NICE National Institute for Health and Care Excellence

Appendix A: Stakeholder consultation comments table

2022 surveillance of CG190 Intrapartum care for healthy women and babies (2014)

Consultation dates: 20th September to 3rd October 2022 and 5th October to 18th October 2022

1. Do you agree with the proposal to not update the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
The Masic Foundation	No	NO We were very disappointed that NICE are not updating recommendation CG190-1.16.5 based on the concerns of one person who expressed concerns. MASIC is the only UK charity which supports women who have suffered OASI. Our aim is to give a voice to women who have suffered OASI by sharing experiences of their care and impact of these injuries on their lives, and campaign for better education of relevant clinicians to ensure OASI are identified and managed effectively. Revising guidance to recommend rectal examination is performed on all women who have a vaginal birth is essential to prevent the consequences of missed OASI. We have feedback from women whose OASI was only identified following the onset of symptoms such as anal	Thank you for your comments. We understand the potentially life-changing impact that OASIS (obstetric anal sphincter injuries) can have on women's lives. We also acknowledge that missed OASIS can result in the need for further ongoing clinical investigations which can be invasive and distressing. These impacts are highlighted by the respondents to MASIC's recent survey of 325 women who experienced severe perineal trauma, and we appreciate you sharing these findings. You have also highlighted a case briefly outlined in the independent review of maternity services in Shropshire and Telford NHS Trust (Ockenden report section 9.76). NICE is unable to comment on individual cases. Additionally, you referenced studies by Keighley et al (2020) and Hayes et al (2006) as evidence for the need for unconditional rectal examination for all women. Keighley et al (2020) is a case summary

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		incontinence, a traumatic and devasting consequence of a birth injury which should have been detected by rectal with vaginal examination at the time of the birth. This has not only been reported by MASIC. Cases and consequences of missed OASI were highlighted in The Ockenden - Final Report (2021) following the independent review of maternity services at the Shropshire and Telford NHS Trust (see p117; sec 9.76): MASIC supports the current RCOG Green Top Guidance recommendation (GTG29) that: All women having a vaginal delivery are at risk of sustaining OASI or isolated rectal buttonhole tears. They should therefore be examined systematically, including a digital rectal examination, to assess the severity of damage, particularly prior to suturing. There is increasing evidence to support the need for this examination due to the devastating consequences of a missed injury (Keighley et al 2020). If an OASI is identified at birth, it can be repaired with a high chance that a woman will be completely asymptomatic (Hayes et al 2006). Failing to check if all women who have a vaginal birth have sustained OASI means potential life-time consequences for women's physical and psychological health and well-being, relationships with their partner, infant and peer group. MASIC advocates have told us that having to cope daily with physical and psychological consequences of OASI results in them reducing their working hours or leaving the employment market altogether. An online MASIC survey in January 2021 explored the	and retrospective cohort analysis (n=175) of women seen by the study author over a period of 12 years. It describes the severity of their injuries and notes that 95/171 were missed at birth and 38 women with fourth degree tears developed rectovaginal fistulas. As you state in your response this details the consequences of OASIS but does not investigate techniques to improve identification. Hayes et al (2006) investigates the outcomes of the immediate repair of third degree tears but also does not investigate identification methods. CG190 makes recommendation 1.16.12 which recommends to undertake repair of the perineum as soon as possible to minimise the risk of infection and blood loss. You also reference the Royal College of Obstetrics and Gynaecology's (RCOG) guideline 'Third- and Fourth-degree Perineal Tears, Management (Green-top Guideline No. 29)' recommendation 6.1 about how the identification of perineal injury can be improved. As you say, it recommends that all women having a vaginal birth should be examined systematically, including a digital rectal examination, to assess the severity of damage, particularly prior to suturing. This is largely based on 2 studies: Groom (2006) and Andrews (2013). Groom was assessed during CG190 development (full guideline p.745- 746) which concluded the study was underpowered to show statistical significance between a control (assessment by attending clinician only) and an increased vigilance group (assessment by attending clinician plus a clinical research fellow). Andrews (2013) aims to establish the prevalence of anal incontinence (AI) and urinary incontinence (UI) in women with confirmed OASIS 4 years following vaginal delivery. It reports symptoms of AI did not change from first vaginal delivery to 4 years post-birth and that there was a

		impact of OASI on the physical and mental health of women and relationships with their child. Over a one-month period, 325 women who self-identified as having severe perineal trauma when giving birth responded. Respondents ranged from 18-74 years old with the majority (89%) in the 25-44 years age bracket. Findings included: • 85% of women who sustained severe perineal injury said it impacted on their physical and emotional relationship with their child. • 77% were affected by traumatic memories of the birth • 55% of women stated they were embarrassed by the symptoms of their birth injury – an inability to control bowel function • 50% of women stated they were unable to do normal activities with their child (eg. playgroups, school run, physical activity) A missed OASI resulted in years of invasive clinical interventions and diagnostic tests, health care appointments, and expense due to need to buy appropriate clothing, pads and other equipment to manage symptoms of anal incontinence. In some cases, a woman's symptoms and its management impact so severely on their health and lives that they opted to have a colostomy. One woman who completed our survey wrote: "All of this would have been avoided had the birth of my daughter been managed better. Those few hours changed my life forever. I often feel heartbroken but	five-fold increase in UI regardless of whether OASIS occurred which significantly interfered with quality of life. The original study covering the period immediately post-delivery (Andrews 2006) aimed to identify risk factors associated with the development of sphincter injuries in a cohort of primiparous women. The study concludes: mediolateral episiotomy and birthweight are independent risk factors for OASIS; that only 13% of the episiotomies observed were genuinely mediolateral; and that structured training in episiotomy is needed for midwives and junior doctors. The study was reviewed during CG190 development (full guideline p.745- 746) and informs CG190-1.13.15 which recommends *'do not carry out a routine episiotomy during spontaneous vaginal birth.'* The studies included in GTG29 and CG190 are not set up to measure the effectiveness of unconditional rectal examination nor do they conclude that rectal examination alone increases the identification of OASIS. They do suggest that increased vigilance resulting from the support of another clinician and good quality training improves identification, and that episiotomies may increase OASIS and should not be used routinely. These findings are reflected in recommendations in GTG29 and CG190. However, the lack of direct evidence about routine rectal examination for all women following vaginal birth for improving OASIS identification, has resulted in differing recommendations in CG190 and GTG29 based largely on consensus. We appreciate this difference may be a source of uncertainty in practice. Therefore, we will update CG190 to re-evaluate when it is appropriate to offer rectal examination taking account of GTG29's recommendations.

		somehow I find a strength to carry on. There have been times when the pain is so intense I have thought seriously about having a colostomy and even suicide." MASIC believes that women who have suffered OASI are the 'experts' in what happened to them and best placed to consider how clinical management could be improved to prevent other women suffering as they did. Women in contact with MASIC are clear that a routine vaginal and rectal examination following their birth could have identified their OASI, resulting in early repair to prevent and/or minimise adverse outcomes. The views of injured women need to be at the forefront of these consultations. We urge NICE to speak to OASI women first hand to understand the impact of their injuries and implications of not revising the current recommendation.	
British Society of Urogynaecology (BSUG)	No	BSUG response to: 2022 exceptional surveillance of Intrapartum care for healthy women and babies investigating angle of episiotomy and rectal examination practice (2017) (NICE guideline CG190) 1. Do you agree with the proposal not to update the guideline? Please could let us know if you agree or disagree (yes/no) and provide your comments BSUG do not agree with the proposal not to update the recommendations in the guideline about angle of episiotomy and rectal examination. 1. Evidence was identified in the surveillance report suggesting "a 60-degree cutting angle coincidental with crowning results in episiotomy suture angles associated	Thank you for your comments. Regarding your comment about episiotomies being performed about 1 in 100 normal births and there being no evidence quoted supporting this figure. This ratio did not originate from a topic expert but was suggested as an option in a questionnaire to topic experts to enable NICE analysts to get a sense of the approximate frequency of pre-crowning episiotomies and was selected by a topic expert to indicate that this was not a very common event. We have since received clarification about the issue of pre-crowning episiotomies with topic experts. We have been advised that pre-crowning episiotomies might be performed if there is concern about fetal condition and there is a need for birth to be hastened. It was reiterated that this is a relatively uncommon situation, but it should

		with a lower risk of obstetric anal sphincter injury (OASI)". Recommendation 1.13.20 covers episiotomy conducted during crowning as well as the circumstances when episiotomy is conducted prior to crowning. One of the two surveillance topic experts has estimated that episiotomy prior to crowning is performed in less than 1 in 100 normal births. No evidence is provided by the expert for this statement. This is not a commonly quoted figure for normal birth. This recommendation should therefore be separated into 2 recommendations: one for episiotomy during crowning (covering the vast majority of occurrences) and a separate recommendation about episiotomy prior to crowning. This will remove the ambiguity that exists in the current recommendation and give clear guidance for the majority of circumstances where episiotomy is performed. should be amended to include this additional reason for performing rectal examination.	be safe to do this at angle of 45 degrees although 60 degrees would be preferable if distension resulting from the use of forceps was equivalent to perineal distension. After considering the consultation comments from BSUG (and other stakeholders) we agree that recommendation CG190-1.13.20 should be updated. We will update CG190 to re-evaluate what episiotomy angles are appropriate at crowning or equivalent perineal distension and during those rarer circumstances where episiotomy must be conducted prior to crowning. Following this consultation, we will also update CG190 to re-evaluate when it is appropriate to offer a rectal examination following vaginal birth.
Royal College of Paediatrics and Child Health	Yes	We are happy with the proposal to leave this guideline unchanged.	Thank you for your response.
St John's Hospital / Livingston / Scotland	No	My organisation disagrees with the proposal not to update. St John's Hospital was one of the pilot sites for the OASI Care Bundle introduction and is currently involved in the OASI2 feasibility study. The OASI Care Bundle includes rectal examination after	Thank you for your comments about episiotomy angle. We are aware of the ongoing OASI2 trial, and we will track this and assess its impact on recommendations when it publishes. The results of the OASI pilot are discussed in the 2022 surveillance report (p.4) which notes that OASIS was reduced by 0.3% a figure that was statistically

		every vaginal delivery and it also advises on the angle for episiotomy of 60 degrees - significant evidence has supported the inclusion of these (as well as routine MPP) in the care bundle. The results of the pilot study were published and showed that the introduction of the care bundle resulted in a significant reduction of OASI. The sequelae of OASI can be debilitating and potentially life-long, and therefore every effort must be made to reduce the incidence which has steadily increased over the last 15-20 years to unacceptable levels in some units. Given the success of the OASI Care Bundle, this part of the guideline must be reviewed and updated to ensure that advice facilitates the reduction of OASI for all women. **Extension addition:** I do not agree with the proposal not to update these recommendations on the basis of my experience as a lead in introducing the OASI Care Bundle to minimise obstetric anal sphincter injuries. An episiotomy angle of any less than 60 degrees at the point of cutting will almost invariably result in a suture angle that is less than 45 degrees and will therefore not protect against OASI - it is of paramount importance that the angle is large enough to be protective against OASI. Regarding rectal examination, genital trauma is at times only identified if a rectal examination is carried out and superficial inspection is not sufficient, specifically to diagnose OASI which could lead to life-long disability if it remains undetected. Rectal examination therefore must be carried out after every vaginal delivery.	significant overall but that did not remain significant for instrumental births. Evidence suggests a 60-degree episiotomy cutting angle timed to coincide with crowning results in fewer OASIS, however there are rare instances where episiotomy needs to be performed prior to crowning and due to differing perineal distension compared with crowning. In this case an angle of 45 to 60 degrees is acceptable, although 60 degrees would be preferable if distension resulting from the use of forceps was equivalent to perineal distension. Therefore, we agree that recommendation CG190-1.13.20 should be updated.. Thank you for your comments about rectal examination after vaginal birth. This exceptional review and previous surveillance reviews of CG190 have found no evidence that unconditional rectal examination after every vaginal birth results in lower rates of OASIS. While the OASI care bundle pilot discussed as part of my response to your comments above did reduce rates in spontaneous vaginal birth it does not demonstrate that this was due to the rectal examination component of the bundle alone. We are aware that the OASI care bundle bases it's rectal examination recommendation on RCOG's GTG29 recommendation 6.1 which recommends a systematic rectal examination for all women. GTG29 and CG190 considered some of the same evidence but a lack of direct evidence about routine rectal examination for improving OASIS identification, has resulted in differing recommendations in CG190 and GTG29 based largely on consensus. We appreciate this difference may be a source of uncertainty in practice. Therefore, we will update CG190 to re-evaluate when it is appropriate to offer rectal examination taking account of GTG29's recommendations.

		Evidence for both points can be found in the results of the Pilot study which introduced the OASI Care Bundle to 16 units in the UK. The OASI rates in the UK have risen to unacceptable levels over the last 2 decades, and leaving these recommendations unrevised will further increase the risks of women sustaining and/or suffering the consequences of an undiagnosed sphincter tear.	
The Royal College of Obstetricians and Gynaecologists/Royal College of Midwives	No	No CG190-1.13.20 that recommends that an episiotomy angle to the vertical axis should be between 45 and 60 degrees at the time of the episiotomy. The RCOG and RCM are concerned at the lack of distinction between the angle of an episiotomy undertaken prior to and during crowning in recommendation CG190-1.13.20. The RCOG's Green-top Guideline No. 29 (GTG29) on The Management of Third- and Fourth-Degree Perineal Tears (2015) states that: Where episiotomy is indicated, the mediolateral technique is recommended, with careful attention to ensure that the angle is 60 degrees away from the midline when the perineum is distended. GTG29 explains that the angle of the episiotomy away from the midline is important in reducing the incidence of obstetric anal sphincter injury (OASI): An episiotomy performed at 40 degrees results in a post-delivery angle of 22 degrees, which is too close to the midline to be maximally protective. A 60-degree episiotomy from the centre of the introitus results in a post-delivery angle of 45 degrees. While the RCOG and RCM acknowledge that there are	Thank you for your comments about angle of episiotomy. We are aware of RCOG's green top guideline (GTG29) recommendation about mediolateral episiotomy of 60 degrees from the midline. We also acknowledge comments about the risks of episiotomy prior to crowning and that this is not currently recommended by RCOG. We have had clarification about the latter which confirmed this is a rare occurrence and would only be used in situations where there is concern about fetal health and there is an imperative for the birth to be hastened. We identified evidence (including the RCOG recommendation referenced in your comments and the evidence supporting it) that suggests a 60 degree cutting angle at crowning results in suture angle associated with a lower rate of OASIS. After considering your comments and those of other stakeholders we agree that recommendation CG190-1.13.20 should be updated. Thank you for your comments about rectal examinations following vaginal deliveries. We are aware of recommendation 6.1 in Third- and Fourth-degree Perineal Tears, Management (Green-top Guideline No. 29) which *states that all women having a vaginal delivery are at risk of sustaining OASIS or isolated rectal buttonhole tears. They should therefore be examined systematically, including a digital rectal examination, to assess the severity of damage, particularly*

		rare occasions when episiotomies are performed prior to crowning at a reduced angle, this clarification is absent in CG190-1.13.20. It is the RCOG and RCM's concern that this lack of clarification may lead healthcare professionals to perform episiotomies at an angle less than 60 degrees away from the midline at crowning. Furthermore, the RCOG and RCM do not endorse the practice of performing episiotomies prior to crowning because vaginal birth may not actually occur, which could leave the woman with a caesarean birth and an episiotomy. If an episiotomy were to be performed before crowning, this can lead to increased blood loss that is unnecessary and constitutes a patient safety issue. The RCOG and RCM would therefore recommend inserting a clarification in CG190-1.13.20 to state that the episiotomy angle to the vertical axis should be at 60 degrees at crowning, or if in the rare circumstance an episiotomy is performed prior to crowning (which is not recommended), an angle of 45-60 degrees may be considered. CG190-1.16.5 which recommends a rectal examination only if genital trauma is identified. The RCOG and RCM challenge the condition upon which to perform a rectal examination only if genital trauma is identified in recommendation CG190-1.16.5. The RCOG's GTG29 states that: All women having a vaginal delivery are at risk of sustaining OASIS or isolated rectal buttonhole tears. They should therefore be examined systematically, including a digital rectal examination, to assess the severity of damage, particularly prior to suturing. The RCOG and RCM are concerned that as currently	*prior to suturing.* It also says as you state that anal sphincter injury cannot be excluded without performing a rectal examination. This is based on 2 studies: Groom (2006) and Andrews (2013). Groom was assessed during CG190 development (full guideline p.745- 746) which concluded the study was underpowered to show statistical significance between a control (assessment by attending clinician only) and an increased vigilance group (assessment by attending clinician plus a clinical research fellow). Andrews (2013) aims to establish the prevalence of AI and UI in women with confirmed OASIS 4 years following vaginal delivery. It reports symptoms of AI did not change from first vaginal delivery to 4 years post-birth and that there was a five-fold increase in UI regardless of whether OASIS occurred which significantly interfered with quality of life. The original study covering the period immediately post-delivery (Andrews 2006) aimed to identify risk factors associated with the development of sphincter injuries in a cohort of primiparous women. The study concludes: mediolateral episiotomy and birthweight are independent risk factors for OASIS; that only 13% of the episiotomies observed were genuinely mediolateral; and that structured training in episiotomy is needed for midwives and junior doctors. The study was reviewed during CG190 development (full guideline p.745- 746) and informs CG190-1.13.15 which recommends *'do not carry out a routine episiotomy during spontaneous vaginal birth.'* The studies included in GTG29 and CG190 are not set up to measure the effectiveness of unconditional rectal examination nor do they conclude that rectal examination alone increases the identification of OASIS. They do suggest that increased vigilance resulting from the support of another clinician and good quality training improves identification, and that episiotomies may increase

		worded, recommendation CG190-1.16.5 may lead healthcare professionals only to perform a rectal examination if they suspect an OASI or complex tearing by visual examination alone. Over 85% of women experience some form of genital tract trauma which, coupled with the risk of an OASI even in the presence of an intact perineum, should mean that healthcare professionals offer systematic examination after vaginal birth to all women. Neglecting to do so will lead to lower detection rates of OASI and this view is underscored by the Level 2+ evidence in GTG29 showing that: Following vaginal delivery, anal sphincter and anorectal mucosal injury cannot be excluded without performing a rectal examination. With increased awareness and training in examination and diagnosis, there appears to be an increase in the detection of OASIS; one observational study showed that increased vigilance can double the detection rate. The RCOG produces its Green-top Guidance with the active involvement of many stakeholders. It includes generation of best practice recommendations from a group of practising obstetricians and patients. The recommendations from GTG29 cited in this response were developed to ensure that injuries such as rectal buttonhole tears, which can occur in the absence of any overt perineal trauma and lead to rectovaginal fistula formation, are detected and treated immediately. Missing such tears can lead to prolonged suffering for women, birthing people and their families, and could be regarded as clinically negligent leading to a greater risk of litigation.	OASIS and should not be used routinely. These findings are reflected in recommendations in GTG29 and CG190. However, the lack of direct evidence about routine rectal examination for all women following vaginal birth for improving OASIS identification, has resulted in differing recommendations in CG190 and GTG29 based largely on consensus. We appreciate this difference may be a source of uncertainty in practice. Therefore, we will update CG190 to re-evaluate when it is appropriate to offer rectal examination taking account of GTG29's recommendations.
University Hospital Plymouth NHS Trust	No	No. At University Hospital Plymouth NHS Trust we feel the	Thank you for your comments about angle of episiotomy.

		45-60degree episiotomy angle is too ambiguous and not in line with the latest evidence. Therefore NICE should recommend 'episiotomy performed at 60 degrees with crowning'. The angle of the episiotomy away from the midline is important in reducing the incidence of obstetric anal sphincter injury (OASI). An episiotomy performed at 40 degrees results in a post-birth angle of 22 degrees with a 10% risk of also sustaining an OASI. A 60-degree episiotomy results in a post-birth angle of 45 degrees and a much lower 0.5% risk of OASI (Sawart & Kumar 2015). While there are rare occasions when episiotomies are performed prior to crowning, this clarification is absent in the current recommendation. The practice of performing episiotomies prior to crowning is not supported and widely discouraged. This is partly because vaginal birth may not actually occur creating unnecessary trauma and, because it can lead to significant blood loss, compromising the woman . Therefore we recommend using the wording of '60 degrees with crowning'. The evidence given in consultation is enough to recommend 60degrees at crowning to reduce risk of OASI due to the distended perineum at the moment of birth (Ginath et al 2017, Kalis 2011, Kastora et al 2021 and Koh et al 2020). All women having a vaginal birth are at risk of sustaining an OASI or anovaginal fistula. They should therefore be	We have considered your comments about the potential ambiguity of 45-60 degrees and lack of clarification about occasions when episiotomy may have to be performed prior to crowning. We are aware from other stakeholders that the latter is widely discouraged but understand there are rare occasions when there is a concern for fetal health, and birth must be hastened that they may need to be performed. After considering your comments alongside those of other stakeholders, and in light of the evidence identified by this surveillance review we agree that CG190-1.13.20 about episiotomy needs clarification. Therefore, we will update CG190-1.13.20. Thank you for your comments about rectal examination. During CG190 development and surveillance, including this surveillance, we have not identified evidence to suggest that rectal examination should be routine for all women. We are aware of RCOG's green top guideline Third- and Fourth-degree Perineal Tears, Management (Green-top Guideline No. 29), which you reference. This says that *all women having a vaginal delivery are at risk of sustaining OASIS or isolated rectal buttonhole tears. They should therefore be examined systematically, including a digital rectal examination, to assess the severity of damage, particularly prior to suturing.* It also says that anal sphincter injury cannot be excluded without performing a rectal examination. This is based on 2 studies: Groom (2006) and Andrews (2013). Groom was assessed during CG190 development (full guideline p.745- 746) which concluded the study was underpowered to show statistical significance between a control (assessment by attending clinician only) and an increased vigilance group (assessment by attending clinician plus a clinical research fellow). Andrews (2013) aims to establish the prevalence of AI and UI in women with

		offered examination systematically, including a digital rectal examination, to assess the severity of damage. There is concern that as currently worded, maternity staff may only perform a rectal examination if they suspect an OASI or complex tearing. Over 85% of women experience some form of genital tract trauma which, if offered and accept a systematic examination after vaginal birth to all women both increases detection of OASI, and awareness and training in examination and diagnosis. You cannot visually see as much damage of an anal sphincter as you can feel. Missing such tears can lead to prolonged suffering for birthing people and their families, and could be regarded as clinically negligent leading to a greater risk of litigation. At UHPNT we follow RCOG green top guidelines which our recommendations are inline with but NICE are not if they choose to not update.	confirmed OASIS 4 years following vaginal delivery. It reports symptoms of AI did not change from first vaginal delivery to 4 years post-birth and that there was a five-fold increase in UI regardless of whether OASIS occurred which significantly interfered with quality of life. The original study covering the period immediately post-delivery (Andrews 2006) aimed to identify risk factors associated with the development of sphincter injuries in a cohort of primiparous women. The study concludes: mediolateral episiotomy and birthweight are independent risk factors for OASIS; that only 13% of the episiotomies observed were genuinely mediolateral; and that structured training in episiotomy is needed for midwives and junior doctors. The study was reviewed during CG190 development (full guideline p.745- 746) and informs CG190-1.13.15 which recommends *'do not carry out a routine episiotomy during spontaneous vaginal birth.'* The studies included in GTG29 and CG190 are not set up to measure the effectiveness of unconditional rectal examination nor do they conclude that rectal examination alone increases the identification of OASIS. They do suggest that increased vigilance resulting from the support of another clinician and good quality training improves identification, and that episiotomies may increase OASIS and should not be used routinely. These findings are reflected in recommendations in GTG29 and CG190. However, the lack of direct evidence about routine rectal examination for all women following vaginal birth for improving OASIS identification, has resulted in differing recommendations in CG190 and GTG29 based largely on consensus. We appreciate this difference may be a source of uncertainty in practice. Therefore, we will update CG190

			to re-evaluate when it is appropriate to offer rectal examination taking account of GTG29's recommendations.
NHS England	No	Yes **Additional comments:** No. The proposal states that 'we did identify evidence that suggests a 60 degree cutting angle coincidental with crowning results in episiotomy suture angles associated with a lower risk of obstetric anal sphincter injury (OASI)'. And then that 'Recommendation 1.13.20 accommodates this situation while also accommodating circumstances where an episiotomy has to be conducted prior to crowning.' However there is no reference within this recommendation to take into account crowning or perineal distension when cutting an episiotomy at the recommended range of angles. This should be explicit within the recommendation to facilitate awareness and avoid confusion.	Thank you for your comments about angle of episiotomy. After reviewing your comments and those of other stakeholders we agree that CG190-1.13.20 needs to be updated.
Croydon University Hospital	No	Disagree CG190-1.13.20 that recommends that an episiotomy angle to the vertical axis should be between 45 and 60 degrees at the time of the episiotomy. The RCOG's Green-top Guideline No. 29 (GTG29) on The Management of Third-and Fourth-Degree Perineal Tears (2015) states that:	Thank you for your comments about angle of episiotomy. We are aware of RCOG's green top guideline Third- and Fourth-degree Perineal Tears, Management (Green-top Guideline No. 29) which recommends a 60 degree cutting angle when the perineum is fully stretched as this results in a suture line angle consistent with reduced rates of OASIS. We are also aware that RCOG does not recommend pre-crowning episiotomy due to the risk to the mother.

		Where episiotomy is indicated, the mediolateral technique is recommended, with careful attention to ensure that the angle is 60 degrees away from the midline when the perineum is distended. GTG29 explains that the angle of the episiotomy away from the midline is important in reducing the incidence of obstetric anal sphincter injury (OASI): An episiotomy performed at 40 degrees results in a post-delivery angle of 22 degrees, which is too close to the midline to be maximally protective. A 60-degree episiotomy from the centre of the introitus results in a post-delivery angle of 45 degrees. Episiotomy should not be performed before crowning as it can lead to unnecessary blood loss and if vaginal birth does not occur a caesarean with an episiotomy. CG190-1.16.5 which recommends a rectal examination only if genital trauma is identified. The RCOG's GTG29 states that: All women having a vaginal delivery are at risk of sustaining OASIS or isolated rectal buttonhole tears. They should therefore be examined systematically, including a digital rectal examination, to assess the severity of damage, particularly prior to suturing. Considering the significant morbidity associated with OASIS everything should be done to prevent it. In addition, missing these tears (which are diagnosed on per rectal examination) is vital as these injuries are associated with a significant impact on a woman's quality of life, mental health and a financial impact for the woman and the health system that serves her for the	However, we have been made aware that there are rare occasions when fetal wellbeing might be compromised when episiotomy may need to be conducted pre-crowning. After considering your comments and those of other stakeholders alongside evidence identified about episiotomy angles by the surveillance review, we will change the surveillance proposal to say that we will update CG190-1.13.20. Thank you for your comments about rectal examination. We did not find evidence that routine rectal examination for every woman reduces OASIS. We are aware of recommendation 6.1 in GTG29 which recommends *that all women having a vaginal delivery are at risk of sustaining OASIS or isolated rectal buttonhole tears. They should therefore be examined systematically, including a digital rectal examination, to assess the severity of damage, particularly prior to suturing.* GTG29 also says that anal sphincter injury cannot be excluded without performing a rectal examination. This is based on 2 studies: Groom (2006) and Andrews (2013), the former was considered during CG190 development (full guideline p.745- 746). The second is a follow-up to a 2006 study by Andrews et al. that was also considered during CG190 development (full guideline p.745- 746). These studies do not demonstrate a direct association between rectal examination and reduced OASIS. Rather they conclude that increased vigilance about OASIS and training for attending clinicians in conducting mediolateral episiotomies at 60 degrees during crowning, result in lower rates of OASIS. These findings are reflected in recommendations in GTG29 and CG190. However, the lack of direct evidence about routine rectal examination for all women following vaginal birth for improving OASIS identification, has resulted in differing recommendations in CG190 and GTG29 based largely on consensus. We appreciate this

		consequences. Litigation due to perineal trauma is increasing and we fail to understand how NICE does not consider this a safety issue.	difference may be a source of uncertainty in practice. Therefore, we will update CG190 to re-evaluate when it is appropriate to offer rectal examination taking account of GTG29's recommendations.
Royal College of Nursing	No comments	We do not have any comments to add on this occasion. Thank you for the opportunity to contribute.	Thank you for your response.
Maternal Mental Health Alliance UK	No	No. Currently, the guideline notes several points about physical assessment and usually specifies what should be done if issues are recognised e.g. the placenta should be checked and, if not intact, the patient transferred to obstetric care. However, the guidance that professionals must conduct 'early assessment of the woman's emotional and psychological condition in response to labour and birth' does not stipulate that action should be taken if issues are noted e.g. appropriate onward referral. Should this be discussed?	Thank you for your comments. Early assessment of the woman's emotional and psychological condition in response to labour and birth is outside the scope of this surveillance review. This surveillance covers the topics of angle of episiotomy and whether all women who have undergone vaginal birth should have a rectal examination, regardless of the presence of genital trauma. Recommendations about women's emotional and psychological wellbeing during pregnancy and birth are included in antenatal and postnatal mental health: clinical management and service guidance (NICE guideline CG192).
Group B Strep Support	No	We disagree - we believe the consultation should be updated. The title is Intrapartum care for healthy women and babies, and yet it does not cover caring for women and other birthing people in labour when they have been found to carry group B Strep. Group B Strep is a normal body commensal, carried by 20-40% of women. Those carrying GBS are healthy, including those in labour and	Thank you for your comments. Group B streptococcus (GBS) infection is outside the scope of this surveillance. This surveillance covers the topics of angle of episiotomy and whether all women who have undergone vaginal birth should have a rectal examination, regardless of the presence of genital trauma. Recommendations

		their babies. HSIB published a report on GBS in July 2020 including learning that should be incorporated into this guideline, for example when women call to say they are in labour, as part of the telephone triage, to identify GBS status (if known) and advise to come in early to receive intrapartum antimicrobial prophylaxis.	about streptococcal B infection are included in neonatal infection: antibiotics for prevention and treatment (NICE guideline NG195).
Avoiding Brain Injury in Childbirth (ABC)	Yes	Yes we agree not to update these two aspects of the guideline after consideration of the evidence reviewed	Thank you for your comments.

2. Do you have any comments on equality issues?

Stakeholder	Overall response	Comments	NICE response
The Masic Foundation	Yes	Suffering OASI causes huge inequalities for women of all ages and ethnic groups, not least of which are fractured relationships with those closest to them and economic impacts due to reduction or loss of income. One woman who responded to our online survey wrote of her experiences of failure to manage her perineal trauma: "I experienced my first episode of faecal incontinence the very next day (of the birth). From that day onwards I continue to be incontinent of faeces and flatus, to have marked faecal urgency and passive faecal incontinence. The physical and psychological consequences over the last 11 years has been devastating. I have lost my career I	Thank you for your comments, for the references you have provided and for the testimony from a woman who experienced the effects of perineal trauma who responded to MASIC's survey. We are aware that OASIS can cause equality issues and CG190 recommendations aim to reduce OASIS rates and its impact on women. Albar et al. (2021) was assessed during this exceptional surveillance and excluded because it does not compare episiotomy angles or the use of rectal examination on OASIS. It is a cohort study that reports Asian ethnicity is associated with a higher risk of OASIS. It concludes that mediolateral episiotomy may protect against OASIS and should be used in high risk patients, a finding consistent with

		worked so hard to achieve, my dignity, everything that defined me as me." We know that women from Asian and Black ethnic backgrounds are under-represented in the MASIC membership, but evidence shows that women in some ethnic groups are at higher risk of severe perineal trauma in the UK (Gurol-Urganci et al 2013), and in other settings (Albar et al 2021). We are concerned that by not assessing all women for OASI following birth, women who are less likely to report symptoms due to language or cultural barriers will be even more likely to endure years of suffering in silence. As a key stakeholder representing women living with the lifelong consequences of OASI, we were very disappointed that we were not informed of this surveillance consultation. Given the importance of these decisions to women giving birth in the future, consultations should be more transparent. A 14-day response window is insufficient for ensuring comments and views are encapsulated given equality issues. We urge you to listen to the evidence of women who have suffered. References Albar M, Aviram A, Anabusi S, Huang T, Tunde-Byass M, Mei-Dan E.J Maternal Ethnicity and the Risk of Obstetrical Anal Sphincter Injury: A Retrospective Cohort Study. Obstet Gynaecol Can. 2021 Apr;43(4):469-473 Gurol-Urganci I , D A Cromwell, L C Edozien, T A Mahmood, E J Adams, D H Richmond, A Templeton, J H	CG190-1.13.20 which recommends mediolateral episiotomy. We did not find any evidence about interventions specifically addressing OASIS risk in women of Asian ethnicity. The Albar et al. study highlights a potential equalities issue, and we will therefore add it to the final surveillance report. We will also add this issue to our issues log for which to look for evidence about interventions that address OASIS risk in this group. Keighley et al (2020) is a case summary and retrospective cohort analysis (n=175) of women seen by the author over a period of 12 years. It describes the severity of their injuries and notes that 95/171 were missed at birth and 38 women with fourth degree tears developed rectovaginal fistulas. As you state in your response this details the consequences of OASIS but does not investigate techniques to improve identification. Hayes et al (2006) investigates the outcomes of the immediate repair of third degree tears and reports generally good outcomes noting that 65% of cases were asymptomatic. This is consistent with CG190-1.16.12 which recommends to undertake repair of the perineum as soon as possible to minimise the risk of infection and blood loss. Gurol-Urganci (2013) is a non-interventional study investigating trends in perineal tears and associated risk factors in the NHS between 2000 and 2012. It concludes that the observed increase (from 1.8 to 5.9%) over the period is probably due to improved recognition following introduction of a standardised classification of perineal tears. CG190-1.16.2 recommends a standardised system for identifying perineal tears based on RCOG's recommendations. We have noted that there are small differences between CG190-1.16.2 and the current RCOG guideline (GTG29) about classification of perineal

		van der Meulen. Third- and fourth-degree perineal tears among primiparous women in England between 2000 and 2012: time trends and risk factors BJOG. 2013 Nov;120(12):1516-25. Hayes J, Shatari T, Tooz-Hobson P, Busby K, Pretlove S, Radley S, Keighley MRB. Early results of immediate repair of obstetric third degree tears: 65% are completely asymptomatic despite persistent sphincter defects in 61%. Colorectal Dis 2006; 9: 332 – 336. Keighley MRB, Clements A, Hall J. A case of missed fourth degree tear with minimal perineal injury: An analysis of the frequency of missed third and fourth degree tears and a comment about support from the MASIC Foundation. Journal of Gynaecology and Women Healthcare 2020. ISSN 2639-2785; volume 2 issue 2.	tears. We will make editorial amendments to CG190 to ensure consistency with the latest GTG29 classifications. Thank you for your comments about the surveillance period. Unfortunately, due to unforeseen IT issues with our stakeholder system some stakeholders were not given advance notice on 6 September about the opening of the consultation on 20 September, or details of the consultation once live. Stakeholder comments are vital for our development processes, and we apologise for any inconvenience and confusion this IT issue caused. When we realised there was an issue, we communicated this and began the consultation process again, contacting all registered stakeholders directly and allowing another 2 weeks (5-18 October) for them to comment. Two weeks is the standard consultation duration as described in chapter 13 of the NICE guideline development manual.
British Society of Urogynaecology (BSUG)	Yes	2. We are concerned that recommendation 1.16.5 is to remain unchanged. Rectal examination may detect a vaginal buttonhole tear (of the rectum and vagina) in the absence of perineal trauma or obvious vaginal trauma. This is a rare but serious complication and can lead to rectovaginal fistula if unrecognised. Although women may find rectal examination unpleasant, there is no associated morbidity. Failure to perform this examination and recognise this complication	Thank you for your comments about recommendation 1.16.5 about rectal examination. Guideline development and subsequent surveillance (including this exceptional surveillance) considered observational studies in addition to RCTs and systematic reviews (see surveillance methods section for 2022 surveillance review). We acknowledge evidence underpinning 6.1 in Third- and Fourth-degree Perineal Tears, Management (Green-top Guideline No. 29) which *states that all women having a vaginal delivery are at risk of sustaining OASIS or isolated rectal buttonhole tears*, suggests increased vigilance may increase OASIS identification. This includes checks by a second clinician, which is recommended by CG190-1.16.9 if there is uncertainty about injury severity. However, it does not provide

		is considered negligent. Unfortunately, there is never likely to be RCT or other high-quality evidence related to this rare but serious complication. This recommendation	direct robust evidence that using unconditional rectal examinations will have the same outcome. We acknowledge that this lack of direct evidence about routine rectal examination for all women following vaginal birth for improving OASIS identification, has resulted in differing recommendations in CG190 and GTG29 based largely on consensus. We appreciate this difference may be a source of uncertainty in practice. Therefore, we will update CG190 to re-evaluate when it is appropriate to offer rectal examination taking account of GTG29's recommendations.
Royal College of Paediatrics and Child Health	No answer	*No answer provided*	
St John's Hospital / Livingston / Scotland	No	None	Thank you for your response
The Royal College of Obstetricians and Gynaecologists/Royal College of Midwives	NA	The RCOG and RCM would like to place on record their disappointment in the manner NICE has conducted this surveillance consultation, with neither the RCOG, RCM nor relevant patient stakeholder organisations including the MASIC Foundation or Birth Trauma Association informed of the consultation. This lack of communication or transparency with registered stakeholders raises doubts as to the integrity of the consultation, with the 14-day response window far too short to enable wider dissemination and input. In future, we would suggest NICE engages with registered stakeholders in advance of identified consultations to ensure the consideration of as wide a range of views as possible.	Thank you for your response. Stakeholder comments are vital for our development processes, and we apologise for any inconvenience and confusion caused by issues with the consultation. These resulted from unforeseen IT problems with our stakeholder system resulting in some stakeholders not receiving advance notice on 6 September about the opening of the consultation on 20 September, or details of the consultation once live. When we realised there was an issue, we communicated this and began the consultation process again, contacting all registered stakeholders directly and allowing 2 weeks (5-18 October) for them

			to comment. Two weeks is the standard consultation duration as described in chapter 13 of the NICE guideline development manual. However, we acknowledge your comments about the issues this caused for you with dissemination and about how it impacts on the integrity of the process. We will ensure that the issue is resolved for future surveillance consultations and that adequate advanced notice is given.
University Hospital Plymouth NHS Trust	NA	The UHPNT agrees with the RCOG/RCM response on equality issues. We would like to place on record our disappointment also in the manner NICE has conducted this surveillance consultation, with neither the RCOG, RCM nor relevant patient stakeholder organisations including the MASIC Foundation or Birth Trauma Association were informed of the consultation. This lack of communication or transparency with registered stakeholders raises doubts as to the integrity of the consultation, with the 14-day response window far too short to enable wider dissemination and input. In future, we would suggest NICE engages with registered stakeholders in advance of identified consultations to ensure the consideration of as wide a range of views as possible.	Thank you for your response. Stakeholder comments are vital for our development processes, and we apologise for any inconvenience and confusion caused by issues with the consultation. These resulted from an unforeseen IT problem with our stakeholder system that meant some stakeholders were not given advance notice on 6 September about the opening of the consultation on 20 September, or details of the consultation once live. When we realised there was an issue, we communicated this and began the consultation process again, contacting all registered stakeholders directly and allowing 2 weeks (5-18 October) for them to comment. Two weeks is the standard consultation duration as described in chapter 13 of the NICE guideline development manual. However, we acknowledge your comments about the issues this caused for you with dissemination and about how it impacts on the integrity of the process. We will ensure that the issue is resolved for future surveillance consultations and that adequate advanced notice is given.

NHS England	No	No	Thank you for your response.
Croydon University Hospital	Yes	It is known that South Asian women are at increased risk of these tears. Everything should be done to prevent OASI and improve diagnosis.	Thank you for your response. Stakeholders have brought to our attention evidence about this that suggests mediolateral episiotomy may mitigate this issue with this group of women. We have also been alerted to a study by Albar et al. (2021) that was assessed during this exceptional surveillance and excluded because it does not compare episiotomy angles or the use of rectal examination on OASIS. It is a cohort study that reports Asian ethnicity is associated with a higher risk of OASIS. It concludes that mediolateral episiotomy may protect against OASIS and should be used in high risk patients, a finding consistent with CG190-1.13.20 which recommends mediolateral episiotomy. We did not find any evidence about interventions specifically addressing OASIS risk in women of Asian ethnicity. The Albar et al. study highlights a potential equalities issue, and we will therefore add it to the final surveillance report. We will also add this issue to our issues log to highlight it as an area to look for evidence about interventions that address OASIS risk in this group.
Royal College of Nursing	None	We do not have any comments to add on this occasion. Thank you for the opportunity to contribute.	Thank you for your response.
Maternal Mental Health Alliance UK	Yes	That mental health assessments should be given parity with physical health assessments in being followed up.	Thank you for your response. Mental health assessments are outside of the scope of this surveillance review. This surveillance covers the topics of angle of episiotomy and whether all women who have undergone vaginal birth should have a rectal examination,

			regardless of the presence of genital trauma. Recommendations about women's emotional and psychological wellbeing during pregnancy and birth are included in antenatal and postnatal mental health: clinical management and service guidance (NICE guideline CG192).
Group B Strep Support	Yes	Black and some Asian women are more likely to carry GBS, and their babies are more likely to develop GBS infection than their white women and babies. Additional efforts should be made to ensure these women and their health professionals are knowledgeable and aware of what steps can be taken to minimise the risk of GBS infection developing in their babies.	Thank you for your comments. Group B streptococcus (GBS) infection is without the scope of this surveillance. This surveillance covers the topics of angle of episiotomy and whether all women who have undergone vaginal birth should have a rectal examination, regardless of the presence of genital trauma. Recommendations about streptococcal B infection are included in neonatal infection: antibiotics for prevention and treatment (NICE guideline NG195).
Avoiding Brain Injury in Childbirth (ABC)	Yes	Part of our team felt there should be recognition of the increased risk of OASI in Asian women who have a higher incidence of short perineums - women should be informed of this risk and counselled regarding episiotomy to reduce risk of OASIs	Thank you for your comments. If you could provide us with a evidence for a higher incidence of shorter perinea in Asian women that would be helpful for our assessment of CG190's currency. The MASIC Foundation responding as stakeholders to this surveillance review (see above) highlighted to us a study by Albar et al. (2021) that reports Asian ethnicity is associated with a higher risk of OASIS. It concludes that mediolateral episiotomy may protect against OASIS and should be used in high risk patients, a finding consistent with CG190-1.13.20 which recommends mediolateral episiotomy. This study was assessed during this exceptional surveillance and excluded because it does not compare episiotomy angles or the use of rectal examination on OASIS. We did not find any evidence about interventions specifically addressing OASIS risk in women of Asian ethnicity. The study highlights a potential equalities issue, and we will therefore add it to the final surveillance report. We will also add this issue to our issues log to flag this population as a group for

			which to look for evidence about interventions that address OASIS risk reduction.
Additional comments			We received the following paper from a topic expert during stakeholder consultation: Edqvist M. et al. The effect of two midwives during the second stage of labour to reduce severe perineal trauma (Oneplus): a multicentre, randomised controlled trial in Sweden. Lancet. 2022 Mar 26;399(10331):1242-1253. doi: 10.1016/S0140-6736(22)00188-X. Epub 2022 Mar 15. The RCT, conducted in 5 obstetric units in Sweden, investigated how the presence of a second, frequently more experienced midwife, acted to reduce the rates of severe perineal trauma (SPT) compared with only 1 midwife (3·9% vs 5·7% (odds ratio (OR) 0·69 (0·49–0·97))). The study is primarily concerned with OASIS and SPT prevention and does not investigate angle of episiotomy, different rectal examination practices or different OASIS identification techniques. The paper is therefore out of scope for this exceptional review. We will pass this paper to colleagues working on the current update of CG190 as the paper discusses the role of the second midwife in fetal monitoring.

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