



2022 exceptional surveillance of intrapartum care for healthy women and babies (NICE guideline CG190)

Surveillance report

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Surveillance decision

Following consultation with stakeholders we will update the NICE guideline on intrapartum care for healthy women and babies to:

- re-evaluate the use of a 60-degree episiotomy cutting angle during crowning and during perineal distension equivalent to crowning
- clarify the range of episiotomy angles that can be safely used in those infrequent instances when an episiotomy must be performed prior to crowning and perineal distension is not equivalent to crowning
- re-evaluate the circumstances in which it is appropriate to offer rectal examination following vaginal birth.

Reasons for the decision

For [recommendation 1.13.20 on angle of episiotomy](#), we identified 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 injuries (OASIS). We also received intelligence that there are rare occasions where an episiotomy may have to be conducted prior to crowning where perineal distension may be less than at crowning. Although the recommendation currently accommodates both situations, stakeholders indicated that episiotomy during crowning is by far the most common timing of episiotomy and that episiotomies prior to crowning are extremely rare. Several stakeholders suggested that the recommendation should be separated into 2 recommendations, 1 for episiotomy during crowning and 1 for episiotomy prior to crowning. We agree with stakeholders that the recommendation needs to be updated to reduce ambiguity about what cutting angles lead to suture angles that result in lower rates of OASIS.

For [recommendation 1.16.5 on rectal examination](#), we didn't identify good quality evidence indicating the circumstances under which a rectal examination should be offered, how it should be administered, and whether it should be offered to all women unconditionally. Several stakeholders highlighted to us the [Royal College of Obstetrics and Gynaecology's \(RCOG\) guideline on Third- and fourth-degree perineal tears](#). This contains recommendation 6.1 which recommends 'all women having a vaginal delivery should be examined systematically, including a digital rectal examination, to assess the severity of

damage, particularly prior to suturing.'

This differs from recommendation 1.16.5 in the NICE guideline, which recommends 'if genital trauma is identified after birth, offer further systematic assessment, including a rectal examination.' Both recommendations, while informed by similar evidence, are largely consensus-based and we recognise their inconsistencies may be a cause of uncertainty in practice. We will therefore update this recommendation and related recommendations to re-evaluate the circumstances in which rectal examinations should be offered following vaginal birth.

For further details and a summary of all evidence identified in surveillance and stakeholder comments, see the [section on evidence considered by this exceptional surveillance](#) and [appendix A](#).

Trigger for the exceptional review

NICE received an enquiry about [RCOG's OASI care bundle \(OASICB\)](#), which has been implemented in several NHS trusts (see [evidence considered by this exceptional surveillance review](#) for an overview of the OASICB). The enquirer expressed concerns the OASICB's recommendations to use manual perineal protection (MPP) during labour (also known as 'hands on technique' where the clinician uses their hands to support the perineum and baby's head) as standard, and to carry out routine rectal examination irrespective of perineal outcome, are based on insufficient data.

During our investigation into the enquiry, it was noted that 3 of the OASICB's recommendations differ from those in NICE's guideline. Specifically, OASICB's recommendations to:

- Carry out mediolateral episiotomy at a 60-degree angle at crowning, which differs from recommendation 1.13.20 that recommends an angle between 45- and 60-degrees at the time of episiotomy.
- Offer rectal examination routinely, which differs from recommendation 1.16.5 that recommends a rectal examination only if genital trauma is identified.

- Use MPP exclusively, which differs from recommendation 1.13.13 that recommends either the 'hands on' (guarding the perineum and flexing the baby's head) or the 'hands poised' (with hands off the perineum and baby's head but in readiness) technique to facilitate spontaneous birth.

The issue of when to use MPP is already being considered as part of the scheduled update of NICE's guideline (see [final scope key issue 7.4](#)). This exceptional review therefore reports the findings of an assessment of the latest evidence about:

- the most appropriate angle for mediolateral episiotomy
- routine versus non-routine rectal examination.

Overview of 2022 exceptional surveillance methods

NICE's surveillance team checked whether recommendations 1.13.20 and 1.16.5 in NICE's guideline on intrapartum care for healthy women and babies remain up to date.

Methods

The exceptional surveillance process consisted of:

- Considering information about the OASICB.
- Considering the issues raised by the enquirer about OASICB.
- Feedback from topic experts comprising NICE's multiple obstetric guidelines update committee.
- Literature searches to identify relevant evidence for angle of episiotomy and rectal examination.
- Considering relevant information from previous surveillance reviews of the guideline in 2016.
- Considering the evidence used to develop the guideline.
- Examining related NICE guidance and quality standards.
- Examining the NICE event tracker for relevant ongoing and published events.

- A search for ongoing research.
- Assessing the new evidence against current recommendations to determine whether or not to update sections of the guideline, or the whole guideline.
- Consulting on the proposal with stakeholders.

For further details about the process and the possible update decisions that are available, see [ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual](#).

Search and selection strategy

We searched for new evidence related to the angle of episiotomy and best practice for rectal examination.

We found 16 studies in a search for randomised controlled trials (RCTs), systematic reviews and observational studies published between 11 February 2014 and 24 June 2022.

See [evidence identified from searches](#) for details of all evidence considered.

Evidence considered by this exceptional surveillance

Multiple obstetric guidelines update committee feedback

The committee advised that differences between their recommendations in the NICE guideline and the OASICB are causing confusion in practice. The committee noted that in many trusts the OASICB is perceived as being more up to date than the NICE guideline but that some professionals have concerns about the evidence for some of the OASICB's elements. The committee therefore advised that the latest evidence about the areas not covered by the scheduled update of the NICE guideline, namely the optimal angle of episiotomy and rectal examination practices needs to be assessed in a surveillance review.

The OASI Care bundle

The OASICB consists of 4 elements:

- antenatal information for women informing them about OASI and what can be done to minimise the risk
- use of MPP in labour (where the clinician uses their hands to support the perineum and baby's head) for all singleton vaginal births, conditional on consent
- mediolateral episiotomy at a 60-degree angle, conditional on clinical indication
- routine rectal examination.

OASICB is based on a multicentre observational study using a stepped-wedge cluster design ([Gurol-Urganci et al. 2020](#)) comparing 28,000 singleton vaginal births that took place before implementation of the care bundle with 27,000 that took place after implementation. The authors found that OASI was reduced overall by 0.3% (odds ratio [OR] 0.80, 95% confidence interval [CI] 0.65 to 0.98, $p=0.03$). A subgroup analysis reports that while this remained significant for spontaneous births it was not significant for forcep-assisted or vacuum assisted births. There was no impact of the OASICB on episiotomy rate.

A qualitative exploratory study ([Bidwell et al. 2020](#)) explored healthcare professionals' ($n=101$) perspectives of the bundle using focus groups in 16 centres. It reports mixed reactions from practitioners about the care bundle and that engagement through awareness-raising and training is the key to clinical buy-in and successful implementation.

Evidence identified from searches

Additional evidence about angle of episiotomy and rectal examination practices was identified by searches and is summarised below from the information presented in their abstracts.

Angle of episiotomy

One RCT ([El-din et al. 2014](#)) of 330 primiparous women conducted in an Egyptian maternity hospital compared 60-degree mediolateral episiotomy with 40-degree from midline. It reported that the 60-degree angle was associated with significantly higher rates of severe-moderate episiotomy-related pain post-partum. At 6-months there was no statistically significant differences between groups for episiotomy-related pain or dyspareunia.

An observational study ([Ginath et al. 2017](#)) of 102 women (50 primiparous, 52 multiparous) investigated the impact of timing of episiotomy on angle. Study authors marked 30-, 45-, and 60-degree angles respectively from midline during the first stage of labour and measured them again during crowning and reported all angles increased by more than 30-degrees. The authors conclude this change needs to be accounted for when marking episiotomy angles for cutting.

Episiotomy tools with cutting angle guides

Episcissors-60

Six studies were identified ([Cole et al. 2019](#); [Divakova et al 2020](#); [Kastora et al. 2021](#); [Koh et al 2020](#); [Van Roon et al 2015](#); and [Mohiudin et al. 2018](#)) about the effectiveness of Episcissors-60, a product designed to enable a cutting angle of 60-degrees at crowning. This technology was assessed in February 2020 by [NICE's medical technologies guidance on Episcissors-60 for mediolateral episiotomy](#), which included 4 studies identified by this surveillance. Two studies post-dating the medical technologies guidance were also identified: [Kastora et al. 2021](#) and [Koh et al 2020](#). The manufacturer submission for the medical technologies guidance included academic in confidence data from the latter study but it had not fully published at the time of guidance development. These studies are summarised below, and we will share them with NICE's medical technologies guidance team for assessment in relation to that guidance.

Episcissors-60 is considered relevant to this surveillance review as the medical technologies guidance reports use of the technology results in post-suture angles between 40- and 53-degrees when it is used during crowning, an angle there is evidence to suggest is associated with a lower risk of OASI, for example: [Kalis et al. \(2011\)](#); [Sawant, G. and Kumar, D. \(2015\)](#). The medical technologies expert advisory committee (EAC) noted that the impact of reusable Episcissors-60 on the incidence of OASIS was uncertain, and that further evidence for the single use version of the technology was needed. Additionally, they noted further evidence is needed to attribute benefit to Episcissors-60 for reducing OASI over and above standard bundles of care.

Overall the medical technologies guidance concludes that the technology is promising but does not recommend routine adoption by the NHS until further research is available about its impact on OASI. This is largely based on a meta-analysis of 5 studies comparing episiotomy performed with Episcissors-60 versus standard scissors that suggests no statistically significant risk difference in favour of Episcissors-60. However, another EAC

meta-analysis of 2 UK studies, Mohiudin et al. (2018) and Van Roon et al. (2015), found that Episcissors-60 when used as part of a bundle of care, reduces OASI rates in women who have had an episiotomy (risk difference -0.04, 95% CI -0.08 to -0.00, $p=0.03$, $n=76$ episiotomies). It is notable that Mohiudin et al. investigates the use of Episcissors-60 as part of a bundle of care based on RCOG guidelines. The medical technologies guidance notes that overall, the evidence base is limited to a small number of before and after studies with a high risk of bias.

The 2 studies identified by this surveillance review post-dating, the medical technologies guidance are as follows:

- Kastora et al. (2021), a meta-analysis of 6 observational studies ($n=14,027$ nulliparous females) before and after implementation of Episcissors-60 that reports a marginal reduction in OASI (relative risk difference -0.02, 95% CI -0.03 to 0.00; $P=0.03$) post-implementation. The authors note high heterogeneity and a need for robust RCTs to confirm conclusions.
- Koh et al. (2020) a time series analysis before ($n=2,342$) and after ($n=4,498$) implementation of Episcissors-60, that reports a reduction of OASI in all nulliparous vaginal deliveries post-implementation which was not statistically significant (7.2% versus 5.1%, $p=0.05$). However, it reports a statistically significant reduction of OASI (7.5% versus 3.7%) in women having operative vaginal deliveries (OVD; $p=0.02$). The study also reports that Episcissors-60 was associated with an increased rate of episiotomies (29% versus 33.7%; $p=0.01$).

Other cutting tools

A cohort study ([Gonzalez-Diaz et al. 2020](#)) investigated the impact of an intervention that could include use of the Triepi-45 tool (designed to enable a 45-degree episiotomy angle) on the rates of OASI during OVD ($n=1,972$). It reports no statistical difference in rates of OASI in the preintervention versus postintervention cohorts (7.1% versus 9.4%) and a low usage rate of the tool (343/986). A subgroup analysis of the cohort where Triepi-45 was used showed a significantly reduced OASI rate (18/375 versus 93/986; odds ratio, 0.47; 95% CI 0.26 to 0.86), but it is notable this is based on small event rates. No detail is provided as to why the tool was or was not used. Neither cutting nor suture angle are reported and the study is therefore of limited value to this surveillance review.

Topic expert feedback

We asked 3 members of the multiple obstetric guidelines update committee the following questions about episiotomy:

- In what circumstances would an episiotomy be performed before crowning of baby's head?
- Is it possible to estimate how frequently this situation arises, for example, 1 in every 20 vaginal births? 1 in 50? 1 in 100? Less than 1 in 100? Less frequently than 1 in 100?

We received 2 responses. One topic expert responded to say that a 60-degree cutting angle at crowning translates into a 42-degree suture angle postnatally, a number within the range reported by NICE medical technologies guidance. They noted that evidence suggests when an episiotomy is cut at more than 60-degrees or less than 40-degrees the incidence of OASI increases. They also noted evidence suggests it is very difficult for a clinician to estimate this cutting angle and that there are tools, for example, Episcissors, that can help to facilitate it and that the OASI care bundle recommendation is partly informed by this. A second topic expert responded to say they agreed that using a 60-degree cutting angle at crowning resulted in a postnatal angle of 42-degrees, an angle associated with lower rates of OASI. However, they also noted that occasionally (less than 1 in 100 normal births), episiotomy can be undertaken in advance of crowning to hasten birth when there is concern about fetal condition and to avoid an instrumental birth. The expert suggested that in those circumstances the cutting angle would be less than 60-degrees.

Impact statement

There is very little evidence that directly compares cutting angles on OASI outcomes. Only 1 RCT directly compared angles and reports more pain immediately post-partum for a 60-degree angle compared with 40-degree in an Egyptian population. Studies assessing the Episcissors-60 tool, designed to guide practitioners to make a 60-degree cut at crowning report resulting suture angles ranging from 40- to 53-degrees, and also there is limited evidence from NICE's medical technologies guidance on Episcissors-60 for mediolateral episiotomy that use of this tool as part of a care bundle is associated with small reductions in the incidence of OASI. New evidence not included by the medical technologies guidance further suggests an association between Episcissors-60 and reduced OASI rates, particularly during OVD.

RCOG's recommendation of a 60-degree angle of episiotomy is based largely on an observational study ([Kalis et al. 2011](#)) that reports suture angle following episiotomy is more important than incision angle in reducing OASI; and a suture angle of 40- to 60-degrees can best be achieved at crowning with a 60-degree cutting angle.

There is limited evidence that the measured angle of cut changes significantly depending on the timing of episiotomy due to distension of the anatomy. A topic expert consulted during this surveillance also noted that although episiotomies conducted prior to crowning are not common, when they are conducted a cutting angle of less than 60-degrees is sometimes required. This evidence supports recommending a range of angles at the time of episiotomy as per recommendation 1.13.20 in the NICE guideline in order to achieve suture angles associated with lower risk of OASI. The recommendation therefore accommodates situations where episiotomy may have to be undertaken prior to crowning. We propose retaining recommendation 1.13.20 as it accommodates use of a 60-degree cutting angle at crowning while also allowing for situations where episiotomies need to be performed prior to crowning.

Rectal examination

One RCT ([Ozyurt et al. 2015](#)) was identified that compared the number of sphincter injuries in primigravid women (n=201, SVD with mediolateral episiotomy after 36-weeks' gestation) identified by physical examination with those identified by transvaginal sonography (TVS). It reports physical examination classified 194/201 cases as not involving the sphincter (second degree tears) while TVS classified 171/201 tears as causing 'no defect to the sphincter.' There were 23 cases (11.5%) of 'occult tears' for example, tears undetected by physical examination but detected by TVS. The injuries resulting from these occult tears were classified by TVS operators as external sphincter partial defects at the lower end of injury severity.

Impact statement

No studies were identified comparing routine with restricted rectal examination and there is no evidence to suggest that restricted rectal examination as per recommendation 1.16.5 in the NICE guideline increases the risk of poor outcomes. One study comparing routine examination with TVS suggests that there may be a role for TVS in supporting OASI identification, but new evidence alone is not enough on which to base a recommendation. We will add this point to the issues log for the NICE guideline.

Views of stakeholders

We received responses from 13 stakeholders comprising: 4 patient organisations, 4 royal colleges, 3 hospitals, 1 professional society and NHS England and NHS improvement. We asked stakeholders if they agreed with the surveillance proposals not to update recommendations 1.13.20 and 1.16.5 in the NICE guideline. Ten stakeholders disagreed with the proposal, 2 agreed and 1 did not respond.

Regarding recommendation 1.13.20 on angle of episiotomy. Several stakeholders commented that there is good evidence that an angle of 60-degrees at crowning is associated with lower rates of OASIS. Some stakeholders noted that this hypothesis was supported by new evidence identified by this exceptional review. The surveillance proposal not to update this recommendation was based in part on topic expert feedback that there are rare occasions where episiotomy may have to be conducted prior to crowning where birth needs to be hastened because of concerns with fetal wellbeing. In these situations, an angle of between 45- and 60-degrees is acceptable because perineal distension can be different to that at crowning. During stakeholder consultation we received clarification about this from a topic expert who noted that episiotomies undertaken prior to crowning are relatively uncommon. They may be undertaken to hasten birth due to concern about fetal wellbeing but in some instances the use of forceps may result in perineal distension equivalent to that at crowning. In these cases, a 60-degree cutting angle is preferable.

Six stakeholders commented that recommendation 1.13.20 is currently ambiguously worded. They commented that it suggests a cutting angle of 45- to 60-degrees results in lower rates of OASIS including during crowning which is by far the most common timing of an episiotomy. Several stakeholders therefore suggested the recommendation would benefit from separate recommendations: 1 about using a 60-degree cutting angle at crowning, and 1 about the use of a range of angles prior to crowning in those rare instances where that intervention is judged necessary.

It is noteworthy that several stakeholders highlighted that RCOG recommends episiotomy at 60-degrees from midline when the perineum is distended in recommendation 5.2 of their guideline on The Management of Third- and fourth-degree perineal tears. Two stakeholders noted that neither RCOG nor the Royal College of Midwives endorse episiotomy prior to crowning because it can lead to non-vaginal birth and result in maternal blood loss that can compromise patient safety. We will re-evaluate episiotomy cutting angles and any safety issues will be considered in the development of new

recommendations.

Regarding recommendation 1.16.5 on rectal examination when genital trauma is identified. Most stakeholders who disagreed with the decision not to update raised concerns that only giving a rectal examination when there is genital trauma risked missing OASIS or isolated buttonhole tears. Several stakeholders referenced recommendation 6.1 in the RCOG guidance, which recommends '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.' This is a consensus recommendation informed by 2 pieces of evidence; 1 of which was seen during the development of NICE's guideline and 1 of which is a follow-up to a study also seen during the development of NICE's guideline. These 2 pieces of evidence 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 the recommendations in both the RCOG and NICE guidelines. However, the lack of direct evidence about routine rectal examination for all women following vaginal birth for improving OASIS identification, has resulted in differing consensus recommendations in both guidelines. We will therefore ask NICE's obstetrics update committee to re-evaluate this issue, considering recommendations in RCOG guidance.

See [appendix A](#) for full details of stakeholders' comments and our responses.

See [ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual](#) for more details on our consultation processes.

Additional topic expert comments

During stakeholder consultation on the surveillance proposal, we received further information regarding the timing of episiotomy and cutting angles from a topic expert. They noted when an episiotomy is conducted prior to crowning and forceps are used to pull a baby's head down, that will act to distend the perineum to an extent similar to crowning, so the episiotomy should still be conducted at 60-degrees. They also noted where there is concern about fetal condition performing an episiotomy prior to crowning will assist in speeding birth. They noted that this is a relatively uncommon event but a cutting angle of 45-degrees should be safe, although 60-degrees would also be fine. This

information was not available when writing the impact statement but has been considered alongside stakeholder comments about episiotomy cutting angles.

Equalities

Three stakeholders commented that Asian women are at higher risk of OASIS, 1 stating that this is potentially due to a higher incidence of shorter perinea, although no evidence was provided supporting this statement. A stakeholder provided an observational study ([Albar et al. 2021](#)) that investigated the role of maternal ethnicity and the rates of OASIS in 11,012 women who had a vaginal birth. It reports that Asian ethnicity is independently associated with increased risk of OASIS (odds ratio [OR] 2.07; 95% CI 1.6 to 2.7). It also reports mediolateral episiotomy is independently associated with a decreased risk (OR 0.64; 95% CI 0.5 to 0.9).

The paper concludes that mediolateral episiotomy may be protective against OASIS for those at high risk which is consistent with recommendation 1.13.20 in the NICE guideline. During the development of the NICE guideline, previous surveillance and this surveillance, we have not identified evidence about interventions specifically addressing Asian women and OASIS risk. We will add this to our issues to log to monitor for emerging evidence.

Overall decision

After considering all the evidence and other intelligence and the impact on current recommendations, we will update the NICE guideline to:

- re-evaluate a 60-degree episiotomy angle at crowning or equivalent perineal distension
- clarify the range of episiotomy angles that are safe to use in those rarer instances when episiotomies need to be performed prior to crowning when perineal distension is not equivalent to crowning
- re-evaluate the circumstances in which it is appropriate to offer rectal examination following vaginal birth.

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