and offer of support (including perinatal mental health support if appropriate, see recommendation 1.2.23), offer a planned caesarean birth for women requesting a caesarean birth. Reads to me... If after having perinatal mental health support you still haven't been able to convince them to go against their wishes... Generally positive but I don't think "if the team aren't willing" to provide MRCS the solution to refer is acceptable. And it doesn't cover places like Oxford JR where women have to be referred to different parts of the country because no one with that Trust will provide it - that is completely unacceptable. Each Trust should be required to ensure that	review of this section of the guideline is required and has asked NICE to carry this out. 3) It was not always possible to identify evidence for a comparison of planned caesarean birth versus planned vaginal birth, for every outcome. However, the benefits and risks tables have been clarified to include details of the exact populations of women for each outcome. The committee agreed that including data by planned mode of birth ("intention to treat", ITT, which is synonymous with 'choice of method of delivery') would be the ideal scenario. Unfortunately, this type of evidence was rarely available and so the committee took a hierarchical approach to the evidence in their analyses preferentially including ITT type analysis, but if none was available they then included analyses conducted by the actual mode of birth women had, but excluding emergency caesareans. However, there was not always evidence available of this type and so for some outcomes the committee accepted evidence from a third category where emergency caesarean births were included in the caesarean birth arm. This does not mean that in those studies the caesarean birth group was exclusively emergency caesareans, just that in those studies the caesarean birth group may have included

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				there are members of their obs/gynae team that will carry out MRCS. I think even giving them the option to refer totally undermines the need to take any of this seriously. Like, how is the discussion going to go if you know you're just going to refer them at the end anyway? I would have this removed ideally. Referral late in the day and to another trust is poor care however you slice it. And I think it makes a total mockery of shared decision making. It's shared as long as you come to an 'acceptable' decision? Why is it even an option to decline to perform it? I still can't see this as an "ethical" issue. I thought the comments explaining the changes at the back of the document were a bit odd. The notes suggest that women who request a CS on a "rational basis" are different from those who have anxiety or tokophobia, with only the latter to be offered mental health support. I just don't see anxiety about vaginal delivery as "irrational", but as an entirely rational response to the data. The guidance wording doesn't match up with the explanation - it doesn't say anywhere that	both emergency and non-emergency caesarean births.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				women making a "rational" choice should have their choice honoured without being required to have mental health support and then not be persuaded out of their preference. If this is the case that we can request one based on facts alone, it would be nice to be stated more clearly. I was pleased there was a reference to an early discussion but there's no best practice timescale provided and referrals by unwilling teams could be very late in pregnancy. I'm confused about Table 1 titled "Outcomes for women and babies that may be more likely with caesarean birth". It seems they have combined all vaginal births and compared them to outcomes in all cesarean births. But this would include emergency cesareans when the mother has laboured, possibly even with assistance, and then had a cesarean. All cesareans are not the same, and the outcomes for planned cesareans are quite different from emergency. That means this chart is really misleading. It makes c-sections look like they have worse outcomes than they do.	

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Caesarean Birth	Guideline	General	General	Finally, a retired NHS consultant in Obstetrics & Gynaecology has asked me to include his comments with my submission as he has no institutional affiliations and is unable to register as a Stakeholder: The update is most welcome and I hope the hard work of the committee will be much appreciated. Especially welcome will be the emphasis on enhancing the counselling of women on their choices to plan their mode of birth. Critical to the process is the information to be provided to women about the comparative risks of Caesarean Birth (CB) and Vaginal Birth (VB) and I have made some points about difficulties regarding the information in the Boxes and Tables provided in the draft that I hope may be presented by registered stakeholders and considered. As a general point, however, the NICE process may inevitably lead to the presentation of information and recommendations that may be outdated by the time it is published or shortly after.	Thank you for your comment. We have made amendments to the benefits and risks boxes and tables based on stakeholder feedback. We are aware that RCOG will be updating its information for women on caesarean birth, based on the risks and benefits tables and other information in this updated caesarean birth guideline, and will discuss your suggestion with them.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				If enhancing maternal choice procedures including improved information about comparative risks and benefits of planned CB and planned VB is the intent perhaps the Box and Table headings might form the basis for a suitable body e.g. the RCOG to provide a regular update service (possibly online) for professionals involved in birth choice counselling including, where possible, comment on applicability to 'low risk' women and babies as well as the more general case. To make the task easier the help of specialist societies e.g. urogynaecological might be enlisted to provide the updates in their particular area of expertise and someone just needs to bring it all together for reasonably frequent regular publication. If not the RCOG then perhaps a new or extended role for NICE?	
Caesarean Birth	Guideline	007-008	Tables 1 and 2	Re: Neonatal mortality Why is "stillbirth" (in primiparous women) or "perinatal mortality" not included in these tables? This appears to be a huge oversight in NICE's evidence review for this guideline, and in providing full information to women. Not only is there significant research in this area, but it is a key concern for pregnant	Thank you for your comment. Perinatal mortality was prioritised for inclusion as a composite outcome of stillbirth and mortality during first 7 days of life. Please see Table 1 and appendix A in Evidence review A for further details. One study meeting eligibility criteria reporting on neonatal mortality by 'intention to treat' type analyses (MacDorman 2008) was included, but no relevant

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				women, and a named government target for reducing adverse outcomes. The risk of a late term stillbirth is a key consideration of women who choose to plan a caesarean birth, and they will expect it to be included here. This is also an example of the importance of comparing mode of birth by intention to treat, and not eventual outcome.	studies were found reporting on the composite outcome perinatal mortality or stillbirth in first pregnancy/birth. For the outcomes that have been reported, additional detail has been added to the benefits and risks table to explain the populations (for example planned mode of birth or actual mode of birth) for each outcome.
Caesarean Birth	Guideline	007-008	Table 1	Is it possible to rephrase the estimated risks in the outcome tables? These deaths read as a fait accompli: About 4 women per 100,000 would be expected to die About 60 babies per 100,000 would be expected to die	Thank you for your comment. The text describes the expected frequency of an outcome. As such it outlines how many outcomes 'would be expected' to occur but does not describe how many definitely will or already have, and the use of about is included to emphasise the residual uncertainty in the estimates. We considered the wording of these tables and agreed this to be an appropriate representation of the evidence and discussion.
Caesarean Birth	Guideline	013-014		'When a woman with no medical indication for a caesarean birth requests a caesarean birth, explore, discuss and record the specific reasons for the request'. The problem is the notion of there being 'no medical indication' for caesarean birth'. Whilst this may have specific meaning to maternity healthcare professionals it risks women	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out. In response to your comment about litigation costs, we recognise that there is the view that litigation costs should be included in any

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				requesting delivery by CS for general reasons that are incontrovertibly medical in nature such as those outlined earlier in the guideline e.g. reduced risk of urinary or faecal incontinence, vaginal injury, birth injury to the baby etc. being treated as not having a good reason for making such a request. Since all or virtually all such requests will be made by women any such perceived denigratory attitude by definition amounts to discrimination albeit unintended on the grounds of gender. Almost certainly if this is left uncorrected it could in the times in which we now live lead to referral to the Equality and Human Rights Commission (EHRC). Similarly healthcare teams unwilling to agree to a woman's request for planned Caesarean birth (1.2.30, p14) without strong medical justification (which in the experience of many obstetricians would be hard to envisage) may be at risk of perpetuating paternalistic attitudes and gender discrimination that may be unlawful. Women who choose to deliver by CB on 'general risk' grounds should be respected, not patronised and not labelled as	consideration of the costs of caesarean birth and vaginal birth. In the previous version of the guideline (2011) a cost-effectiveness analysis was carried out as part of the review of maternal request for caesarean birth. This was not within the scope of this update and therefore we are unable to revise it. However, we have added the following text to Section 13.3 of the 2011 guideline to clarify the position with regard to litigation costs: "In line with standard NICE methods, the 'downstream' costs do not include litigation costs or compensation for harm. Maternity claims feature prominently amongst the clinical negligence claims made to the NHS Litigation Authority (https://resolution.nhs.uk/wp-content/uploads/2018/11/Ten-yearsof-Maternity-Claims-Final-Report-final-2.pdf) and so are an important issue for funding healthcare. However, economic evaluation in NICE guidelines is based on care being provided according to NICE guidelines and NHS best practice, rather than care that is sometimes negligent or sub-standard in some respect.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				necessarily being 'tokophobic' as though this was some sort of mental aberration. Perhaps consideration should be given to recommending that expressions such as 'no medical indications' or 'no medical reason' as applied to maternal request CB should either be dropped altogether or replaced by a less pejorative term e.g. 'personal choice based on general risks' (e.g. 'PCGR' or similar). As a further comment on this, it is unfortunate that revision of the economics of CB and VB has been beyond the scope of the guideline update. Although the existing economic analysis makes it clear that maternal request CB may be cost-effective under some assumptions e.g. if downstream costs of urinary incontinence are taken into account, there is a perception that planned CB is a more expensive choice than planned VB. This leads to unwarranted resistance to maternal request CB and further potential humiliation for the woman making the request.	

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Since the previous guideline, it has been pointed out that the previous cost analysis did not include indemnity costs for litigation and compensation for harm. It would have been helpful if NICE could have examined these costs since they show that when taken into account planned CB is significantly less costly than planned VB.	
Caesarean Birth	Guideline	001	Intro	Suggest: "This guideline covers when to offer **and discuss** caesarean birth" There can be a reluctance to discuss planned caesarean birth (e.g. even when concerns are identified, choice is often presented to women as awaiting spontaneous labour or scheduling an induction), and this is an issue highlighted in Montgomery (#111: "That is not necessarily to say that the doctors have to volunteer the pros and cons of each option in every case, but they clearly should do so in any case where either the mother or the child is at heightened risk from a vaginal delivery. In this day and age, we are not only concerned about risks to the baby. We are equally, if not more, concerned about risks to the mother. And those include the risks associated with giving birth, as well as any	Thank you for your comment. We have amended the guideline's introduction to say: "This guideline covers when to offer and discuss caesarean birth" as you have suggested. The committee agrees that there may be other risks not included in the benefits and risks tables, and there is an existing recommendation in the section of benefits and risks of caesarean and vaginal birth about explaining to women that there are other risks relevant to the woman's individual circumstances. The committee did not prioritise pelvic organ prolapse as an outcome but included bladder/bowel/ureteric injury as a short-term outcome, and urinary and faecal incontinence as long-term outcomes, so the committee agreed

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				aftereffects."). How many women are told what the chance is of having an instrumental delivery (12%), or how likely perineal laceration or emergency caesarean is in their age group (https://digital.nhs.uk/data-and-information/publications/statistical/nhs-maternity-statistics/2019-20)? How many women are informed about pelvic organ prolapse (likelihood and even existence)? Notably, prolapse is not referred to in this guideline draft, yet it is an important consideration for women who choose caesarean birth.	these would give an indication of how the pelvic area is affected.
Caesarean Birth	Guideline	001	Intro	Suggest: We have reviewed the evidence on the benefits and risks of **planned** caesarean birth compared to **planned** vaginal birth"	Thank you for your comment. Although this was the aim of the review of benefits and risks, due to the availability of evidence for different outcomes from populations of women who had planned or actual births by caesarean, it would not be correct to say this in the introduction. However, the benefits and risks tables have been clarified to include details of the exact populations of women for each outcome.
Caesarean Birth	Guideline	002	Intro	Re: "In some cases, we have made minor wording changes for clarification." Clarification is welcomed, as described in #2.	Thank you for your comment.
Caesarean Birth	Guideline	002	Intro	Re: COVID-19 issues	Thank you for your comment. The committee discussed how COVID may affect

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				My organisation needed to intervene in two serious cases of maternal request refusal (e.g. https://caesareanbirth.org/2020/05/12/nhs-hospitals-blanket-policy-to-deny-caesarean-birth-choice/), and there have been others. This birth preference should not be adversely affected during a pandemic. There is lower risk to maternity care staff than an emergency caesarean, women can wear a mask, if advised, and maternal satisfaction is higher when birth outcome aligns with birth plan. The response by some NHS Trusts has been similar to their response to pressure to reduce caesarean birth rates; maternal request is an easy target, with reasons for refusal steeped in outdated ideas of increased cost and/or 'unnecessary' surgery. If a woman chooses a caesarean, then supporting and scheduling her birth is no less important than ensuring women going into labour are appropriately supported, pandemic or no pandemic. Addressing these refusals is critical.	recommendations, but agreed with NICE not to make COVID-specific recommendations in an effort to future-proof the guideline. Furthermore, the maternal choice section of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
Caesarean Birth	Guideline	004	001	"People have the right to be involved in discussions and make informed decisions about their care, as described in *Making*	Thank you for your comment. The guideline now includes recommendations that all pregnant women should be offered information and support

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				decisions about your care (https://www.nice.org.uk/about/nice-communities/nice-and-the-public/making-decisions-about-your-care). This reads: "Shared decision making…means that: **different choices available to the patient are discussed**… care or treatment **options are explored in full**, along with the risks and benefits" During their antenatal care, women are routinely informed (in person and online) about their different 'place of birth' options, but not always their 'mode of birth' option. In fact, in some NHS settings, women are actively encouraged to give birth at home or in a midwife-led unit (with some women reporting no choice but to give birth in a midwife-led unit due to being labelled 'low risk'). This statement sets the tone for NICE's guideline recommendations, but for this right to become a reality, women need to be informed, consistently, about the different mode of births available in the NHS (i.e. planned vaginal and planned caesarean).	to enable them to make informed decisions about the mode of childbirth, and the updated benefits and risks section of this guideline aims to provide information to help with that discussion. Recommendation 1.1.2 has been updated to clarify that this discussion should be held with all women. The maternal choice section of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Without this, women cannot make a truly informed decision about their maternity care. Furthermore, should something go wrong during or after the birth, women can rightly claim (and increasingly do, through litigation) that they were not fully informed of the risks and benefits of all different place and mode of births. Importantly, mode of birth choice is available to midwives and obstetricians working in the NHS, with research showing that decisions can differ between individual health professionals (e.g. more obstetricians choose caesarean birth than midwives). Yet currently, the NHS maternity model operates on the default position that all pregnant women should plan for a vaginal birth, with caesarean birth reserved for special indications, or maternal request; and even then, not always offered or agreed consistently. NICE does recommend discussing mode of birth in 1.1.2, but it is not clear whether this is for women who want or need a caesarean birth, or for all pregnant women.	
Caesarean Birth	Guideline	004	014-015	1.1.1 Suggest: the women's **preferences** and concerns are central to the decision-making process.	Thank you for your comment. We have changed 'views' to 'preferences' as you suggested.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				This is an excellent recommendation, thank you. I have suggested including the term "preferences" here (in addition to or instead of "views), as described in its *Methods* (https://www.nice.org.uk/guidance/GID-NG10081/documents/supporting-documentation): "…professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users."	
Caesarean Birth	Guideline	004	016-020	1.1.2 Thinking about the women who will be reading this guideline (some of whom want a caesarean birth, and others who definitely do not), some of the language/wording in this section could be improved. Re: "Discuss mode of birth with pregnant women early in their pregnancy." Suggest: Discuss mode of birth with pregnant women, **and support preferences**, early in their pregnancy. Not all women will decide on mode of birth early in pregnancy (and some women may change their decision as their pregnancy progresses), but some will. Too often, when women want to plan a caesarean birth, they	Thank you for your comment. As per your previous comment, we have amended the wording of the last bullet point of this recommendation to state that it is the woman's preferences that should be central to the decision-making process and so have not amended the stem of this recommendation to include the word preferences here too. In relation to your point about decisions being made late in pregnancy it appears this relates to caesarean birth for maternal choice. This part of the guideline is outside the scope of the current committee's work. However, the committee agree

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				do not receive timely assurance that their preference will be supported, and are made to wait until as late as their 36th gestational week (or longer) before a decision is made. This causes unnecessary and unhealthy maternal stress and anxiety, and in cases where their request is denied, it can leave women with insufficient time to arrange alternative caesarean birth care, or neighbouring NHS hospitals trying to accommodate surgeries at short notice. Re: "around 25% to 35% of women will have a caesarean birth" Suggest: around 25% to 35% of women have a caesarean birth Otherwise this could be understood by some women as feeling they have limited choice. Re: "factors that can increase the likelihood of having a caesarean birth (for example, maternal age and BMI)" The words "increase the likelihood" are akin to "increase the risk". This wording is also often used in the context of communicating place of birth benefits (for example): 'women are less likely to need a caesarean in a	that a review of this section of the guideline is required and has asked NICE to carry this out. We have amended the wording relating to the percentage of women who have a caesarean birth as you have suggested. We have amended the wording relating to maternal age and BMI as you have suggested.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				midwife-led birth unit'. Likelihood and risk makes sense in the context of emergency caesarean birth, but not planned caesarean birth. Again, interpretation may depend on the preferences of the woman reading ('I'm an older mum and I know I'm overweight, but I don't want a caesarean' versus 'I don't have either of those factors, but I still want a caesarean'), but the distinction between emergency and planned caesarean birth is always important. Suggest: reasons you **may need** a caesarean birth (for example, maternal age and BMI)	
Caesarean Birth	Guideline	005	006-007	1.1.2 Re: "what the caesarean birth procedure involves [and] implications for future pregnancies and birth after caesarean birth" These can both differ significantly with planned and emergency caesarean births.	Thank you for your comment. The committee agreed that general discussions about what the caesarean birth procedure involved would cover all types of caesarean birth and so did not amend the recommendation.
Caesarean Birth	Guideline	005	008-009	1.1.2 Re: "(for example, after a caesarean birth the chances of caesarean birth being necessary in a future pregnancy may be increased)." The language here is very risk laden (chances increased), and lacking in autonomy (necessary), especially in the	Thank you for your comment. We have removed the words 'being necessary' so this now reads more clearly as a statement of fact, that 'after a caesarean birth the chances of caesarean birth in a future pregnancy may be increased' to make this a clearer statement of fact, as you suggest.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				context of 1.2.22 on page 13. It is also ironic given the numbers of women who *want* a second caesarean birth, and see this as a positive outcome, yet can be advised/encouraged to plan a VBAC instead, depending on which healthcare team they have). Suggest: (for example, after a caesarean birth **you may be advised** to plan another caesarean birth in a future pregnancy), or: another caesarean birth in a future pregnancy **may be needed**	
Caesarean Birth	Guideline	005	012	1.1.3 Re: "Discuss the benefits and risks of both caesarean and vaginal birth…" It is very important that this is changed to: both **planned** caesarean and **planned** vaginal birth	Thank you for your comment. The review aimed to look at differences in outcomes between planned caesarean birth and planned vaginal birth, but due to a lack of evidence for some outcomes, evidence based on actual mode of birth was used. The benefits and risks tables have been clarified to include details of the exact populations of women for each outcome.
Caesarean Birth	Guideline	005	013	1.1.3 Please insert a comma after "priorities" in this sentence.	Thank you for your comment. It is not usual NICE formatting to use the Oxford comma and so this change has not been made.
Caesarean Birth	Guideline	005	015-016	1.1.4 The information contained within boxes 1 and 2 is unhelpful for communicating risks and benefits to pregnant women. Ignoring the principle of intention to treat, the information	Thank you for your comment. The committee agreed that including data by planned mode of birth ("intention to treat", ITT, which is synonymous with 'choice of method of delivery')

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				mixes planned and emergency caesarean birth outcomes, and compares these with actual vaginal births, including "unassisted vaginal birth". When a woman is pregnant, she needs information about outcomes for and comparisons of **planned** birth modes. If it is not available, say so, but substituting like this is worse than having nothing to report. Some of the information in boxes 1 and 2 is akin to comparing homebirth and hospital birth outcomes, while excluding all the planned homebirths outcomes that required emergency transfer to hospital. This is a fundamental issue, and one highlighted by numerous NICE Stakeholders involved in the 2011 CG132 guideline. It is both disappointing and shocking that 10 years on, it remains so difficult to identify research that would improve upon this for the 2021 update.	would be the ideal scenario. Unfortunately, this type of evidence was rarely available and so the committee took a hierarchical approach to the evidence in their analyses preferentially including ITT type analysis, but if none was available they then included analyses conducted by the actual mode of birth women had, but excluding emergency caesareans. However, there was not always evidence available of this type and so for some outcomes the committee accepted evidence from a third category where emergency caesarean births were included in the caesarean birth arm. This does not mean that in those studies the caesarean birth group was exclusively emergency caesareans, just that in those studies the caesarean birth group may have included both emergency and non-emergency caesarean births. The benefits and risks tables have been clarified to include details of the exact populations of women for each outcome. The committee agreed that there was limited evidence informing maternal and infant short-term and long-term outcomes and has made a research recommendation.
Caesarean Birth	Guideline	005	017-018	1.1.4 Re: "there are benefits and risks associated with both vaginal and caesarean	Thank you for your comment. The review aimed to look at differences in outcomes between

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				birth" Again, please change to: both **planned** vaginal and **planned** caesarean birth	planned caesarean birth and planned vaginal birth, but due to a lack of evidence for some outcomes, evidence based on actual mode of birth was used. The benefits and risks tables have been clarified to include details of the exact populations of women for each outcome.
Caesarean Birth	Guideline	005	020	1.1.4 Re: "risks are more acceptable to them" Suggest: risks are more **(or less)** acceptable to them	Thank you for your comment. We have made this change to the recommendation.
Caesarean Birth	Guideline	005	021-025	1.1.4 Re: "there are other risks not included in these tables that might be relevant to their individual circumstances (for example placental adherence problems from multiple caesarean births, fetal lacerations in caesarean birth, term birth injuries with vaginal birth or caesarean birth)" Why are pelvic organ prolapse, and 3rd and 4th degree tears, not included here and in other places in the draft?	Thank you for your comment. The committee prioritised 28 outcomes for this review and the outcome of bladder/bowel/ureteric injury was included as a short-term outcome, and urinary and faecal incontinence as long-term outcomes, so the committee agreed these would give an indication of pelvic organ problems. These are included in the tables of benefits and risks so it was not thought necessary to mention them again in this recommendation. The outcome of 3rd and 4th degree tears was not prioritised by the committee, but the information on 'injury to the vagina' was carried forward from the previous guideline and included in the benefits and risk tables. However, the terminology has been changed to 'vaginal tears' to better represent the outcome reported by the study.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Caesarean Birth	Guideline	005	026-028	1.1.4 Re: "these tables give summary estimates only and are intended to help discussions, but personal risk estimates cannot be given for individual women." Back in 2006, the USA's NIH stated the importance of communicating individualized risks for women during antenatal care discussions (https://pubmed.ncbi.nlm.nih.gov/17308552/). Almost 15 years of additional research later, it seems strange that NICE would state so categorically that "personal risk estimates cannot be given for individual women". It may be true that an exact or precise percentage for each risk cannot be calculated for each woman (and this is not necessarily what most women want), but it is not true that general information cannot be interpreted, communicated and valued in a more individual context (e.g. maternal age, parity, height, weight, estimated foetal weight, foetal scans, assisted reproductive technology, family history).	Thank you for your comment. We agree it is important to have individualised discussions with women and recommendation 1.1.3 highlights that healthcare professionals should take into account a woman's circumstances, concerns and priorities when these discussions occur, so any discussion would be individualized. The statement 'personal risk estimates cannot be given for individual women' means that women cannot be told an exact numerical risk of an event occurring for them personally. We have amended the wording of the recommendation to clarify this.
Caesarean Birth	Guideline	006	Box 1	Re: "likely to be similar for caesarean or vaginal birth" Unless this means planned caesarean birth and planned caesarean birth, it is	Thank you for your comment. The evidence relating to haemorrhage outcomes was mixed, with different studies showing different results. The committee noted that a reason why studies

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				meaningless for antenatal care. My organisation's concerns about this box are outlined in #13, but to emphasise the point, "major obstetric haemorrhage" is not likely to be similar in planned caesarean and planned vaginal births, and this has been recognised for many decades: (1992) Risk factors for major obstetric haemorrhage https://www.ejog.org/article/0028-2243(93)90047-G/pdf Elective caesarean section carried an increased risk of major haemorrhage compared to spontaneous vaginal delivery (RR 3.94,99% CI 2.52-6.17) but not compared to operative vaginal delivery (RR 1.65, 99% CI 0.98-2.78). (2012) Severe postpartum haemorrhage and mode of delivery: a retrospective cohort study https://obgyn.onlinelibrary.wiley.com/doi/pdf/10.1111/j.1471-0528.2011.03267.x "Compared with intended vaginal delivery, planned caesarean delivery was associated with a reduced risk of severe postpartum	were showing opposite estimates could be because of the definition of haemorrhage used. Two of the studies reported this outcome as 'postpartum haemorrhage' and 'bleeding complications', however they did not provide sufficient information to differentiate between major obstetric haemorrhage and other types of haemorrhage, so the committee concluded that it was likely that they had included major obstetric haemorrhage amongst other haemorrhage-related complications. A third study reported 'major obstetric haemorrhage' defined as '1500 ml or more of visually estimated blood loss within 24 hours postpartum'. Because this definition matched the definition currently used in clinical practice, the committee based the estimates provided in the benefits and risks table on this study, concluding major obstetric haemorrhage was likely to be the same for planned caesarean birth and planned vaginal birth. The benefits and risks tables have been clarified to include details of the exact populations of women for each outcome. To ensure we have not missed any evidence we have checked the references provided in your

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				haemorrhage indicated by use of red blood cell transfusion" (2019) ACOG Committee Opinion no. 761 Cesarean Delivery on Maternal Request https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/01/cesarean-delivery-on-maternal-request The frequency of postpartum hemorrhage associated with planned cesarean delivery is less than that reported with the combination of planned vaginal delivery and unplanned cesarean delivery.	comment. Please see below our response to each reference: 1. Stones 1993: is not eligible for inclusion because results were not adjusted for confounders. 2. Holm 2012: reported transfusion rates, not postpartum haemorrhage. Furthermore, in Table 2, where adjusted ORs are reported, the risks are not reported by caesarean birth type (planned and unplanned). In Table 3, where risks are reported by type of caesarean birth, the reported ORs have not been adjusted for confounders. 3. Birsner 2013: this is an opinion piece by the ACOG committee on obstetric practice. Only peer-reviewed published full texts papers were eligible for inclusion, therefore it does not meet inclusion criteria.
Caesarean Birth	Guideline	006	Box 1	Similarly, "faecal incontinence" following an unassisted birth. The reported rate of instrumental deliveries (forceps/ventouse) is 12%, and both short- and long-term pelvic floor damage is an important consideration for many women. Frankly, the inclusion of faecal incontinence as a 'similar outcome', in a summary box	Thank you for your comment. The committee agreed that the ideal evidence would have compared the whole cohort of women planning to have a planned caesarean birth with those planning to have a vaginal birth, regardless of their mode of birth. As a consequence, where possible, evidence including both assisted and unassisted vaginal births in a single group was

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				designed for use in mode of birth discussions with women, including those who are requesting a caesarean, insults their intelligence. Faecal incontinence does appear in Table 2 (in the context of assisted vaginal birth), but it is entirely conspicuous here, and risks reducing trust in the guideline.	prioritised. Women rarely get to choose whether their vaginal birth will be unassisted or assisted, the latter is typically a result of opting for a vaginal birth and some complication or delay arising. Unfortunately for the outcome faecal incontinence, the only available evidence was reported separately for caesarean birth compared to assisted and unassisted vaginal birth groups. The evidence showed that there was no difference in the risk of faecal incontinence between caesarean birth and unassisted vaginal birth but that there was a lower risk of faecal incontinence with caesarean birth compared to assisted vaginal births, so the committee decided to report it separately in the interest of transparency. Full information on the evidence underlying these statements is available in evidence report A and we have also provided additional information alongside the tables to explain why this evidence has been presented in this way.
Caesarean Birth	Guideline	006	Box 1	There are a number of issues in the comparative outcomes for babies and children here too, but to highlight just a few: Re: "persistent verbal delay" How did NICE decide this is a key outcome concern for pregnant women?	Thank you for your comment. The outcome 'persistent verbal delay' was prioritised by the committee over other outcomes, such as 'breastfeeding' or 'bonding' because not all women choose to breastfeed and because bonding is a very loosely defined term in the

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Why is breastfeeding and/or bonding not included in this box? What does "infectious morbidity" mean in lay terms (given that this guideline is also for women)?	literature, so it would be difficult to reach meaningful conclusions. 'Persistent verbal delay' is an outcome which significantly impacts families' quality of life and the committee agreed would be a good indicator of moderate or severe neurodevelopmental delay. The term infectious morbidity' has been changed to 'infections' in the guideline as we agreed that this will be clearer for users of the guideline.
Caesarean Birth	Guideline	007	Table 1	Please add the "a" here, and in all subsequent references when referring to women having a caesarean birth: "About 70 more women per 100,000 who had **a** caesarean birth",	Thank you for your comment. We have made this amendment.
Caesarean Birth	Guideline	007	Table 1	Re: "may be more likely with caesarean birth" Again, treating all caesarean births as one in this type of birth comparison table cannot inform women appropriately (and certainly not 'fully') during antenatal discussions.	Thank you for your comment. We have made some changes to the format of the tables, included more information on the populations (for example planned or actual mode of birth) for each outcome and moved them to a new location where there is more information for caveats and contextual information, and we hope this will aid understanding.
Caesarean Birth	Guideline	007	Box 2	Suggestion: It would be helpful if NICE included a statement here addressing the reasons why birth mode evidence can be conflicting or limited. Again, given the	Thank you for your comment. Information about the limitations and conflicting evidence is

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				guideline's readership, explain that there are differences between planned and emergency caesarean births, primary and repeat caesarean births, planned vaginal births and actual (spontaneous or assisted) vaginal births. Bias exists on all sides, and while NICE may not want to include this, many women are acutely aware of it, and a prominent acknowledgement of the challenges involved in creating these summary boxes will be better received than the way they are currently presented.	discussed in detail in the "benefits and harms" discussion section in Evidence review A. We have made some changes to the format of the tables, included more information on the populations (for example planned or actual mode of birth) for each outcome and moved them to a new location where there is more information for caveats and contextual information, and we hope this will aid understanding.
Caesarean Birth	Guideline	007	Box 2	Re: "Outcomes for women: stillbirth in a subsequent pregnancy" Can this be moved to "Outcomes for babies/children"?	Thank you for your comment. We believe it is more appropriate to keep the outcome where it stands, as this is an outcome that impacts that women/future births.
Caesarean Birth	Guideline	007	Box 2	Re: "cerebral palsy" The risk of cerebral palsy is lower in planned caesarean birth compared to planned vaginal birth, and especially when congenital abnormality and prematurity are excluded. Did NICE consider searching information such as this 2017 NHS Resolution report, in which only 1 of the 50 CP cases (2%) occurred as a result of a planned caesarean birth (https://caesareanbirth.org/2017/11/19/my-	Thank you for your comment. The 2017 NHS Resolution report was not considered because only peer-reviewed, published full text studies meet the protocol criteria for inclusion.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				interview-with-dr-michael-magro-author-of-five-years-of-cerebral-palsy-claims/)? If not, can you provide the reason. Thank you.	
Caesarean Birth	Guideline	008	Table 1	Uterine rupture in future pregnancy Suggest: Uterine rupture in future pregnancy **or birth**	Thank you for your comment. We have made this change as you suggested.
Caesarean Birth	Guideline	008	Table 2	Re: "About 560 per 100,000 women would be expected to have an injury to the vagina" What is the definition of "injury to the vagina"? Why is this phrase being used here? Women have become increasingly well versed in more specific terminology related to their pelvic floor, and terms including perineal tears, 3rd and 4th degree tears, and prolapse are less taboo than they were in the past. The recent mesh scandal (involving many women whose repairs were a result of vaginal births) is just one reason for this. Moreover, they know that the numbers of women who experience 'injury to the vagina' are much greater than the 560 per 100,000 cited here. This citation may be from a research paper included in the NICE review, but it will ring alarm bells for readers because it is so far removed from reality (see Birth Trauma Organisation, MASIC, and others for further information). In fact, perineal	Thank you for your comment. The outcome 'injury to the vagina' was carried through from the previous guideline and this was the terminology used, but we have looked at the evidence upon which this was based and it refers to vaginal tears, so we amended this to 'vaginal tears' to better reflect the meaning of the outcome reported by the study. We have also added a new appendix to the evidence report that supports this table. It includes additional details about the outcomes in this table that are derived from the previous version of the guideline. Thank you for the reference provided. We have reviewed it but it does not meet the protocol criteria as only peer-reviewed, full text publications are eligible for inclusion. The benefits and risks tables shows that vaginal tears are unlikely in women having a caesarean

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				lacerations are the most common delivery complication in England (est. 41%: https://digital.nhs.uk/data-and-information/publications/statistical/nhs-maternity-statistics/2019-20). Perineal lacerations and episiotomies are both avoided with a planned caesarean birth, which is not to say there are no significant maternal risks with this birth mode (there are), but again, presented in this way, it will not give women confidence in NICE's evaluation and presentation of comparative planned birth mode risks.	birth so this agrees with your statement that they are avoided with this mode of birth.
Caesarean Birth	Guideline	010	012-013	1.2.2 Re: "external cephalic version" Caesarean Birth welcomes the amendment here to include "has been declined". However, the order in which information is presented here is problematic. Is NICE suggesting that the benefits and risks of planned birth versus planned caesarean birth are only discussed ***after*** ECV has been declined, contraindicated or unsuccessful? It is important this is discussed at the same time, and certainly before any ECV.	Thank you for your comment. The order of these 2 recommendations has been switched so the discussion of benefits and risks of vaginal birth, caesarean birth and external cephalic version are all discussed before the offer of external cephalic version.
Caesarean Birth	Guideline	012	006	1.2.13 Please change to: Do not use the following for decision-making about	Thank you for your comment. The sub-heading for these recommendations clarifies that this is

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				intrapartum mode of birth My organisation would comment on "maternal height" here, but it is shaded in grey, and therefore not invited.	decision-making in labour, so intrapartum care has not been added to the recommendation.
Caesarean Birth	Guideline	012	014-017	1.2.14 This is a great example highlighting the importance of providing information early in pregnancy.	Thank you for your comment. We are pleased you agree with the recommendation to discuss this early in pregnancy.
Caesarean Birth	Guideline	012	018-022	1.2.15 My organisation is concerned that in examples like this, "Do not offer" may be interpreted by some healthcare providers as "Do not discuss", when it appears that what NICE means is "Do not recommend or advise"? Can this be made clearer?	Thank you for your comment. 'Do not offer' is the standard NICE terminology used when there is good evidence that an intervention is not beneficial, and so this has not been changed. It would always be expected that any 'Offer' or 'Do not offer' recommendation would require a discussion with the woman about why the intervention was being offered or not offered.
Caesarean Birth	Guideline	012	024-028	1.2.16 and 1.2.17 As above in #33 ("Do not offer" and "Offer" here are without information or discussion).	Thank you for your comment. 'Do not offer' is the standard NICE terminology used when there is good evidence that an intervention is not beneficial, and so this has not been changed. It would always be expected that any 'Offer' or 'Do not offer' recommendation would require a discussion with the woman about why the intervention was being offered or not offered.
Caesarean Birth	Guideline	013	002-007	1.2.18 and 1.2.19 As above in #33	Thank you for your comment. 'Do not offer' is the standard NICE terminology used when there is good evidence that an intervention is not beneficial, and so this has not been changed. It

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					would always be expected that any 'Offer' or 'Do not offer' recommendation would require a discussion with the woman about why the intervention was being offered or not offered.
Caesarean Birth	Guideline	013	011	Re: "Shared decision making" Caesarean Birth communicated its concerns about this phrase in Stakeholder comments submitted to the NICE consultation on its 'Shared decision making' guideline in 2019 (see pgs.13-23: https://www.nice.org.uk/guidance/gid-ng10120/documents/consultation-comments-and-responses). These concerns remain, though NICE has explained its reasoning (keeping the terminology consistent across national strategies, plans, policy and initiatives, including the NHS Long Term Plan and NHS England's Personalised Care Group's shared decision making programme). NICE also "amended the scope to clarify that while the process of reaching a decision is shared, ultimately this is to support the person to reach a decision about their care." It would be greatly appreciated if NICE could also emphasise that here too; it is the woman's decision.	Thank you for your comment. Shared decision-making is the agreed NICE terminology and is defined by NICE as: 'Shared decision making is when health professionals and patients work together. This puts people at the centre of decisions about their own treatment and care.' We think this encompasses the process you have described so we have not changed this heading.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Caesarean Birth	Guideline	013	012-015	1.2.21 "Ask for consent for caesarean birth only after providing pregnant women with evidence-based information. Ensure the woman's dignity, privacy, views and culture are respected, while taking the woman's clinical situation into account." There are discussions around whether consent should be requested for vaginal birth too (a reported 57% of births in England are spontaneous: https://digital.nhs.uk/data-and-information/publications/statistical/nhs-maternity-statistics/2019-20/deliveries---1920-hes#delivery-complications), but these discussions aside, this recommendation is a good example for a maternity care pathway more generally. Provide evidence-based information, communicate place and mode of birth choices, and respect the woman's personal preferences.	Thank you for your comment. We interpret your comment to mean that you are content with this recommendation.
Caesarean Birth	Guideline	013	022	1.2.23 Caesarean Birth welcomes the assertiveness in this recommendation.	Thank you for your comment.
Caesarean Birth	Guideline	013	022	Re: "Maternal request for caesarean birth" Since the risks with planned caesarean birth increase with multiple surgeries, one of the most important factors for women to consider when planning a caesarean birth is family size. Would it be possible for NICE to include	Thank you for your comment. The impact of caesarean birth on future pregnancies is important for all women, not just those who are requesting a caesarean, so this is already included, as you point out, in recommendation 1.1.2, so it has not been repeated in this section.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				a specific mention of this in its recommendations here (perhaps similar to the 1.1.2 examples given in brackets)?	
Caesarean Birth	Guideline	013	022	Re: "Maternal request for caesarean birth" Please change all the "If" statements in this section to "When" (consistent with 1.2.24), apart from 1.2.30. Thank you	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
Caesarean Birth	Guideline	013	022	Re: "Maternal request for caesarean birth" The term "maternal request" is not attached to other birth choices (place or mode) in maternity care, and my organisation would like to see its use reduced in the coming years. Shortly after the Montgomery judgment in March 2015, the RCOG published patient information titled, "Choosing to have a caesarean section" https://www.rcog.org.uk/en/patients/patient-leaflets/choosing-to-have-a-caesarean-section/), and the very nature of 'requesting' a caesarean birth exposes women to the possibility of it being declined. I have used the word 'request' throughout my comments, as this is where the NICE guideline is at, and it is how this birth preference is more widely understood at present. However, I would like to ask NICE to consider changing the	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				language to reflect its assertion that women have the right to be involved in discussions and to make informed decisions about their care, as per Montgomery. Suggest: "Planning a caesarean birth" or "Choosing a caesarean birth" Recommendation 1.2.23 is a good example of effective language in this context. For the 1.2.24 to 1.2.30 recommendations, suggest (for example): When a woman chooses/plans a caesarean birth, explore, discuss and record her specific reasons. 1.2.25 When a woman chooses/plans a caesarean birth discuss the overall benefits and risks of planned caesarean birth compared with planned vaginal birth… and record that this discussion has taken place.	
Caesarean Birth	Guideline	013	023-025	1.2.24 My organisation strongly recommends including a timeframe here. For example, "at the time of the request". In practice, the process of exploring, discussing and recording can be drawn out over many months, with multiple midwives, obstetricians and other healthcare team members involved, which women do not want.	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out..

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Caesarean Birth	Guideline	013	023	1.2.24 Re: "with no medical indication for a caesarean birth" Can NICE please advise the reason behind this new qualification please? I wonder whether it is to provide clarity that women requesting a caesarean birth should not be thought of solely in the context of having 'reasons' (e.g. previous birth or other trauma)? This is appreciated, however it can be a controversial term in the context of maternal request caesarean birth, and is often understood by the general public as 'unnecessary', 'not needed' or a 'lifestyle choice' the NHS can ill afford. In my organisation's experience, women often choose a caesarean birth for its prophylactic benefits, grounded in their own personal tolerance for risk, and a desire to avoid certain risks associated with planned vaginal birth. What constitutes "medical indication" can be subjective, and an alternative suggestion may be: "When a woman requests a prophylactic caesarean birth,…" or simply: "When a woman requests a caesarean birth…"	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
Caesarean Birth	Guideline	013	026-029	1.2.25 Similar to #43, my organisation would appreciate NICE stating that this does not	Thank you for your comment. This part of the guideline is outside the scope of the current

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				mean numerous, repeated discussions, over a prolonged period of time, with different healthcare professionals (e.g. midwives of increasing authority/experience, a psychiatrist or psychologist, numerous obstetricians). This is stressful for women, creates unnecessary anxiety, and there is a financial/resource cost for the NHS.	committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
Caesarean Birth	Guideline	014	001-004	1.2.26 My organisation strongly recommends changing this to: "If a woman requests a caesarean birth, **offer** discussions…" "and other members of the team **if requested**" It should not be deemed 'necessary' by anyone but the woman making the request/decision to plan a caesarean birth to meet with 'other members of the team, such as an anaesthetist', and certainly not to 'ensure that she has accurate information'. If the first healthcare professional she meets with uses this guideline to conduct the maternal request discussion, and the NICE guidance recommends supporting a maternal request caesarean birth, why is it suggested here that she might still need further	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				"discussions" (plural) to ensure accuracy of information? Aside from health economics for the NHS, this presumes that the woman has additional time available to meet with all these other members of the team. Also, in the age of social media communication, many women know and understand that in some hospitals, where maternal request is openly not supported, it doesn't matter how many members of the team they meet with to discuss their request. It is not to ensure accurate information, but to attempt to change their mind about a caesarean birth plan (this is documented in NHS maternity CQC inspections: https://caesareanbirth.files.wordpress.com/2018/09/september-2018-five-years-of-care-quality-commission-cqc-maternity-inspections-2013-2018-part-1-target-rates-pm-hull.pdf). It is very concerning that NICE guidance could be used to defend and continue this type of practice. The addition of "arrange discussion" is new for 2020, so my hope is that it is an oversight, and can easily be changed to "offer discussion", and	

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				similarly "if necessary" changed to "if requested". Thank you	
Caesarean Birth	Guideline	014	017	1.2.29 Re: If a vaginal birth is still not an acceptable option after discussion Please remove the word "**still**" here. It suggests that the purpose of a maternal request discussion is to convince women that planned vaginal birth is a more acceptable option, and that a concerted effort to dissuade be made before offering a caesarean birth.	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.
Caesarean Birth	Guideline	014	022-024	A November 25th 2020 update from Birthrights on its communication with Oxford University Hospitals NHS Foundation Trust (https://www.birthrights.org.uk/2020/11/25/update-on-maternal-request-caesarean-at-oxford-university-hospitals/) refers to a meeting with a group of consultant obstetricians to discuss the OUH policy of not supporting caesarean birth requests. It states that 13 out of 16 consultant obstetricians were present at the meeting, and all those present who expressed an opinion were in favour of maintaining this policy (this follows a May 2017 campaign launch to engage with NHS Trusts that do not support maternal request, beginning with OUH:	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				https://www.birthrights.org.uk/2017/07/21/do-i-have-a-right-to-a-c-section-update-on-oxford-university-hospitals/). In April 2017, Caesarean Birth highlighted a **2014** leaflet the OUH was sharing with women **(**https://twitter.com/PaulineMHull/status/852315838602293248 **and** (https://caesareanbirth.files.wordpress.com/2017/04/2014-june-cdmr-leaflet-oxford-university-hospitals.pdf), which made its maternal request policy very clear; it would not be supported. Again, this is a key issue my organisation would like NICE to address in this updated guideline. How can it be acceptable that in an NHS Trust the size of OUH, there may not be one single obstetrician who is willing to support caesarean birth choice (https://caesareanbirth.org/2017/04/12/nhs-trusts-still-refusing-maternal-requests/)?	
Caesarean Birth	Guideline	014	022-024	1.2.30 Please add: If a woman requests a caesarean birth but her current healthcare team are unwilling to offer this, refer the woman to an obstetrician willing to perform a caesarean birth **at the earliest opportunity, within the same NHS Trust**. The onus should not be on women to travel	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				outside their local maternity hospital in order to receive what should be a standard of care throughout the NHS healthcare system.	
Caesarean Birth	Guideline	016	016-018	1.2.22 In addition to this statement affirming a woman's legal right to decline a caesarean birth, can NICE include a statement reflecting the legal position on mode of birth autonomy in Montgomery too? Thank you	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out..
Caesarean Birth	Guideline	024	016-018	1.5.3 Re: "Encourage and facilitate early skin-to-skin" Please change this to "**Offer** and facilitiate…" as it should not be assumed that this is something all women want.	Thank you for your comment. We have amended the wording to 'Offer and facilitate'.
Caesarean Birth	Guideline	024	002	1.4.48 Suggest: Accommodate the **woman's** preferences for **her** caesarean birth	Thank you for your comment. We have made these changes.
Caesarean Birth	Guideline	031	027	1.7.9 Suggest: "**Inform** women who have had a caesarean birth **they may** resume…"	Thank you for your comment. The wording of this recommendation has been changed as you suggest, to make it clear that resuming activities should be discussed with women but they can resume such activities when they feel ready to do so.
Caesarean Birth	Guideline	032	003-006	1.7.10 Is this statement true for depression and post-traumatic stress symptoms following an emergency caesarean birth?	Thank you for your comment. This section of the guideline was not included in the scope of this update and the committee did not review the evidence so were unable to assess if these factors are still correct.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Caesarean Birth	Guideline	032	007-011	1.7.11 Caesarean Birth welcomes the clarification that discussion should only be necessary in women who have had an emergency or unplanned caesarean birth.	Thank you for your comment.
Caesarean Birth	Guideline	033	010	"Recommendations for research" This subject of tokophobia/fear of birth has been a key focus of NICE caesarean birth maternal request guidance since 2004 (CG13), and my organisation would strongly urge a change for 2021. What more women need far more urgently is research focusing on foetal/infant and maternal health short- and long-term outcomes with maternal request. In preparing this draft guideline, NICE has repeatedly cited challenges in gathering relevant evidence on the outcomes of different planned birth modes, and I expect that numerous Stakeholders will comment on the way comparative risks are presented here. This situation can only change if more research is carried out, and it should be more achievable going forward given NICE's 2011 recommendation that all maternal request discussions are recorded. My organisation has also been asking for nationwide NHS	Thank you for your comment. The committee agreed that more research was needed to determine the short and long-term outcomes of caesarean birth and have made a research recommendation.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				tracking of "maternal request" as a caesarean birth indication for more than a decade, as this alone would could help provide evidence-based information for future NICE guidance.	
Caesarean Birth	Guideline	033	010	Recommendations 1 and 2 seem to focus on emergency and unplanned caesareans, rather than planned. Is there an opportunity to include a planned caesarean birth research question (separate to maternal request)?	Thank you for your comment. The committee agreed that more research was needed to determine the short and long-term outcomes of caesarean birth and have made a research recommendation.
Caesarean Birth	Guideline	035	020-021	3. Re: "psychological interventions" To reiterate, assessing outcomes with maternal request caesarean birth is more critical than exploring psychological interventions for women who want that support. Most NHS hospitals have these support systems in place, yet 10 years on from CG132 (17 years since CG13), there is still insufficient evidence for NICE to complete tables that compare mode of birth outcomes. The priority needs to be providing the evidence in order for all women to be able to make informed decisions, and not just those who may or may not want support and/or interventions when they have a fear of vaginal childbirth. Furthermore, the idea that fear of vaginal birth is predominantly	Thank you for your comment. This update of the guideline did not include a full review of the research recommendations relating to maternal request. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out. .

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				pathological or irrational is beginning to wane. There *are* risks associated with planning a vaginal birth, just as there are risks with planning a caesarean birth (and many women fear a caesarean birth, yet even those with risk factors that make them more likely to have surgery are not led towards special support or psychological intervention pathways as part of their antenatal care). Future research focus needs to be on establishing what the risks and benefits are for each planned birth mode.	
Caesarean Birth	Guideline	035	023-024	3. Re: "Fear of vaginal childbirth can stem from… fear of damage to the maternal pelvic floor" Consider rewording: **concerns** about damage to the **pelvic floor**	Thank you for your comment. This research recommendation was carried forward from the previous version of the guideline and was not included in this update so this change has not been made.
Caesarean Birth	Guideline	036	002-008	3. Re: "Currently there is a wide variation in practice and limited resources lead to limited availability of effective interventions. Interventions that might be appropriate include:" This is very important. Of the four options listed here, none of them include "agreeing to and scheduling a caesarean birth", which is a proven intervention that resolves fear of	Thank you for your comment. This research recommendation was carried forward from the previous version of the guideline and was not included in this update so this change has not been made.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				vaginal birth in many women. Otherwise, what is NICE saying here?	
Caesarean Birth	Guideline	036	013-018	3. Re: "The proposed research would compare in sa randomised controlled trial or more of these interventions in women requesting a caesarean birth. In the absence of any evidence, there is a case for comparing these interventions with routine antenatal care (that is, no special intervention). This research is relevant because it would help to guide the optimal use of these limited resources and future guideline recommendations." In addition to my comments above, there are a number of studies like this that have already been carried out, which NICE could refer to instead of continuing with more of the same.	Thank you for your comment. This research recommendation was carried forward from the previous version of the guideline and was not included in this update so this change has not been made.
Caesarean Birth	Guideline	037	004	Re: "some limitations with the quality of the evidence." This highlights the need for research in this area.	Thank you for your comment. The committee agreed that more research was needed to determine the short and long-term outcomes of caesarean birth and have made a research recommendation.
Caesarean Birth	Guideline	037	007-009	Re: "conflicting or limited evidence,… a number of outcomes for which no evidence was identified for inclusion"	Thank you for your comment. The committee agreed that more research was needed to determine the short and long-term outcomes of

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Again, this highlights the need for research in this area.	caesarean birth and have made a research recommendation.
Caesarean Birth	Guideline	037	011	See comments above (#28) regarding "injury to vagina" terminology versus outcomes women are familiar with; I think these outcomes warranted inclusion in the current review.	Thank you for your comment. The committee chose not to prioritise the outcome of injury to the vagina. The outcome 'injury to the vagina' was carried through from the previous guideline and this was the terminology used, but we have looked at the evidence upon which this was based and it refers to vaginal tears, so we amended this to 'vaginal tears' to better reflect the meaning of the outcome reported by the study.
Caesarean Birth	Guideline	037	016-017	Re: "It is already current practice to discuss the risks and benefits of alternative modes of birth during the antenatal period" Planned caesarean birth (CB) is an alternative to planned vaginal birth (VB) for women with a number of conditions diagnosed antenatally, or on request for women with no specific medical indication. However, there can be risks associated with both 11 modes of birth for both the woman and baby, and there is also the potential for the 12 mode of birth to lead to longer-term risks for the woman and her child. Can you please advise what/where was the evidence for this (I was unable to locate the	Thank you for your comment. The statement that discussing the risks and benefits of modes of birth is current practice was based on the knowledge and expertise of the committee members who confirmed this was current practice.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				citation in the draft's supplementary documents)? Thank you.	
Caesarean Birth	Guideline	037	027	Re: "hypothermia in women having caesarean birth (caesarean birth)," Typo.	Thank you for your comment. We have corrected this duplication typo.
Caesarean Birth	Guideline	043	017-019	Re: "It provides evidence-based information for healthcare professionals and women about the risks and benefits of planned caesarean birth compared with planned vaginal birth," Suggest: It provides **some** evidence-based information… This is a very confident statement given all the limitations and inclusion of studies with mixed mode of birth studies. It was certainly the 'aim' of the guideline, but is it true to say this represents the outcome?	Thank you for your comment. We have amended this to say 'some' as you suggest.
Caesarean Birth	Guideline	043	021-023	Suggest: effective management strategies to avoid **unwanted/unplanned** caesarean birth	Thank you for your comment. We have added 'unplanned' as you suggest.
Caesarean Birth	Guideline	043	022-023	Re: "effective management strategies to avoid caesarean birth and the organisational and environmental factors that affect caesarean birth rates" Why are caesarean birth rates mentioned here? The CQC has advised inspectors to stop focusing on these (and 'normal birth' rates), and this NICE statement could be	Thank you for your comment. The mention of caesarean birth rates does not imply that this is or should be a target, but rates can be an indicator of outliers, which may be useful information.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				misconstrued by NHS Trust managers, healthcare workers, and others (including those outside the UK) as support for strategies to reduce caesarean birth rates. This is not only important in the context of maternal request caesarean birth (and the decision by some Trusts to refuse requests and/or make arranging one extremely difficult), but also in the context of ensuring fully informed choice and reducing litigation. With one eye always on caesarean birth rates, clinical decisions risk being biased to the extent of endangering lives, and quality of lives.	
Caesarean Birth	Guideline	043	014	Re: "who have had a caesarean birth (caesarean birth)" Typo.	Thank you for your comment. We have corrected this duplication typo.
Caesarean Birth	Guideline	044	008-009	Re: "We have reviewed the evidence on the benefits and risks of caesarean birth compared to vaginal birth" Page 43 (#67, above) says: "planned caesarean birth compared with planned vaginal birth" Can this be consistent? I suggest changing this line to include "planned", since this is what NICE did, and removing planned from	Thank you for your comment. This has now been made consistent and the risks and benefits tables have been clarified to include details of the exact populations of women for each outcome.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				#67, since this is not what NICE was able to find and report.	
Caesarean Birth	NICE CG132	212		Re: "In line with standard NICE methods, the 'downstream' costs do not include litigation costs or compensation for harm. Maternity claims feature prominently amongst the clinical negligence claims made to the NHS Litigation Authority (https://resolution.nhs.uk/wp-content/uploads/2018/11/Ten-yearsof-Maternity-Claims-Final-Report-final-2.pdf) and so are an important issue for funding healthcare. However, economic evaluation in NICE guidelines is based on care being provided according to NICE guidelines and NHS best practice, rather than care that is sometimes negligent or sub-standard in some respect. Furthermore, to the economy as a whole, litigation costs and compensation for harm are "transfer payments" rather than "costs", as they primarily result in a redistribution of income and wealth rather than the use of finite resources." Shortly before CG132 was published in 2011, litigation costs were estimated at £27 million per year	Thank you for your comment. The section "maternal request for caesarean birth" was not within the scope of this update and therefore we are unable to make changes to this area. Although not strictly within the remit of the guideline we added the text to Section 13.3 of the 2011 guideline, to recognise that litigation is an important issues, which is cited in your comment. As far as we are aware there are no plans to include litigation costs in future NICE analysis. As noted in our revision, economic analysis in NICE guidelines aim to evaluate cost-effectiveness of practice that is undertaken in accordance with NICE guidelines - negligent care will not generally be clinically effective or cost-effective.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				(https://www.standard.co.uk/news/childbirth-and-maternity-failures-cost-nhs-27m-a-year-in-compensation-7281173.html0). Just over a decade later, a record £37 million settlement was awarded in one claim alone (https://www.independent.co.uk/news/health/maternity-safety-nhs-negligence-guys-thomas-a9357501.html). Many of these costs can be directly attributed to delayed or absent caesarean births, and often in hospitals with caesarean rate targets in place. Is this something NICE could address directly in its guideline? Also, as litigation costs is an issue being looked at by some researchers (The true relative financial costs of Planned Caesarean Section (PCS) versus Planned Vaginal Birth (PVB) in England taking into account litigation and compensation for harm, 2019: https://f1000research.com/posters/8-518), might future litigation studies be included in NICE economic reviews?	
Caesarean Birth	Search strategies	General	General	Why is maternal "prolapse" not included as a search term (it does not appear in the draft guideline either)? Pelvic organ prolapse is an important complication associated with (planned and actual) vaginal birth, and	Thank you for your comment. In order to conduct a sufficiently detailed and rigorous systematic evidence review we had to prioritise a set of key outcomes to be considered in the comparison between vaginal birth and caesarean birth. The

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				especially assisted vaginal birth. It can have a significant impact on a woman's life, and there are significant NHS downstream costs for treatment. Furthermore, having read all the information provided by NICE (and thank you for this; NICE conducts a very open, collaborative and transparent process in its guideline development), my organisation remains unclear about aspects of the evidence review search strategy, and is concerned that we have not progressed very far since the 2011 guideline development. A few months after CG132 was published, the book 'Choosing Cesarean, A Natural Birth Plan' presented hundreds of medical journal references that defended NICE's controversial decision to recommend support for maternal request. There is much less controversy today, but it still exists (e.g. the WHO and FIGO positions; NHS Trust blanket policies), and importantly, research study designs can be influenced by a research team's view of caesarean birth more generally (especially views on caesarean birth rates).	committee did not prioritise pelvic organ prolapse as an outcome, but included bladder/bowel/ureteric injury as a short-term outcome, and urinary and faecal incontinence as long-term outcomes, so the committee agreed these would give an indication of how the pelvic area is affected. During the evidence sifting process, records are only excluded on title scanning and abstract checking if they are clearly irrelevant (these can still be captured by search strategies), anything that looks potentially relevant will progress to a full text checking stage. Your suggestions around a living review will be taken forward for further discussion at NICE.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				The NICE guidelines manual states (6.1 Selecting relevant studies): "Before acquiring papers for assessment, the information specialist or systematic reviewer should sift the evidence identified in the search in order to discard irrelevant material. First, the titles of the retrieved citations should be scanned and those that fall outside the topic of the guideline should be excluded. A quick check of the abstracts of the remaining papers should identify those that are clearly not relevant to the review questions and hence can be excluded." Scanning titles and conducting a quick check of abstracts is simply not sufficient for the complex research question above. Indeed it could be decades before NICE is able to conduct a standard systematic review, confidently relying on key search terms relating to planned mode of birth and outcomes, and especially in countries where caesarean data is collecting according to 'primary and repeat' versus 'planned and emergency' (much less 'maternal request'). My concern is that if the selection/review process is not changed, we will be in the	

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				same position for the next guideline update. There is evidence available, and in fact, despite its challenges, the UK has an excellent reputation for collecting maternity care data. Would NICE consider developing a living review for its caesarean birth guideline? Thank you.	
Cochrane Wounds Group	Guideline	030	007-016	The draft guidance contains the following recommendations with respect to the use of negative pressure wound therapy (NPWT) for women following caesarean section: • Offer negative pressure wound therapy after caesarean birth for women with a BMI of 35 kg/m2 or more to reduce the risk of wound infections. [2020] • Consider negative pressure wound therapy after caesarean birth for women with a BMI of 30 kg/m2 or more, but less than 35 kg/m2. [2020]	Thank you for your comment and for highlighting this new evidence. We have updated the search for this intervention within the guideline and incorporated 2 new studies into Evidence report B (Tuuli 2020 and Hussamy 2019). Having reviewed this updated evidence we agree that the basis for recommending NPWT is now weaker and have removed the recommendation for the BMI 30-35 kg/m^2 group and retained the recommendation for the BMI >35 kg/m^2 group but downgraded it to a weaker 'consider' recommendation. We are unable to include unpublished evidence at this point in the guideline development cycle but will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				• Advise women that: there is insufficient evidence to determine if one type of standard (not negative pressure) wound dressing is better than another at reducing the risk of wound infections after caesarean birth. The supporting evidence for these recommendations included five RCTs [1-5]. **Comment** Our current Cochrane review of NPWT for closed surgical wounds (surgical wounds healing by primary intention) was recently updated [6]. The review concludes there is moderate certainty evidence NPWT probably reduces the incidence of surgical site infection (SSI) in closed surgical wounds. Moderate certainty evidence means there is a possibility that the true effect is substantially different from the effect estimate obtained [7].	

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				This recent review update [6] includes two additional randomised controlled trials (RCTs) assessing the relative effects of NPWT in obese women following a caesarean section, [8, 9] giving a total of seven RCTs (1886 participants) in this patient group. Our pre-planned subgroup analysis reports the relative effect estimate of NPWT on SSI risk in this patient group as RR 0.73 (95% CI 0.55 to 0.98). We are aware however, of two further RCTs relevant to the recommendations being considered (neither are yet included in our Cochrane review). The first study is recently published [10] and has 1608 participants with a mean BMI of 39.5, meaning it almost doubles the number of obese women in NPWT trials following caesarean section. This trial was stopped early due to futility and concludes that, in this population, prophylactic use of NPWT does not significantly reduce the risk of SSI compared with standard care. The findings of this trial	

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				may call into question the recommendation to offer NPWT to this group of women. The second RCT [11, 12] has just been submitted for publication. We understand it presents the relative effects of prophylactic NPWT on around 2000 obese women undergoing caesarean section; we would strongly recommend contacting the trial investigators to obtain information about the outcomes for SSI, given the findings of the other recently published large trial [10]. **Cochrane Wounds (Gill Norman, Jo Dumville, Nicky Cullum)** **References** 1. Chaboyer W, Anderson V, Webster J, Sneddon A, Thalib L, Gillespie BM. Negative pressure wound therapy on surgical site infections in women undergoing elective caesarean sections: a pilot RCT. Healthcare 2014;30(2):417-28	

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				2. Gunatilake RP, Swamy GK, Brancazio LR, Smrtka MP, Thompson JL, Gilner JB, et al. Closed-incision negative-pressure therapy in obese patients undergoing cesarean delivery: a randomized controlled trial. American Journal of Perinatology Reports 2017;7(3):e151-7. 3. Hyldig N, Vinter CA, Kruse M, Mogensen O, Bille C, Sorensen JA, et al. Prophylactic incisional negative pressure wound therapy reduces the risk of surgical site infection after caesarean section in obese women: a pragmatic randomised clinical trial. BJOG: An International Journal of Obstetrics & Gynaecology 2019;126(5):628-35. 4. Ruhstaller K, Downes K, Chandrasekaren S, Elovitz MA, Srinivas S, Durnwald C. PROphylactic wound VACuum therapy after cesarean section to prevent wound complications in the obese population:	

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				a randomised controlled trial (the PROVAC study). American Journal of Obstetrics and Gynecology 2017;216(1 Suppl 1):S34. 5. Wihbey KA, Joyce EM, Spalding ZT, Jones HJ, MacKenzie TA, Evans RH, et al. Prophylactic negative pressure wound therapy and wound complication after cesarean delivery in women with class II or III obesity: a randomized controlled trial. Obstetrics and Gynecology 2018;132(2):377-84. 6. Norman G, Goh EL, Dumville JC, Shi C, Liu Z, Chiverton L, Stankiewicz M, Reid A. Negative pressure wound therapy for surgical wounds healing by primary closure. Cochrane Database of Systematic Reviews 2020, Issue 6. Art. No.: CD009261. DOI: 10.1002/14651858.CD009261.pub6. 7. GRADE Working Group (2013). GRADE Handbook. Handbook for grading the quality of evidence and	

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				the strength of recommendations using the GRADE approach. H. Schünemann, J. Brożek, G. Guyatt and A. Oxman. 8. Hussamy DJ, Wortman AC, McIntire DD, Leveno KJ, Casey BM, Roberts SW. A randomized trial of closed incision negative pressure therapy in morbidly obese women undergoing cesarean delivery. American Journal of Obstetrics and Gynecology 2018;218(1):S35. 9. Tuuli MG, Martin S, Stout MJ, Steiner HL, Harper LM, Longo S, et al. Pilot randomized trial of prophylactic negative pressure wound therapy in obese women after cesarean delivery. American Journal of Obstetrics and Gynecology 2017;216(1 Suppl 1):S245. 10. Tuuli MG, Liu J, Tita ATN, et al. Effect of Prophylactic Negative Pressure Wound Therapy vs Standard Wound Dressing on Surgical-Site Infection in	

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Obese Women After Cesarean Delivery: A Randomized Clinical Trial. JAMA. 2020;324(12):1180–1189. doi:10.1001/jama.2020.13361 11. Gillespie BM, Webster J, Ellwood D, Stapleton H, Whitty JA, Thalib L, et al. ADding negative pRESSure to improve healING (the DRESSING trial): a RCT protocol. BMJ Open 2016;6:e010287 12. ACTRN12615000286549. Negative pressure wound therapy versus standard care dressing to prevent surgical site infections in obese women undergoing caesarean section. www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=368069	
Healthcare Safety Investigation Branch	Guideline	General	General	The guideline does not mention the role of optimal cord clamping at CB. Guidance on this would be welcomed.	Thank you for your comment. Cord-clamping was not within the scope of this update, no evidence was reviewed and therefore we are unable to make any recommendations. However, the NICE guideline on Intrapartum care is being updated in 2021 and it is anticipated that this topic is likely to

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					be covered in that guideline (including after caesarean birth).
Healthcare Safety Investigation Branch	Guideline	General	General	The guideline does not mention advice, when booking an elective CB, about the need to document a plan of care is case of the onset of spontaneous labour or rupture of membranes before the agreed date of CB. Guidance on this would be welcomed.	Thank you for your comment. The committee did not look at issues of planning and booking planned caesarean birth as this was not included in the scope of this update, so were unable to make recommendations about this topic, but agree that this may be helpful, and have passed this suggestion to the NICE surveillance team for consideration in a future update.
Healthcare Safety Investigation Branch	Guideline	General	General	As many units are now using enhanced recovery pathways for elective CB, is there scope for including guidance about this?	Thank you for your comment. We agree that enhanced recovery pathways are being used, but it was not within the scope of this update to address this topic. However, we believe that some of our amended recommendations, for example on prevention of shivering and pain control, may help improve the experience of women having a caesarean birth.
Healthcare Safety Investigation Branch	Guideline	007-009	General	Is the denominator of 10 000 the best way to explain this data? HSIB is concerned that this may be confusing. Is the way of framing the data [would have made no difference] the best way? If this outcome has happened to you, is it useful to be told how many women it has NOT happened to?	Thank you for your comment. The committee agreed that the most appropriate denominator for the number of events such as those reported in the benefits and risks table is per 100,000. Framing data in the ways presented here (number of women affected by the difference, and number not affected) is generally considered appropriate and is the method usually used in NICE guidance.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Healthcare Safety Investigation Branch	Guideline	027-028	021-026	The guidance about the use of codeine during breastfeeding is welcomed. It may benefit from being moved to the top of the section, so that the guidance is read in the context of understanding advice about codeine and breastfeeding.	Thank you for your comment. The guidance about codeine has been moved higher up in the section about pain relief.
Healthcare Safety Investigation Branch	Guideline	008	Table	HSIB suggests clarification of the first row of the table on page 8 – longer hospital stay About 1 to 2 days longer on average **following caesarean birth**.	Thank you for your comment. We have added a new appendix to the evidence report that supports this table. It provides additional details about the outcomes in this table that are derived from the previous version of the guideline, and this includes the longer hospital stay.
Healthcare Safety Investigation Branch	Guideline	009	Table	HSIB suggests clarification of the last row of the table on page 9 – Perineal/abdominal pain during birth and 3 days after birth Reduction in pain scores of 6.3 during birth and 0.7 3 days after birth (scored out of 10) **following caesarean birth.**	Thank you for your comment. We have added more detail to the benefits and risks table to clarify the scoring system used. We have also added a new appendix to the evidence report that supports this table. It includes additional details about the outcomes in this table that are derived from the previous version of the guideline.
Healthcare Safety Investigation Branch	Guideline	019	014, 015	Should this be in line with NICE CG65 where the emphasis seems to be more on prevention of hypothermia? NICE CG 65 section 1.2.4 says - If the patient's temperature is 36.0°C or above, start active warming at least 30 minutes	Thank you for your comment. The NICE guidelines on pre-operative warming do not apply to pregnant women as physiological changes in pregnancy result in an increased basal metabolic rate, with a further rise in metabolic rate seen in labour. The evidence that led to these recommendations was specific to pregnant

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				before induction of anaesthesia, unless this will delay emergency surgery. [new 2016]	women, so we have not amended this recommendation.
Healthcare Safety Investigation Branch	Guideline	025	001-018	Would NICE consider highlighting in this section the RCOA guidelines for the provision of anaesthetic services, which recommends; **'1.8 A minimum of two members of staff should be present (of whom at least one should be a registered practitioner) when there is a patient in the PACU who does not fulfil the criteria for discharge to the ward. If this level of staffing cannot be assured, an anaesthetist should stay with the patient until satisfied that the patient fulfils discharge criteria'**. Chapter 4: Guidelines for the Provision of Anaesthetic Services for Postoperative Care 2019 | The Royal College of Anaesthetists (rcoa.ac.uk)	Thank you for your comment. We have amended the recommendations on monitoring to include that this should be carried out continuously by a trained practitioner.
Healthcare Safety Investigation Branch	Guideline	025	001-006	HSIB considers this wording maybe confusing and a suggested change to the wording is; After caesarean birth under a general anaesthetic, following the removal of an airway device such as an ETT, the anaesthetist should ensure there is a robust	Thank you for your comment. The committee agreed that the aim of these recommendations was to help guide the midwife or recovery nurse about the level of care that is required and the frequency of observations during various phases of recovery. In addition, some of these actions are not applicable in the context of obstetric anaesthesia as no woman who has had caesarean birth under a general anaesthetic

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				formal handover to the qualified staff member recovering the woman. When handing over the care the anaesthetist would ensure the woman • was maintaining her own airway • had respiratory and cardiovascular stability The woman should be continuously monitored until they no longer need any form of airway support, are breathing spontaneously, alert, responding to commands and speaking. Minimum monitoring should include • Pulse oximeter • NIBP • ECG • Capnography if the patient has a tracheal tube, supraglottic airway device in situ or is deeply sedated • Temperature Reference - Recommendations for standards of monitoring during anaesthesia and recovery 2015 (rcoa.ac.uk)	should be handed over to recovery staff with an endotracheal tube or supraglottic airway in situ, and formal handover is part of standard anaesthetic practice. However, the recommendation has been amended to state that the monitoring should be carried out continuously by a trained practitioner with airway skills.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Healthcare Safety Investigation Branch	Guideline	025	020-022	Would NICE consider highlighting in this section the RCOA guidelines for the provision of anaesthetic services, which recommends; **'1.8 A minimum of two members of staff should be present (of whom at least one should be a registered practitioner) when there is a patient in the PACU who does not fulfil the criteria for discharge to the ward. If this level of staffing cannot be assured, an anaesthetist should stay with the patient until satisfied that the patient fulfils discharge criteria'**. Chapter 4: Guidelines for the Provision of Anaesthetic Services for Postoperative Care 2019 | The Royal College of Anaesthetists (rcoa.ac.uk)	Thank you for your comment. We have amended the recommendations on monitoring to include that this should be carried out continuously by a trained practitioner with airway skills.
Healthcare Safety Investigation Branch	Guideline	025	020-022	HSIB considers staff would find it more useful if the exact observations required are included here.	Thank you for your comment. The committee has added detail to include that pulse and blood pressure should have returned to baseline values to clarify this recommendation.
Healthcare Safety Investigation Branch	Guideline	025	013-014	HSIB considers advice to use the local MEWS system for the ongoing observations would be best practice.	Thank you for your comment. The committee discussed whether to amend the wording of local protocols to local MEWS systems, but as this still varies between hospitals, and is called different names in different hospital, agreed to leave it as local protocols.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Healthcare Safety Investigation Branch	Guideline	026	009-012	HSIB considers advice to use the local MEWS system for the ongoing observations would be best practice.	Thank you for your comment. The committee discussed whether to amend the wording of local protocols to local MEWS systems, but as this still varies between hospitals, and is called different names in different hospital, agreed to leave it as local protocols.
Healthcare Safety Investigation Branch	Guideline	026	009-012	HSIB considers staff would be better supported if the frequency of observations could be recommended here.	Thank you for your comment. The committee agreed that the frequency of monitoring would be included in the local protocols and so they did not need to state it here.
Healthcare Safety Investigation Branch	Guideline	027	016-019	HSIB suggests the use of sub-cutaneous morphine could be added to this section.	Thank you for your comment. Subcutaneous morphine has been added as an alternative route of administration.
Healthcare Safety Investigation Branch	Guideline	027	016-019	HSIB suggests the inclusion of the use of both regular and rescue antiemetic medication in this section.	Thank you for your comment. Additional recommendations about the use of anti-emetics and laxatives have been added to this section.
National Patient Safety Team, NHS England	Guideline			While we appreciate that the section on breech presentation has not been reviewed as part of this update, please could the committee consider adding something to ensure that the position of babies is checked on the day of the CS? An incident recently reported through the National Reporting and Learning System, in which a woman received an unnecessary caesarean section, has	Thank you for your comment. Although this section of the guideline was not included in the update, as this relates to a patient safety issue, we have added a new recommendations in the breech presentation section to advise that an ultrasound scan should be performed prior to a caesarean birth.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				highlighted that there is variation in this area. Having national guidance on this matter would help to remove this variation.	
National Wound Care Strategy Programme	Guideline	030	008	"Offer negative pressure wound therapy after caesarean birth for women with a BMI of 35 kg/m2 9 or more to reduce the risk of wound infections" The evidence base for NPWT is highly complex and developing rapidly. We understand the evidence is still changing following the publication of the Cochrane review of NPWT, which included a c-section subgroup, and that there are two large trials on c-sections in obese women which have either reported or are about to report since the review was published; the trial which has already published was stopped for futility. Given this, as continue to be considerable margins of uncertainty around the current evidence and the possibility ongoing research may lead to a different conclusion around effectiveness. More cautious wording might be: "**Consider** negative pressure wound therapy after caesarean birth for women 8 with a BMI	Thank you for your comment and highlighting this new evidence. We have updated the search for this intervention within the guideline and incorporated 2 new studies into Evidence report B (Tuuli 2020 and Hussamy 2019). Having reviewed this updated evidence, we agree that the basis for recommending NPWT is now weaker and have removed the recommendation for the BMI 30-35 kg/m^2 group and retained the recommendation for the BMI >35 kg/m^2 group but downgraded it to a weaker 'consider' recommendation. This decision to weaken the recommendations based on the clinical data was also reinforced by a revised economic analysis that suggests that NPWT is only likely to be cost-effective in women with a BMI over 35 kg/m^2, and as this is now a weaker 'consider' recommendation, the resource implications of implementing it are likely to be much lower.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				of 35 kg/m or more to reduce the risk of wound infections."	
National Wound Care Strategy Programme	Guideline	030	021	"removing standard dressings 6 to 24 hours after the caesarean birth" The rationale for this advice is unclear. The authors of the NWCSP Recommendations for Surgical Wounds (due to be published imminently and which also follow the NICE Guideline on Surgical Site Infection) have chosen not to make a time recommendation around dressing change because there is variation according to clinical need.	Thank you for your comment. The previous version of the guideline had recommended removing dressings after 24 hours but the evidence in this review suggested there was no difference between 6 and 24 hour removal in terms of efficacy and that women may prefer the former. This was in agreement with the committee's experience and therefore they widened the range of time in which dressings could be removed.
National Wound Care Strategy Programme	Guideline	031	001 and 010	"assessing the wound for signs of infection (such as increasing pain, redness or discharge), separation or dehiscence" There does not appear to be any guidance around what to do if the wound oozes or breaks open. In our clinical experience, this group of women often receive limited support and advice from midwives and health visitors in relation to this situation about this. In Section 1.7.6 (Management of symptoms) there is no mention of managing the symptoms of wound breakdown.	Thank you for your comment. This section of the guideline was not included in the scope of this update, and so the committee were unable to add recommendations to this section.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				The European Wound Management Association has recently published guidance on Birth Related Wounds https://ewma.org/what-we-do/projects/birth-related-wounds which may be a useful resource.	
National Wound Care Strategy Programme	Guideline	031	005	"gently cleaning and drying the wound daily" The rationale for this advice is unclear. While good wound hygiene is to be encouraged, the frequency of wound cleansing will be related to the frequency of dressing change. We are also concerned that this recommendation does not sufficiently address peri-wound skin management as skin-fold maceration can be a major problem in some of these women.	Thank you for your comment. The review on methods to reduce infectious morbidity did not find any new evidence relating to the frequency of wound cleaning or peri-wound skin management and so were unable to update these recommendations.
NHS England/NHS Improvement	Guideline	General	General	Any significant post-op issues need to be highlighted to the GP on discharge. Any actions that need to be undertaken by a patient's practice (for example, repeat full blood count if there has been a large amount of blood loss) need to be communicated clearly with the plan and the course of action if the subsequent result is abnormal. (KC)	Thank you for your comment. We agree this is a common sense issue, and so have added a recommendation to the end of the guideline to this effect.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
NHS England/NHS Improvement	Guideline	005	011	The mode of delivery would usually be discussed with a midwife or obstetrician, and not routinely by a GP. However, advice where to signpost a woman to (by these non-specialists) could be helpful. (KC)	Thank you for your comment. The committee agreed that healthcare professionals would only be expected to have discussions with women within the levels of their own competence, and so did not think it was necessary to specify who should have these discussions as some women may wish to discuss with their GP, midwife and an obstetrician (albeit at different levels of detail).
NHS England/NHS Improvement	Guideline	027	029	Most of this guideline relates to specialist perinatal advice or to surgical intervention. Most does not therefore directly relate to primary care management. However, the section on post-operative pain management is relevant to primary care. Very useful to have specific advice about types of analgesia that are appropriate when breast feeding. Medication safety advice during breastfeeding is a common scenario. (KC)	Thank you for your comment and positive feedback.
NHS Grampian	Guideline	006	001	Box 1 is a very helpful resource. In Box 1 – 'faecal incontinence (occurring more than 1 year after birth; compared to unassisted vaginal birth)' is presented with reference to unassisted vaginal birth. Why is it not simply stated whether the risk of faecal incontinence is increased/reduced/the same when comparing planned vaginal birth with	Thank you for your comment and positive feedback. Unfortunately, no studies were identified that provided comparisons of planned caesarean birth with planned vaginal birth (including those that both went on to have assisted and unassisted vaginal birth in a composite group) for this outcome. The only evidence available reported the two comparisons

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				planned caesarean birth? Unassisted vaginal birth is unhelpful as a group as it cannot be predicted in advance. It also implies a bias towards presenting risks in favour of vaginal birth which is misleading as it ignores the risks associated with assisted vaginal birth (extremely relevant to first-time mothers). At the least, could it refer to Table 2 to show that figures compared to assisted vaginal birth are also provided?	(caesarean birth versus unassisted vaginal birth and caesarean birth versus assisted vaginal birth) separately and therefore they are reported separately here. Full information on the evidence underlying these statements is available in evidence report A and we have also provided additional information alongside the tables to explain why this evidence has been presented in this way.
NHS Grampian	Guideline	037	016-018	I am concerned regarding the committee's impression that '*it is already current practice to discuss the risks and benefits of alternative modes of birth during the antenatal period*'. It is very clear from discussion with practitioners from all over the UK that this is not standard practice and that there are many barriers to achieving it. The Birthrights/Mumsnet survey of 1500 women who had recently given birth in 2020 confirmed this impression with less than half of women having had a discussion about both risks and benefits of each mode of birth. This enormous implementation gap since the previous guideline was published has not been acknowledged and this guideline will	Thank you for your comment. It is useful to know that you are aware of evidence that the NICE guidelines are not being implemented and your comments will be considered by NICE where relevant support activity is being planned

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				perpetuate the ignorance around this issue if it makes the statement as it stands just now.	
Obstetric Anaesthetists' Association	General	General	General	You state that comments are only invited on the 2020 updated recommendations and not on guidelines shaded grey. However, several of the grey shaded statements also have 'amended 2020' beside them and are highlighted in yellow. It is therefore confusing as to whether comments on these will be accepted. We have significant concerns about several of these, so offer the following comments.	Thank you for your comment. Recommendations that are shaded in grey and marked (amended 2020) are not included in the scope of the update, but will have had had minor editorial changes made to them (these are highlighted in yellow), but there will be no change to the meaning of the recommendation and no evidence review has been conducted. We have addressed your individual comments.
Obstetric Anaesthetists' Association	Guideline	General		The sections on anaesthesia are poorly written and consideration should be given to rewording several of current recommendations. It would be better to refer to "neuraxial" rather than "regional" anaesthesia.	Thank you for your comment. Based on your feedback we have responded to your detailed comments and made some amendments to wording of recommendations. From an anaesthetic perspective, neuraxial is the specific term which covers spinal, epidural and combined spinal-epidural whereas regional anaesthesia is a wider term that could also be used for upper limb blocks or ankle block. In clinical obstetric practice, the majority of regional anaesthetics will be neuraxial blocks. However, this is a technical term and may not be easily understood by lay people or non- anaesthetists,

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					so we have been advised by the committee to continue to use the term regional anaesthesia.
Obstetric Anaesthetists' Association	Guideline	general	general	Typo throughout - sulphate not sulfate.	Thank you for your comment. The recognised spelling of sulfate, as listed in the BNF, is now with an 'f'.
Obstetric Anaesthetists' Association	Guideline	general	general	The guideline doesn't include recommendations on fasting times prior to elective CS.	Thank you for your comment. This was not in the scope of our update, and so no evidence was reviewed for this topic. However, we will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
Obstetric Anaesthetists' Association	Guideline	025-026	023-029, 001-009	1.6.5 The whole statement is problematic and without an evidence base. How is 'increased risk of respiratory depression defined? The examples of BMI >40 and obstructive sleep apnoea syndrome (OSAS) are flawed; a BMI cut-off of 40 is arbitrary. Re OSAS - does this mean all pregnant women should be formally assessed for OSAS? Clinically significant respiratory after spinal or epidural diamorphine is very rare, e.g. In a 10-year audit of almost 600 women who received neuraxial fentanyl and diamorphine moderate or severe sedation was observed in only 0.25% between 4 and 16 hours after	Thank you for your comment. The committee agreed with your view that the recommendation should not include a definitive BMI cut-off of 40, and should include those with a diagnosis of obstructive sleep apnoea syndrome and have amended the recommendation accordingly. The references you highlight in your comment are not included in our evidence review as they did not meet the protocol criteria (they are reports of prevalence of adverse outcomes as opposed comparative studies of differing monitoring techniques).

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				surgery (1); most had received intramuscular opioids in labour. There were no cases of respiratory depression. A systematic review evaluating *Neuraxial Morphine and Diamorphine-Associated Respiratory Depression After Caesarean Delivery* identified 78 articles with 18,455 parturient receiving neuraxial morphine or diamorphine for caesarean delivery. The highest and lowest prevalences of clinically significant respiratory depression (CSRD) with all doses of neuraxial opioids were 8.67 per 10,000 (95% CI, 4.20-15.16) and 5.96 per 10,000 (95% CI, 2.23-11.28), respectively. The highest and lowest prevalences of CSRD with the use of clinically relevant doses of neuraxial morphine ranged between 1.63 per 10,000 (95% CI, 0.62-8.77) and 1.08 per 10,000 (95% CI, 0.24-7.22), respectively (2). These results indicate that the prevalence of CSRD due to neuraxial morphine or diamorphine in the obstetric population is low. We would suggest that this recommendation be modified 'to those at risk of sedation i.e. those with **significantly** raised BMI' (being	

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				deliberately vague) and 'diagnosed' OSAS and comment that postoperative monitoring should be continued for longer and should be stepped down in accordance with local guidance. References 1) O'Shea E, Jee R, Wee M. A 10 year retrospective audit of monitoring following intrathecal and epidural opioids. Int J Obstet Anesth. 2010 Jul;19(3):345. doi: 10.1016/j.ijoa.2010.03.005. Epub 2010 Jun 3. PMID: 20605434. Sharawi N, Carvalho B, Habib AS, Blake L, Mhyre JM, Sultan P. A Systematic Review Evaluating Neuraxial Morphine and Diamorphine-Associated Respiratory Depression After Cesarean Delivery. Anesth Analg. 2018 Dec;127(6):1385-1395. doi: 10.1213/ANE.0000000000003636. PMID: 30004934.	
Obstetric Anaesthetists' Association	Guideline	017	001-003	Re-introducing 30 minutes as a clinical guide is not evidence based - there is no new evidence and the rationale that audit standards are not appropriate in guidance is	Thank you for your comment. The recommendation includes the phrase 'as soon as possible' and the committee agreed that moving the 30 minutes time period from an audit

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				nonsensical. Losing the phrase 'as soon as is safe' has safety implications.	requirement into the recommendation itself provided greater clarity.
Obstetric Anaesthetists' Association	Guideline	018	002-022	Recommendation 1.4.16 on use of ephedrine is confusing. It would be better to state 'When using a phenylephrine infusion, hypotension combined with bradycardia may be treated with small doses of ephedrine and/or an anticholinergic drug (glycopyrrolate or atropine).'	Thank you for your comment. We have moved this recommendation so it is directly below the recommendation on phenylephrine, and edited to make it clear that the ephedrine is used in conjunction with the phenylephrine infusion, as you suggested.
Obstetric Anaesthetists' Association	Guideline	018	009-013	1.4.14: The use of phenylephrine infusions is not unreasonable for elective surgery but is unlikely to widely adopted for emergency (Cat 1) surgery.	Thank you for your comment. Phenylephrine infusions have been shown to be the best vasopressor choice for both elective surgery and for emergency cases where there is evidence of fetal compromise. However, it is well recognised that the incidence of hypotension following spinal anaesthesia is reduced during emergency cases and it is also essential not to delay rapid delivery of the baby by taking time to prepare a phenylephrine infusion. However, the committee were aware that if there are more than one ODP and anaesthetist available, this is not an issue. By including this recommendation the committee hope that NICE guidelines will help increase the use of phenylephrine infusions for all categories of caesarean births by making this routine practice for non-urgent and semi-urgent operations.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Obstetric Anaesthetists' Association	Guideline	018	001-003	1.4.11: The recommendation as written does not follow GMC guidance on consent. All forms of anaesthesia should be "offered". Neuraxial anaesthesia should be recommended in the majority of cases.	Thank you for your comment. NICE terminology uses the term 'offer' to mean that is the preferred intervention. In accordance with GMC guidance, anaesthetists would offer both regional and general anaesthesia as treatment options as both are effective treatments but then go on to recommend regional unless it is contraindicated as this is safer for mother and fetus.
Obstetric Anaesthetists' Association	Guideline	018	006-008	1.4.13: The 15-degree tilt is not evidence-based. It would be better to state that aortocaval compression and maternal hypotension should be avoided by appropriate uterine displacement. Additionally, as it is currently written it is unclear as it sounds like you only need tilt during surgery. Please clarify that you need to avoid aortocaval compression throughout anaesthesia and surgery	Thank you for your comment. The aim of this recommendation is to highlight the importance of aortocaval syndrome which is exacerbated by the presence of regional and/or general anaesthesia. We have stated that a left lateral tilt should be applied once the woman is supine but there may be some confusion caused by adding the wording "before beginning a caesarean birth procedure" so we have removed this. We agree that the 15-degree tilt is poorly evidence based and hardly ever achieved in clinical practice, which is why we have stated "up to 15 degrees" instead. Appropriate uterine displacement may be difficult to sustain during surgery, but we have included this as an option in the recommendation.
Obstetric Anaesthetists' Association	Guideline	018	004-005	1.4.12: If we are recommending induction of anaesthesia in theatre, this should not be limited to neuraxial blocks.	Thank you for your comment. We have amended the wording of this recommendation to make it clear that it is all anaesthesia, but to emphasise that this includes regional.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Obstetric Anaesthetists' Association	Guideline	018	014	1.4.15: There is no compelling evidence to support colloid pre-loading.	Thank you for your comment. We did not look at evidence for this recommendation as it was not included in the scope of the update, but the committee agree that colloids are no longer widely available or used and so we have removed the reference to colloid pre-loading and left only crystalloid co-loading.
Obstetric Anaesthetists' Association	Guideline	018	025	1.4.18 H2 receptor antagonists are no longer used.	Thank you for your comment. We are aware that H2 receptor antagonists are no longer widely used, but we have not reviewed the evidence for their efficacy as part of this update, and the recommendation gives the option of proton pump inhibitors as well (an unlicensed use), so we have not amended this recommendation
Obstetric Anaesthetists' Association	Guideline	025	002-006	After general anaesthesia until a patient can maintain their airway, they must be CONTINUOUSLY observed by staff WITH AIRWAY SKILLS on a one-to-one basis [this is important as midwives don't necessarily have training in caring for patients who have received general anaesthesia).	Thank you for your comment the recommendation has been amended to state that the monitoring should be carried out continuously by a trained practitioner with airway skills.
Obstetric Anaesthetists' Association	Guideline	027	029	1.6.14: would it not be best to recommend dihydrocodeine (i.e. dihydrocodeine + paracetamol) rather than co-dydramol which may not be available in all units. There is no specific evidence that co-dydramol carries additional benefit.	Thank you for your comment. This recommendation has been amended to state that dihyrocodeine can be added to paracetamol, or that co-dydramol can be prescribed, as this allows flexibility depending on what medicines maternity units stock or are used to using.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Furthermore, the risks of confusing co-dydramol and co-codamol should not be overlooked.	
Obstetric Anaesthetists' Association	Guideline	028	006-015	1.6.16: Why are oxycodone and tramadol recommended? There is no compelling evidence that they offer superior analgesia to women after CS. The only reason to use either is when women are unable to take oral morphine or dihydrocodeine. The potential risks of oxycodone and tramadol in breastfeeding must be stressed if they are to be included.	Thank you for your comment. We have recommended a variety of other pain relief options prior to oxycodone and tramadol (including oral morphine and dihydrocodeine in the combination co-dydramol). These are only included as an option if all else is ineffective as you highlight. The risks of these drugs, and the need to make women aware of their effects if breastfeeding, are highlighted in the recommendations.
Obstetric Anaesthetists' Association	Guideline	061		Note on page 61, second column, recommendation 1.4.14 on use of prophylactic phenylephrine infusions has been repeated but states 'offer....a prophylactic infusion of **ephedrine or** phenylephrine....'. I think the inclusion of 'ephedrine' here is a typo, as it is not included in the main draft recommendation on page 18.	Thank you for your comment. Table 2 is a summary of the changes that have been made to the guideline and will be removed before publication, but you are correct that a late change was made to recommendation 1.4.14 to remove ephedrine, and this was not carried over to Table 2. We have corrected this error.
Pelvic Partnership	Guideline	General	General	The Pelvic Partnership welcomes the decision of the committee to refer to caesarean sections as caesarean births in this guideline.	Thank you for your comment and for supporting the change of name to caesarean birth.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Many women with pregnancy-related pelvic girdle pain (PGP) choose to have a planned caesarean birth in consultation with their medical team as a result of their PGP or trauma from a previous birth, while others may undergo an emergency caesarean birth due to a range of complications in the birth. Whatever the cause, this change in nomenclature reflects the validity of this mode of birth and will have significant impacts on maternal mental health antenatally and postnatally.	
Pregnancy Associated Osteoporosis (PAO) Patient Expert Group	Evidence review A	024	038-047	While it is welcomed the benefits and risk of different types of birth be discussed with women, it should be noted that caesarean birth is preferable for pregnancy associated osteoporosis, given this places least strain to the maternal skeleton & so reduces the risk of spinal and hip fractures during labour. Where women have known risk factors for their bone health, caesarean birth should be the preferred birth. Pregnancy associated osteoporosis is well documented in medical literature, leading to spinal and hip fractures during childbirth and around the time of pregnancy. No research has been undertaken into different birth methods in	Thank you for your comment. Mode of birth in the context of pregnancy related conditions was not within the scope of this update, and therefore the committee was unable to make recommendations in this area. However, there is an existing recommendation in the section of shared decision making about ensuring the woman's clinical situation, as well as her dignity, privacy, views and culture are taken into consideration. Therefore, a woman with pregnancy related osteoporosis would be eligible for planned caesarean birth, and this should form part of the discussions with her healthcare professionals and shared decision-making. Thank you for the reference provided in your comment by Yeon

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				relation to fracture risk and fractures, but the Royal Osteoporosis Society state www.ros.org "bones break easily around the time a woman is giving birth,causing pain and disability." One patient commented "you cannot underestimate the terrible pain and physical and mental anguish of my spine collapsing during vaginal delivery labour. I had complained of terrible back pain to my GP, midwives & in hospital prior to giving birth. If I had been allowed to have a caesaerean birth, my spinal collapse in labour could probably have been prevented because there would have been less impact and strain on my spine". Most research focuses on causes and treatment, but some research papers do mention fracture risk factors. For example in "Pregnancy related osteoporosis & spinal fractures", Karen Yeon Yun,Simon Eun Han et al, Obstetric & Gynaecology Science, 2017, Jan,60 (1), 133-137,ncbi.mlm.nih.gov states "we should recognize the potential risk factors & main symptoms to prevent osteoporotic fractures & further sequelae" Current thinking of UK metabolic bone specialists is to recommend caesarean births for PAO patients for any	2017. The study does not meet inclusion criteria for study type because it is a case series. Furthermore, it is about the management of pregnancy related osteoporosis, and mode of birth in the context of pregnancy related conditions is outside the scope of this guideline.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				subsequent births to protect the spine and prevent further trauma.	
Pregnancy Associated Osteoporosis (PAO) Patient Expert Group	Guideline	013 and 014	019-029 and 001-024	While we welcome the fact that women can personally choose to have a caesarean birth, it would be beneficial if this could be recommended in relation to women with risk factors for poor bone health, known low bone density or any clinical concerns in relation to their bones and delivery. As the ROS state regarding pregnancy associated osteoporosis "bones break easily around the time a woman is giving birth, causing pain and disability" www.ros.org Also current thinking of UK metabolic specialists is to recommend caesarean births for PAO patients for any subsequent births to protect the spine and prevent further trauma.	Thank you for your comment. Caesarean birth in the context of pregnancy related conditions was not within the scope of this update, and therefore the committee was unable to make recommendations in this area. However, there is an existing recommendation in the section of shared decision making about ensuring the woman's clinical situation, as well as her dignity, privacy, views and culture are taken into consideration. Therefore, as you noted, a woman with pregnancy related osteoporosis would be eligible for planned caesarean birth, either at her first or subsequent births.
Resuscitation Council UK	Guideline	017-019	027-008	'Anaesthesia for caesarean birth'. Again, somewhere within these 10 bullet points there should be a statement that all staff involved with anaesthesia for caesarean should be familiar with current maternal resuscitation guidelines. Failed intubation is mentioned, and this is a risk for hypoxic cardiac arrest and similarly we know from the UKOSS study on cardiac arrest in pregnancy	Thank you for your comment. We agree that it is essential that all staff involved with anaesthesia for caesarean birth are familiar with maternal resuscitation guidelines, not just anaesthetists. However, this level of detail on training is beyond the remit of NICE guidelines.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				that regional anaesthesia is a significant cause of cardiovascular collapse.	
Resuscitation Council UK	Guideline	011	016	Morbidly adherent placenta - in particular 'placenta percreta' overlying a previous caesarean scar is a very high-risk procedure. Perhaps there should be a further bullet point suggesting that all senior staff present for these cases should be familiar with current maternal cardiopulmonary resuscitation guidelines (as this is a real risk in this setting).	Thank you for your comment. The committee agreed that senior staff (as listed in the recommendation) who were involved in surgery for morbidly adherent placenta would have skills in maternal cardiopulmonary resuscitation and so it was not necessary to specify this in the recommendation.
Royal College of Anaesthetists	Guideline	General		NICE have said they cannot accept comments about the grey shaded areas but on page 18 point 1.4.14 the document says give a phenylephrine infusion which seems correct to me but this is different in table 2 on page 61 where ephedrine or phenylephrine is mentioned. These 2 statements should agree and I think the one in the text is correct	Thank you for your comment. Table 2 is a summary of the changes that have been made to the guideline and will be removed before publication, but you are correct that a late change was made to recommendation 1.4.14 to remove ephedrine, and this was not carried over to Table 2. We have corrected this error.
Royal College of Anaesthetists	Guideline	General		TAP blocks are becoming increasingly popular as part of multimodal analgesia following caesarean section. The evidence suggests that they may produce an opioid sparing effect although there is, as far as I know, no evidence regarding their use in women who have had neuraxial opioids. Did	Thank you for your comment. We did not review the evidence on the use of TAP blocks as part of this update, as the use of regional blocks for analgesia was not included in the scope of this update.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				the committee consider the use of TAP blocks?	
Royal College of Anaesthetists	Guideline	007-009		Tables 1 and 2 on pages 7-9 are a discussion of risk. The authors have decided on a way of expressing risk that I found quite confusing. It works fairly well in table 1 where the risk of an outcome is greater if the woman has a caesarean but in table 2 I found it more confusing. I obviously understood what was being said but am not sure it is the clearest way of saying it.	Thank you for your comment. We have made some changes to the format of the tables, included more information on the populations (for example planned or actual mode of birth) for each outcome and moved them to a new location where there is more information for caveats and contextual information, and we hope this will aid understanding.
Royal College of Anaesthetists	Guideline	025	023 1.6.5	I do not think that a BMI of over 40 is a sufficient risk to suggest monitoring women hourly for 12 hours after a caesarean section. This is a huge burden with no evidence to suggest that it is necessary and will not be adhered to. Most units discontinue anything more than routine 4 hourly observations for all women after caesarean section once they return to the postnatal wards. Those who remain in HDU or equivalent will receive more frequent monitoring but a BMI over 40 is not a reason to go to HDU.	Thank you for your comment. This recommendation was to help healthcare professionals identify women who may be at increased risk of respiratory depression, and the committee agreed it may therefore be preferable to amend this recommendation to state 'for example, significantly raised BMI or diagnosed obstructive sleep apnoea syndrome'. If women are not thought to be at increased risk, they can (as stated in the next recommendation) be on a routine (usually 4 hourly) monitoring.
Royal College of Gynaecologists	Guideline	General		May want to refer to RCOG guidance or add in recommendations on 1. Decision to delay planned CS when women have COVID- personalised	Thank you for your comment. The committee discussed how COVID may affect recommendations, but agreed with NICE not to make COVID-specific recommendations in an

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				assessment should be carried out to determine whether it is safe to delay CS 2. Take into account urgency of the birth and the risk of transmission to other women, healthcare workers and baby 3. Senior decision making involving obstetric and medical staff is indicated when urgent birth is indicated to aid supportive care of the mother with severe or critical COVID when vaginal birth is not imminent 4. Women should be informed that donning of PPE for CS is time consuming but essential and may affect time to delivery interval with potential adverse outcomes as a result	effort to future-proof the guideline. NICE has produced some guidance relating to COVID and pregnancy and the committee were aware that RCOG had also produced guidance in this area.
Royal College of Gynaecologists	Guideline	010	010	What is the evidence for these recommendations? There is very limited evidence as far as I am aware concerning contraindications and only PET, abnormal fetal doppers or CTG and placental abruption are supported by evidence (RCOG GTG 20a) ECV appears to be safe and successful after one caesarean section so I am concerned that the recommendation here is that it is contraindicated with uterine scar.	Thank you for your comment. The section of the guideline on breech presentation was not included in the update of the guideline so the committee did not review evidence on the contraindications to external cephalic version (ECV), but were aware that a uterine scar was not an absolute contraindication to ECV and so they removed this line. From their knowledge and experience the committee were also aware that hypertension in pregnancy was a medical

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				What are the medical conditions that the authors refer to?	condition that would make ECV unadvisable so they added this as an example.
Royal College of Gynaecologists	Guideline	011	016	Any recommendations about cell salvage? Interventional radiology? Management by a specialist team experienced in the management of placenta accrete spectrum?	Thank you for your comment. This section of the guideline had not been included in the scope of this update and so the committee had not looked at the evidence for interventional radiology or cell salvage and so were unable to make any recommendations relating to these. The committee were aware that commissioning of specialist centres was being planned, but they were not in place everywhere and would be subject to commissioning arrangements and so did not agree this should be included in the guideline.
Royal College of Gynaecologists	Guideline	007–009		Tables 1 and 2 have been set out very clearly in portraying the relative risk of outcomes between CA and vaginal birth, by communicating the risk as number of women per 100,000	Thank you for your comment and positive feedback.
Royal College of Gynaecologists	Guideline	028	016	"use opioid analgesics" - please state which opioid analgesic e.g. oral morphine as the line after this point states not to use opioids to breast feeding women so it could confuse some readers	Thank you for your comment. The recommendation has been clarified by including which opioids it refers to – morphine, dihydrocodeine, tramadol or oxycodone.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Royal College of Midwives	Guideline	007-009	Table 1	The risks are not presented consistently which can generate confusion for clinicians using the guideline to inform consultations with women; clinicians should be able to use wording from the guideline. The wording should be clear and consistent: if there is a 2 fold increase or a 5 fold increase such in the case of hysterectomy and maternal death, the numbers should be presented clearly despite the minimal significance. Moreover the risk should be presented in the same way for vaginal birth than it is for caesarean birth: hence one column with estimated risk of vaginal birth, one column with estimated risk of caesaren birth (without fewer/more but rather a total number) and possibly a third column with the risk difference. It is important same risk presentation is used, hence if the statistic is presented as n. of women that will not experience X the same should be added in the vaginal birth column. We **strongly suggest** revising the entire table.	Thank you for your comment. The issue with presenting the risk in the caesarean birth arm relates to the adjusted relative effects being used to determine which outcomes represent true differences between arms. This is discussed in detail in evidence report A. We have however included a calculated caesarean birth group risk in an attempt to make the information clearer, alongside text in the appendix to explain exactly what this is. We have also made some changes to the format of the tables, included more information on the populations (for example planned or actual mode of birth) for each outcome and moved them to a new location where there is more information for caveats and contextual information, and we hope this will aid understanding.
Royal College of Midwives	Guideline	004	018	This includes UK rate, however it shoul also include WHO recommendation of 10-15% https://apps.who.int/iris/bitstream/handle/10665/161442/WHO_RHR_15.02_eng.pdf?sequence=1	Thank you for your comment. The WHO rate is, for a variety of reasons, much lower than the UK rate, and the committee did not feel this would provide useful information for women in England.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Royal College of Midwives	Guideline	004	019-020	It should say increased maternal age and BMI.	Thank you for your comment. We have amended this recommendation to make it clear that it is increased age and BMI.
Royal College of Midwives	Guideline	005	021-024	This should include risk of secondary infertility and not just risks for subsequent pregnancies	Thank you for your comment. We did not include secondary infertility as an outcome for this review and so were unable to make recommendations on this.
Royal College of Midwives	Guideline	008	Table 1	There are some long-term child health outcomes that do not seem to have been included here. *Children born by cesarean delivery were particularly at statistically significantly increased risk for infections, eczema, and metabolic disorder, compared with spontaneous vaginal birth. Children born by emergency cesarean delivery showed the highest association for metabolic disorder, aOR 2.63 (95% CI 2.26-3.07).* https://pubmed.ncbi.nlm.nih.gov/29577380/ Peters LL, Thornton C, De Jonge A, Khashan A, Tracy M, Downe S, Feijen-de Jong EI, Dahlen HG. The effect of medical and operative birth interventions on child health outcomes in the first 28 days and up to 5 years of age: A linked data population-based cohort study. Birth. 2018 Dec;45(4):347-57.	Thank you for your comment. The long-term outcomes of infections, metabolic disorder and eczema were not extracted from Peters 2018 paper because these outcomes were not prioritised in the review protocol. Infectious morbidity and respiratory morbidity were included as short-term outcomes (early neonatal period, up to 7 days of life) and asthma as a long-term outcome, so the committee agreed that these would be good indicators of infections and respiratory disease. Childhood obesity and type 1 diabetes were also included as long-term outcomes, so the committee agreed that these would be a good indication of metabolic disorders in children. The committee discussed the fact that there were a large number of outcomes which could be considered as potential benefits or risks of either caesarean birth or vaginal birth. The committee agreed to prioritise 28 outcomes as they believed these were the most direct

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				We suggest revising the babies/children health outcome.	indicators of safety for mode of birth and would be the most informative ones for women's decision making. However, they acknowledged that there could be more outcomes relevant for decision-making. This is reflected in the committee discussions of the evidence under 'the outcomes that matter most' in Evidence review A.
Royal College of Midwives	Guideline	012	019	Given that only some babies require immunoglobuline, this recommendation may lead to confusion- it can be interpreted as risk is reduced if all babies receive both immunoglobulin and vaccination.	Thank you for your comment. This section of the guideline was not included in the scope of this update, so no evidence was reviewed and so the committee were unable to update this recommendation. However, as you have identified this as a potential area of confusion we will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date
Royal College of Midwives	Guideline	015	024	One-to-one continuos support in labour does not qualify as 'active management'. All women should receive one-to-one care in labour, the inclusion in here seems to imply that they do not. We strongly suggest removing.	Thank you for your comment. We have removed 'one-to-one continuous support' as you suggested.
Royal College of Midwives	Guideline	025	023	The example may be confusing, it can be read as hourly observation to be necessary for all women with a BMI over 40 for 12 hours who have had a spinal. In contradictions with 1.6.6. We suggest removing the example.	Thank you for your comment. We have amended the example to make it clear that it is only women who are at an increased risk of respiratory depression who should receive this additional

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					monitoring and not all women with a BMI above 40
Royal College of Midwives	Guideline	030	008-012	This recommendation may not be updated with the recent RCT in the JAMA, women with a BMI >39 were randomised to negative dressings or normal dressings showed that there was no difference in frequency of deep or superficial infections. The study was stopped early because of the rate of skin reactions were 7% in the negative pressure group compared to 0.6% in the control group. Tuuli, M.G., Liu, J., Tita, A.T., Longo, S., Trude Shanks, A., Woolfolk, C., Caughey, A.B., Warre A.O., 2020. Effect of prophylactic negative pres vs standard wound dressing on surgical-site inf women after cesarean delivery: A randomized trial. Jama, 324(12), pp.1180-1189.	Thank you for your comment and highlighting this new evidence. We have updated the search for this intervention within the guideline and incorporated 2 new studies into Evidence report B (Tuuli 2020 and Hussamy 2019). Having reviewed this updated evidence we agree that the basis for recommending NPWT is now weaker and have removed the recommendation for the BMI 30-35 kg/m^2 group and retained the recommendation for the BMI >35 kg/m^2 group but downgraded it to a weaker 'consider' recommendation.
Royal College of Nursing	General	General	General	Thank you for the opportunity to contribute to this guideline. We do not have any comments to add on this occasion.	Thank you for your comment and for reviewing the draft guideline.
Royal College of Paediatrics and Child Health	General			Thank you for inviting the Royal College of Paediatrics and Child Health to comment on the caesarean section update. We have not received any responses for this consultation.	Thank you for your comment and for reviewing the draft guideline.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Smith & Nephew UK Limited	Evidence Review **B**	General	General	We are concerned that this recommendation needs to be more prescriptive around the length of time that negative pressure needs to be applied to achieve the treatment effects and outcomes cited in Hyldig 2018 and 2019, which is seven days. It would be beneficial to the end user to outline the minimum treatment time to maximise the clinical and economic benefits of the therapy.	Thank you for your comment. The recommendation about negative pressure wound therapy is intended to highlight when this type of therapy should be used, and in which women. It is not usual for NICE guidelines to contain detailed recommendations on dosing or duration of therapies unless there is something very specific that has been highlighted as an area of uncertainty for the NHS. The healthcare professionals using this guidance would therefore be expected to use negative pressure would therapy in accordance with the manufacturer's recommendations.
The Breastfeeding Network	Guideline	027	1.6.10	Surely it is inappropriate to prescribe any drug post section (particularly analgesic) which is not compatible with bf if that is mother choice	Thank you for your comment. The committee were very careful to recommend pain relief medication that was compatible with breastfeeding wherever possible, and made it clear in the recommendations that if medication was prescribed that was likely to have an effect on breastfeeding, it should be discussed with the woman so she could make an informed choice.
The Breastfeeding Network	Guideline	027	1.6.13	Add naproxen and diclofenac to NSAID – both compatible with breastfeeding	Thank you for your comment. The committee had provided ibuprofen as an example, but agreed that this was not an exhaustive list, and that there may be more concerns over side-effects with diclofenac, so they did not add these medicines to the list.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
The Breastfeeding Network	Guideline	027	1.6.14	Add that codeine should not be prescribed during lactation	Thank you for your comment. A recommendation at the end of this section states that codeine should not be prescribed during lactation. However, to highlight this earlier in the pain section, the committee have reordered the recommendations.
The Breastfeeding Network	Guideline	028	1.6.16	Tramadol and oxycodone do not require cessation of breastfeeding, just observation of the baby	Thank you for your comment. The recommendation did not mean to imply that these medicines required cessation of breastfeeding, but as this was unclear, we have clarified the wording of the recommendation by removing the caveat 'or is breastfeeding'.
The Breastfeeding Network	Guideline	041		The committee developed separate recommendations for women receiving regional 19 or general anaesthesia, based on their knowledge of the likely differences in 20 analgesia requirements. For all women, the committee agreed that any post21 operative analgesia should be suitable for use while breastfeeding, but that women 22 should be made aware of any potential adverse effects on their baby. This is not apparent in the recommendations e.g. need to advise mother to observe baby at home, often discharged in opioids or prescribed by GP once home	Thank you for your comment. The recommendations include only pain relief medication that is safe to use in breastfeeding, or where there may be an effect on the baby this is included in the recommendations, and warnings about how the baby should be monitored are also included. The wording has been amended to clarify that if women are discharged home on opioids they should be advised to contact their healthcare provider if they have concerns about their baby.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
The Breastfeeding Network	Guideline	042 missing missing		From their knowledge and experience, the committee agreed that paracetamol and a 9 non-steroidal anti-inflammatory drug (NSAIDs) such as ibuprofen should be offered 10 in combination to all women to limit the amount of opioids required, and to allow 11 opioids to be stopped. So why was UKDILAS not consulted as experts in the area? However, in women 22 with severe pain the committee agreed that a short-course of tramadol or oxycodone 23 could be considered as long as the woman was informed of the risks and chose to 24 use them this is not how the recommendation reads – it suggests breastfeeding should be interrupted No mention of use of low molecular weight heparinoids and compatibility with breastfeeding – usually continued after discharge but patient information leaflets say not compatible – leads to confusion No mention of constipation following use of opioids and use of laxatives suitable for breastfeeding	Thank you for your comment. The pharmacist on the committee provided advice on the safety of medicines in breastfeeding and consulted other specialist resources as necessary to provide this advice to the committee. The recommendation has been amended to make it clear that women do not have to stop breastfeeding when taking tramadol or oxycodone, but that monitoring of the baby is required. No evidence was reviewed by the committee on the use of low molecular weight heparinoids and this was not included in the scope of this guideline update so the committee are unable to make any recommendations on their use. An additional recommendation has been added to advise the use of laxatives to prevent opioid-induced constipation.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
UK Clinical Pharmacy Association	Guideline	027	016	Offer oral morphine sulfate **solution.** Formulation should not be restricted to oral solution as both modified release and immediate release solid dosage forms (capsules or tablets) are routinely used in many NHS Trusts.	Thank you for your comment, The specific mention of morphine sulfate solution has been removed, to allow use of other morphine oral formulations.
UK Clinical Pharmacy Association	Guideline	028	001 & 002	Consider **co-dydramol**…. Many Trusts try to minimise the use of combination preparation as they are more difficult to titrate against pain. Using co-dydramol results in woman continuing with this when paracetamol alone might be sufficient, thus adding to her likelihood of developing constipation. Dihydrocodeine taken at a higher dose (max per dose is 30mg) is more likely to give better analgesia; woman must however be counselled on minimising use and observe baby for over sedation. This could be limited to 3 days as per recommendation in 1.6.1 Consider removing co-dydramol and add '**dihydrocodeine. In addition it is more**	Thank you for your comment. This recommendation has been amended to state that dihyrocodeine can be added to paracetamol, or that co-dydramol can be prescribed, as this allows flexibility depending on what medicines maternity units stock or are used to using.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				cost effective to use separate individual drugs.	
UK Clinical Pharmacy Association	Guideline	028	004	Consider adding **'such as ibuprofen'** after non-steroidal anti-inflammatory drug as this is routinely used first-line in many Trusts. This is because most Trusts use this as first-line.	Thank you for your comment. Ibuprofen had already been suggested as an example of a non-steroidal anti-inflammatory drug in an earlier recommendation so it was not felt necessary to state this again here.
UK Clinical Pharmacy Association	Guideline	028	014-015	…a short course of tramadol or oxycodone at the lowest effective dose (2020). Tramadol or oxycodone is not routinely used in many Trusts and we would be concerned particularly post discharge as information in lactation is limited. Additionally, being controlled drugs, it adds to delay in getting discharge as TTOs will require doctor to prescribe and dispense from Pharmacy. Dihydrocodeine would be our preferred choice if an opioid is needed as most Trusts kept this as TTO overlabelled prepacks on the ward and supplied against a doctor's prescription or under PGD	Thank you for your comment. Tramadol and oxycodone are recommended only in women with severe pain that cannot be controlled with paracetamol, non-steroidal anti-inflammatory drugs, dihydrocodeine or co-dydramol. Warning about their possible effects on the baby and the need for monitoring are included in the recommendations, as is the advice to prescribe for short courses at the lowest effective dose. The availability of TTO packs is a local operational issue and not something on which NICE would base its recommendations.
UK Drugs in Lactation Advisory Service	Guideline	024	022	At the end of the sentence add (or similar): Consider medicines the woman may be exposed to as a result of the caesarean	Thank you for your comment. We have made specific recommendations about the compatibility of drugs with breastfeeding in specific sections of the guideline (such as the pain section). We do

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				section and thei compatibility with breastfeeding.	not think that making a general statement here would be helpful as it would be unclear what drugs should be included and who would be responsible for implementation.
UK Drugs in Lactation Advisory Service	Guideline	028	002	Has dihydrocodeine been considered as well? The combination paracetamol/dihydrocodeine (500mg/10mg) offers a lower strength dihydrocodeine dose than could be used. If dihydrocodeine considered as an addition (rather than in a combination preparation) a higher strength can potentially be used and may prevent transition to tramadol or oxycodone. Dihydrocodeine (max dose) still compatible with breastfeeding if required with good neonatal monitoring. This could be considered if pain is severe or co-dydramol is not sufficient	Thank you for your comment. This recommendation has been amended to state that dihyrocodeine can be added to paracetamol, or that co-dydramol can be prescribed, as this allows flexibility depending on what medicines maternity units stock or are used to using.
UK Drugs in Lactation Advisory Service	Guideline	028	014	Delete: 'or is not breastfeeding'. This implies that tramadol and oxycodone are not ok to use whilst breastfeeding. Looking at the evidence review I don't think this is the intention, but the meaning is not clear as written. For clarity, both tramadol and oxycodone are compatible with breastfeeding with good infant monitoring	Thank you for your comment. We have removed the wording 'or is not breastfeeding' to make this recommendation clear,

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Winton Centre for Risk & Evidence Communication	Guideline	007-009	Tables 1&2	These tables have the potential to be incredibly useful but at the moment are a little confusing because they miss a crucial column. It would be much more helpful if they had four columns: Outcome – Estimated risk with vaginal birth – Estimated risk with Caesarean birth – Risk difference At the moment, leaving out the estimated absolute risk with a Caesarean birth, means that the clinician/woman has to do the maths in their head to work out the absolute risks from the risk with vaginal birth and the difference between the two. (It would also help readability to have the numbers in bold text and the widths of the columns improved – it may make sense for these tables to be on a landscape rather than portrait page layout).	Thank you for your comment. The difficulty with presenting the risk in the caesarean birth arm relates to the adjusted relative effects being used to determine which outcomes represent true differences between arms. This is discussed in detail in evidence report A. We have now included a calculated caesarean group risk now in the tables, this is not the same as the reported risk but is essentially the intermediate step in calculating the estimated absolute risk difference and should aid understanding. The supporting information alongside the benefits and risks tables explains in detail how this information was derived. We have also made some changes to the format of the tables, included more information on the populations (for example planned or actual mode of birth) for each outcome and moved them to a new location where there is more information for caveats and contextual information, and we hope this will aid understanding.
Winton Centre for Risk & Evidence Communication	Guideline	013	019	The guideline states 'When a woman decides to have a caesarean birth, document the factors that are important to the woman when making her decision.' This should apply whether the woman decides to have a caesarean OR DECIDES	Thank you for your comment. We have amended the recommendation to state that this should be documented whatever the final decision.

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				NOT TO. The Shared Decision Making process and the outcome of the discussion should always be documented. This is perhaps even more important if the woman has decided NOT to have a caesarean, as then – in the case of an emergency during the birth – the woman's values and decision-making process will be outlined in her records for her family and healthcare professionals to guide them if they need to make decisions on her behalf.	
Winton Centre for Risk & Evidence Communication	Guideline	014	001-005	Having guidelines 1.2.25 and 1.2.26 together seems as though it might come across to the woman as coercive. It is important that women are able to make their own decisions in the light of the evidence. Guideline 1.2.25 quite reasonably suggestions that a woman requesting caesarean birth should go through a shared decision-making process, where they discuss the potential risks and benefits with a clinician and together make a decision. However, 1.2.26 then goes on to say that the woman should (then?) be referred to senior healthcare professionals (and the guideline implies more than one) to 'explore the	Thank you for your comment. This part of the guideline is outside the scope of the current committee's work. However, the committee agree that a review of this section of the guideline is required and has asked NICE to carry this out.

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				reasons for the request' and 'ensure the woman has accurate information'. For a woman to be referred to several healthcare professionals, with senior rank, and insisting that she is again given 'accurate information', could put the woman in a position where she feels coerced and that she is somehow not understanding or ignoring the 'information'. (Looking at p55, it appears that the wording change from 2011 was not meant to have this effect: the wording 'and other members of the team if necessary' was perhaps not meant to imply that referral to a senior midwife or obstetrician was compulsory and other members of the team, including anaesthetist could also be invited if deemed necessary – but that any further referral at all was only an option?) It is important that ALL women are provided with accurate information and are enabled to make a shared decision with their healthcare providers. I would suggest removing 1.2.26 and instead to reinforce in 1.2.25 that the	

Caesarean section (update)

Consultation on draft guideline - Stakeholder comments table
15 October – 26 November 2020

.

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				decision-making process in all cases should be documented, so that the woman's reasons and values are recorded.	