NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation: MT457 Episcissors

Supporting documentation – Committee papers

The enclosed documents were considered by the NICE medical technologies advisory committee (MTAC) when making their draft recommendations:

1. **EAC assessment report** – an independent report produced by an external assessment centre who have reviewed and critiqued the available evidence.
2. **Assessment report overview** – an overview produced by the NICE technical lead which highlights the key issues and uncertainties in the company's submission and assessment report.
3. **Scope of evaluation** – the framework for assessing the technology, taking into account how it works, its comparator(s), the relevant patient population(s), and its effect on clinical and system outcomes. The scope is based on the sponsor's case for adoption.
4. **Adoption scoping report** – produced by the adoption team at NICE to provide a summary of levers and barriers to adoption of the technology within the NHS in England.
5. **Sponsor submission of evidence** – the evidence submitted to NICE by the notifying company.
6. **Expert questionnaires** – expert commentary gathered by the NICE team on the technology.
7. **EAC correspondence log** – a log of all correspondence between the external assessment centre (EAC) and the company and/or experts during the course of the development of the assessment report.
8. **Company fact check comments** – the manufacturer's response following a factual accuracy check of the assessment report.

Please use the above links and bookmarks included in this PDF file to navigate to each of the above documents.

External Assessment Centre report

The purpose of the External Assessment Centre (EAC) report is to review and critically evaluate the company's clinical and economic evidence and may include additional analysis of the submitted evidence or new clinical and/or economic evidence.

Assessment report: Episcissors-60 Document cover sheet				
Version number	Brief description of changes	Author/Reviewer (e.g. J. Smith)	Date (DD/MM/YY)	Date sent to NICE (if applicable)
0.1	First draft	SO'C	05/06/2019	
0.2	Data extraction tables QA's and added to the report	SO'C	13/06/2019	
03	Continuing draft clinical report	SO'C/HM		
0.4	Addition of meta-analysis section and clinical evidence conclusions First draft economic evidence	SO'C	24/06/2019	
0.5-0.7	Continuing drafts of economics section	SO'C		
1.0	First draft to NICE	SO'C	17/07/2019	17/07/2019
1.1	Changes made following comments from NICE on 08/07/2019	SO'C	18/07/2019	
1.2	Continuing draft with tracked changes	SO'C		
1.3	Continuing draft – health economics section Clean version	SO'C	24/07/2019	
1.4	Conclusions added, narrative around economic results added, sensitivity analysis added	SO'C	25/07/2019	
1.6 1.7 2.0	Final edits before submission Final QA Final Report for submission	SO'C GCR/KW SO'C	29/07/2019 29/07/2019 30/07/2019	 30/07/2019

3.0	Changes made post fact check • Date for vanRoon publication corrected • Correction made to rates reported in the overview section • Extra detail added to section 3.8 • Correction made to table of EAC assumptions • Corrections made to table 9 • Extra detail added to Section 6 – summary of clinical and economic section • Extra detail added to section 7 – key considerations • Extra scenarios added to appendix			
5.0	Minor edits • Extra detail added to table 1 and text on page 45 to clarify Condell data.	SO'C		
6.0	Minor Edits • Clarification added to table on page 56 • Percentages added to van Roon results in table of included/excluded studies	SO'C		

	• Minor correction to table in appendices			

Title: Episcissors-60 for guided mediolateral episiotomy

Produced by:	Cedar
Authors:	Dr Susan O'Connell, Senior Healthcare Researcher Dr Helen Morgan, Senior Information Specialist and Systematic Reviewer Prof Grace Carolan Rees, Cedar Director
Correspondence to:	CEDAR Healthcare Technology Research Centre Cardiff and Vale University Health Board Cardiff Medicentre Heath Park, CARDIFF CF14 4UJ

Date completed:	30/07/2019

Declared interests of the authors

Description of any declared interests with related companies, and the matter under consideration. Please refer to NICE's Policy on managing interests for board members and employees.

None

Acknowledgements

The EAC wish to thank the following for their contribution to this report:

Abdul Sultan, Consultant Gynaecologist, Croydon Health Services NHS Trust

Ranee Thakar, Royal College of Obstetricians and Gynaecologists (RCOG) Council Member

Ashish Pradhan, Consultant Gynaecologist, Addenbrookes Hospital, Cambridge

Myles Tyler, British Maternal & Fetal Medicine Society (BMFMS) President

Rider on responsibility for report

The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

Contents

ABBREVIATIONS

Term	Definition
CI	Confidence interval
DHSC	Department of Health & Social Care
EAC	External Assessment Centre
IQR	Interquartile range
MAUDE	Manufacturer and User Facility Device Experience
MHRA	Medicines & Healthcare products Regulatory Agency
MTEP	Medical Technologies Evaluation Programme
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NICE CG	NICE clinical guideline
NICE MTG	NICE medical technology guidance
NICE QS	NICE quality standard
OASI/OASIS	Obstetric Anal Sphincter Injury
OVD	Operative Vaginal Delivery
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QUORUM	Quality of Reporting of Meta-analyses
RCT	Randomised Controlled Trial
RD	Risk Difference
SD	Standard deviation
SVD	Spontaneous Vaginal Delivery
VAS	Visual Analogue Scale
vs	Versus

1 Executive Summary

The company submission included evidence from 2 sytematic reviews (which included data from 5 observational studies and 1 abstract) and one unpublished study. The EAC included 2 further abstracts and one unpublished study report.

The quality of the published studies was considered to be very low and at high risk of bias by the EAC and there was not enough information to assess the quality of the unpublished abstracts or studies.

Overall, the current clinical evidence suggests that there are potentially some benefits to using Episcissors-60 over standard episiotomy scissors. Evidence suggests that Episcissors-60 results in episiotomy post-suture angles within the safe range recommended by RCOG. Pooled analysis suggests no significant risk difference in favour of Episcissors-60 for OASIS rates in women who had an epistiomy with Episcissors-60 compared with standard episiotomy scissors, though there is evidence from the pooled results of two studies that Episcissors-60 as part of a bundle of care may significantly reduce OASIS rates in women who have an episiotomy.

There was no published economic model comparing Episcissors-60 with standard scissors so the company submitted a de novo cost model and the results indicated that Episcissors-60 was cost saving on a per birth basis. The EAC agrees with the model structure but does not agree with some of the inputs in the model, specifically the population. The EAC included only patients who had an episiotomy as per the scope of this assessment and the results indicate that Episcissors-60 is cost saving in this population.

There is some suggestion that Episcissors-60 results in a behavior change and an increase in episiotomies. The EAC included scenario analysis to investigate the impact of an increase in episiotomy rates following introduction of Episcissors-60, the results of which indicate that the Episcissors-60 is cost saving.

2 Background

2.1 Overview and critique of company's description of clinical context

NICE clinical guidance on intrapartum care (CG190) recommends a 45-60° angle but does not specify whether this is a cutting angle or suture angle. The clinical submission highlights evidence that the cutting angle has an impact on the suturing angle which in turn can result in significantly higher OASIS (section 2.2).

More recent best practice guidelines (RCOG, 2015) state that the best angle to cut an episiotomy is 60° to prevent obstetric anal sphincter injury (OASIS). There is evidence to suggest that 'eyeballing' the angle of episiotomy is not a reliable method to ensure a 60° angle and a safe mediolateral episiotomy (Sawant et al 2015). The company submissions description of the clinical pathway indicates that replacing standard episiotomy scissors with Episcissors-60 negates the need to 'eyeball' the angle of episiotomy at the time of crowning and when used correctly ensures a cutting angle of 60°.

The clinical context provided by the company establishes the importance of achieving the correct angle of episiotomy for patients to prevent obstetric anal sphincter injury (OASI) and provides an estimate of the number of women who might be at risk. The EAC consider that it is important to clearly highlight the issues associated with OASIS also known as third or fourth degree tears, as women can experience both short and long term impacts including pain, faecal and/or urinary incontinenece and sexual dysfunstion as a result as well as impacting delivery of future pregnancy (Ness, 2017; RCOG, 2015). Nulliparous women (women who have not previously given birth) are more likely to sustain a third or fourth degree tear; the National Maternity Audit reports that in primiparous women, 5.4% sustained OASIS in spontaneous births. Instrumental births in nulliparous women increases the risk of OASIS; 7.8% of women sustained OASIS in operative vaginal or instrumental deliveries (OVD) compared with 1.6% of women with spontaneous births and 4.8% for OVD in multiparous women (RCOG 2017).

During the period 1 April 2000 to 31 March 2010, data identified the receipt of 441 claims in which allegations of negligence arising out of third and fourth degree tears during labour were made. The total value of the claims (including damages and legal costs) was estimated to be £31.2million (NHS Litigation Authority, 2012)

The company submission indicates that there were 626,203 births reported in England in 2017-2018 (HES, 2018) and that there were approximately 94,556 episiotomies performed in England each year representing approximately 15% of births in England although there may be variation in this as one report gives a rate of 22% for England, Scotland and Wales (RCOG 2017). The company states that episcissors would be suitable for use in all episitomies.

2.2 Critique of company's definition of the decision problem

Decision Problem	Company Submission	Matches Decision Problem (Y/N)	EAC Comment
Population	Women who have a clinical need for an episiotomy such as for instrumental deliveries or in cases of suspected fetal compromise	Y	
Intervention	Episcissors-60	Y	The EAC note that Episcissors-60 relates to both a reusable and a disposable version. The published evidence will relate to the reusable Episcissors-60 only as the disposable version is not yet widely available. The reusable version however is currently being phased out and replaced with the disposable version. The outcomes of interest will be the same for both versions in the majority of cases however device related adverse events may differ and there may be an environmental impact to consider for disposable Episcissors-60 although this would also be the case for disposable standard scissors.
Comparator	Standard episiotomy scissors	Y	The EAC note this will include both reusable and disposable episiotomy scissors.
Outcomes	Procedural outcomes • Device related adverse events • Incidence and severity of	Y	

	OASIS • Complication rates (wound breakdown, wound infection, anal incontinence, and post-partum haemorrhage • Ease of use of instrument including right/left handedness • Operator learning curve • Cost of complications (including OASI repair) Duration of follow-up should be sufficient to capture all relevant complications • Post delivery suture angles • Length of epsiotomy • Post delivery distance from midline Patient Outcomes • Length of stay • Quality of life		
Cost Analysis	Costs will be considered from NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	Y	The economic submission included a Return on Investment report (NHS perspective). Possible costs avoided are discussed in the report but they are not quantified. The submitted economic model compared the costs of Episcissors-60 and standard episiotomy scissors. Costs associated with OASIS repair and extended length of stay were included in the model. Long term costs associated with OASIS were not included in the model
Subgroups	Ethnicity	Y	Women of Asian family origin may be more at risk of OASIS

Special considerations, including issues related to equality

Women of Asian family origin may be more at risk of OASIS due to a shorter perineal body length. The National Maternity and Perinatal Audit 2017 (RCOG 2017) reports that 12.4% of birth in England were to women of Asian ethnicity. One retrospective cohort study in California (n=22,741) reported an increased risk of OASIS in Asian women compared with white women (Adjusted

OR=2.31; 95% CI 1.99-2.69) (Ramm, 2018) . A second cohort study (n=32,653 births) in Australia reported an increased risk of OASIS in South Asian (Adjusted OR=2.6; 95% CI 2.2-3.3) and South East/East Asian women (Adjusted OR=2.1; 95% CI 1.7-2.5) (Davies-Tuck 2015). The National Maternity and Perinatal Audit did not report the incidence of OASIS by ethnicity.

Episcissors has been designed for right-handed use and there is some concern as to how it would be used by left-handed staff. The company submission states that there are no issues related to left handed users. Two clinical experts stated that they were not aware of any issues with left-handed use and one clinical expert stated that all left handed staff in their unit used the scissors right handedly and reported no issues. The EAC briefly searched the literature base and could find no evidence that left handed users would be disadvantaged although in one study, one operator reportedly was unable to orientate herself to to align the scissors as she is lefthanded (Freeman et al, 2014). There is a lack of published evidence relating to left handed users of surgical equipment in general. The EAC suggest that is may be useful to record whether a clinician using Episcissors-60 is left or right handed and whether it presented a problem for use as part of audit procedures.

3 Clinical evidence

3.1 Critique of and revisions to the company's search strategy

The company submission references the search strategies from two systematic reviews (Divakova et al 2019 and Cole et al 2019), stating that they 'used and reproduced their methodolgy'. The EAC can see no evidence to suggest that the searches were run independently by the company to account for extra time periods. Searches in Cole et al (2019) were up to May 2018, leaving almost 12 months gap while Divakova et al (2019) searches were up to September 2018 again leaving 9 months gap. The EAC considered both search strategies were not reported in sufficient detail to be reproduced and there is a risk that not all relevant search terms were included and therefore do not represent comprehensive literature searches.

The EAC undertook their own literature search and identified a total of 7 published studies and 4 unpublished studies for inclusion. Full details of the EAC search strategy are in Appendix A.

3.2 Critique of the company's study selection

Studies in nulliparous women, requiring an episiotomy at the time of crowning were included.

The company submission included 2 systematic reviews (Divakova et al, 2019 and Cole et al, 2019) which included data from 5 observational studies (Freeman et al, 2014; Patel et al 2014; Sawant et al, 2015; van Roon et al, 2015; Mohiudin et al 2018), 1 conference abstract (Lou et al, 2016) and data from one unpublished study (Koh et al).

The observational studies included one proof of concept study (Freeman et al, 2019) which indicatated that operators considered the Episcissors easy to use but highlighted an issue with blade length which was subsequently changed and the blade now measures 5cm in length. One operator reportedly was unable to orientate herself to to align the scissors as she is lefthanded.

One comparative cohort study (Sawant et al, 2015) and one non comparative case series study (Patel et al, 2014) were conducted in Indian hospitals. These have been included as the company states that Asian women may be more at risk of OASIS and these studies provide evidence of the possible benefit of Episcissors in this patient group which may be applicable to the UK setting.

Two before and after studies (Van Roon et al, 2015 and Mohiudin et al, 2018) were conducted in UK hospitals and provide directly applicable evidence related to the use of Episcissors in an NHS setting.

No randomized controlled trials (RCTs) were identified although the EAC agrees with the company's assertion that an RCT would potentially be unethical in this patient group.

3.3 Included and excluded studies

The clinical submission included 2 systematic reviews (Divakova et al, 2019 and Cole et al, 2019) and one unpublished study (Koh et al). Details from the individual studies included in the systematic reviews are reported in a number of tables throughout the clinical submission however the EAC could find no overall summary of the clinical evidence barring a reproduction of the text from the systematic reviews. The company submission offers no discussion or interpretation of the evidence beyond those stated in the included systematic reviews (Divakova et al, 2019 and Cole et al, 2019). The conclusions presented in both reviews indicate that the introduction of Episcissors-60 along with other interventions such as manual perineal support shows promise in terms of a reduction in OASIS. Episcissors-60 was reported as being easy to use and a significant improvement in the accuracy of episitomies was observed. Both systematic reviews however cautioned that the currently available data was limited and low quality and should be interpreted with caution.

The EAC agrees with the studies relating to the use of Episcissors included in the company submission. The EAC did not identify any additional published studies for inclusion in the Assessment Report, however an additional two abstracts (Condell et al, 2017 and Farnworth et al, 2019) were identified and an Episcissors Implementation Report from the North of England (Ayuk et al, 2018) was identifed. A summary of the studies (n=11) included by the EAC is presented in table 1.

The clinical submission refers to a number of studies not related to the use of Episcissors in both the section for summarizing strengths and limitations of the published evidence (section 6.9.1 of clinical submission) and in the relevance of the evidence base to the scope (6.9.2 of clinical submission). The EAC considers that some of the information referred to in these sections may be of interest and some relevance but should be confined to the clinical context and background section and has therefore not discussed them in any detail in this report.

The EAC excluded one study (van Roon et al, 2017) as this compared clinicians ability to cut episiotomies and the recommended 60° angle with a standard episitomy scissors compared with Episcissors-60 in a birth simulation model and did not include patients.

Details of adverse events are reported in section 3.7.

Table 1: Included and Excluded Studies

Published Studies

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
Published Studies						
Divakova (2019) Searches up to September 2018 *Studies Included* Van Roon (2015) Sawant (2015) Lou (2016) Mohiudin (2018)	Systematic Review and Meta-analysis	Studies including pregnant women who underwent mediolateral or lateral episiotomy with episcissors-60 or standard episiotomy scissors. Studies were only included if they were comparative	• Rate of OASIS • Episiotomy • Rate • Post delivery suture angle	Only Meta-analysis results are presented here *Rate of OASIS (3 studies)* Risk of OASIS is significantly lower with Episcissors-60 in women who have an episiotomy • Episcissors-60: 15/797 • Standard Scissors: 70/1122 • Risk Difference Episcissors 60 versus standard episiotomy scissors: -0.04 (-0.07 to -0.01), p=0.005, I^2=41%	None	Quality Assessment for each individual study was performed using a tool designed and tailored by the authors. No details on validation of the modified tool though it was based on the national Heart, Lungs and Blood Institute tool for assessing before and after studies. However it was modified to provide an overall score which is not recommended (Cochrane Collaboration) The review included data from one abstract (Lou et al, 2016) however the data in the abstract and the data used in the meta-

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
				• Number need to treat =25 Risk of OASIS in all births is significantly reduced with Episcissors-60 (3 studies). • Episcissors-60 (125/3483) • Standard scissors (295/4668) • Risk difference: -0-02 (-0.04 to -0.01), p=0.002, I^2=59% *Episiotomy Rate before and after Episcissors-60 (3 studies)* Episiotomy rate increased following introduction of Episcissors Before (standard scissors): 28% (1160/4044) After (Episcissors-60): 26% (829/3171)		analysis are different. The EAC have contacted the author of the review for clarification. Transcription error for van Roon 2015 before total events should be 791 not 792 in fig 2.

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
				Risk Difference: 0.03 (-0.04 to 0.10), p=0.44, I^2=92% *Post delivery suture angle (1 study)* 12° difference in post delivery suture angles with Episcissors-60 closer to the recommended 40-60° Episcissors Mean: 40.6° Standard scissors mean: 28.3° Mean Difference: 12.30 [9.51-15.09], p<0.0001		
Cole (2019) Searches up to May 2018 *Studies Included* Freeman (2014) Patel (2014) Van Roon (2015)	Systematic Review	Studies including pregnant women who underwent mediolateral or lateral episiotomy with episcissors-60 Non-comparative studies were included	• Rate of OASIS • Episiotomy Rate • Post delivery suture angle	No meta-analysis carried out, results presented narratively for each study. Results for the relevant studies are presented for each study indivudally below	None	Quality assessments of individual studies were done using the Newcastle-Ottawa Scale and risk of bias was assessed using the Cochrane Risk of Bias tool

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
Sawant (2015) Mohiudin (2018)						
Freeman (2014) UK October 2011-February 2012	Proof of concept study Case series (no comparator) ● Intervention Comparator – no comparator	One NHS hospital N=17 women giving birth (instrumental vaginal delivery) ● Primary outcome is clinical staff experience. Population of interest is not confined to women undergoing instrumental vaginal delivery.	Ease of use of the Episcissors-60 protoype. ●	Ease of use of the instrument as N=10 ‘strongly agree’ N=5 ‘tend to agree’ N=1 ‘neither agree nor disagee’ N=1 ‘strongly disagree’ Reasons for ‘tend to agree’ related to the length of the cut (e.g. the incision could not be extended because the blades were too short) Reason for ‘strongly disagree’ was that the accoucher was left handed and unable to orientate herself into a position to align the scissors.	None	No details on the number of trainees/consultants providing feedback. It is not clear whether the feedback is provided on a per episiotomy basis or whether each response was from a unique trainee/consultant. Small sample size with no comparator in a partially applicable population means potentially limited generalizability to wider population.
Patel (2014) India	Case Series (no comparator)	Maternity unit in an Indian hospital	Post- delivery suture angle.	• Median post-delivery suture angle of episiotomy was 50°	None	Small sample size with no comparator in a partially applicable population

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
	● Intervention: Episcissors-60	N=25 women (spontaneous vaginal delivery requiring episiotomy) N=2 experienced obstetricians performed episiotomies ● Population not confined to women with spontaneous vaginal delivery	Pre suturing examination for OASI. Post-delivery angle measured by obstetrician. ●	(SD 3.5; IQR 48-54; range 45-55). • No cases of OASI were reported.		means potentially limited generalizability to wider population.
Sawant (2015) India May 2014-October 2014	Cohort Study ● Intervention: Episcissors-60 (n=31) Comparator: Braun-Stadler episiotomy scissors (n=32)	N=63 nulliparous women undergoing episiotomy for indications such as prolonged second stage of labour, instrumental delivery and foetal distress ●	Post-delivery suture angle Length of episiotomy Distance from the caudal end of the episiotomy to the anus ●	Mean post-delivery suture angle was significantly different between the groups (p<0.0001): ***Episcissors-60:*** 40.6° (range 30-50; IQR 35-45; SD 5.7; 95% CI 38.6-42.6) ***Standard Scissors:*** 28.3° (range 20-45; IQR 25-30; SD 5.6; 95% CI 26.3-30.3) Post delivery distance from Midline was	None	This study describes itself as a randomised trial however the EAC disagree as no formal method of randomisation has been detailed in the study. The study is powered to detect a difference in mean post delivery suture angle but not in rates of OASIS

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
				significantly different between the groups (p<0.0001) ***Episcissors-60:*** 35mm (95% CI ±2.2; IQR 30-39mm; SD 6.29 ***Standard Scissors:*** 19.6mm (95% CI ±1.3; IQR 14.75-22.5; SD 6.6) Length of episiotomy was significantly different between the groups (p<0.0001) ***Episcissors-60*** 47.2mm (95% CI±3.5) *Standard Scissors:* 40mm (95% CI±1.9) OASIS Episcissors-60 = 0 Standard Scissors = 1 (grade 3)		Small sample size with no comparator in a partially applicable population means potentially limited generalizability to wider population. There were some discrepancies in the paper related to reporting between text and tables.
Van Roon (2015) UK January 2015 – May 2015	Before and After Study ●	2 NHS hospitals Nulliparous women (n=838) Hospital 1: n=197 Hospital 2: n=641	• Perineal Body Length (PBL) • Uptake of episiotomy	Data were available for 838 nulliparous vaginal deliveries across two hospitals.	None	The EAC noted some discrepancies in the reporting between text and tables. The EAC contacted the author of this study to

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
	Intervention: Episcissors-60 Comparator: No details given		• Post suturing angles • Effect on OASIS • User Feedback	N=589 were spontaneous vaginal deliveries (SVD) N=249 were operative vaginal deliveries (OVD) Data collection forms were completed for 100 nulliparous vaginal deliveries and these formed the basis for PBL measurements, post-episiotomy suturing angles and user feedback. Mean PBL • SVD: 37mm (SD 8.3, 95% CI 34-39) • OVD: 38mm (SD 8, 95% CI 35-40) • PBL followed normal distribution and average length similar to other studies Episiotomy Angles		seek clarification on how the figures were reported.

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
				• SVD: 53° (SD 6.5, 95% CI 50.7-55.8) • OVD: 52° (SD 9.6, 95% CI=49-54) • 100% of midwives and 86% of doctors achieved a post suture angle between 40° and 60°. Episiotomy Usage • Hospital 1: 16.5% increase in the number of episiotomies (59/60) in nulliparous OVDs compared with 2014 (203/239) (p=0.003) • Hospital 2: 47% increase in the number of episiotomies (74/452) in nulliparous SVDs compared with 2014 data (122/1084) (p=0.007)		

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
				• Overall: 11% increase in episiotomy numbers (321/838) in nulliparous vaginal deliveries compared with 2014 (667/3156) (p=0.08) OASIS Incidence • 14.2% reduction in OASIS in nulliparous OVDs given episiotomies 12/223 (5.4%)) compared with 2014 (37/583 (6.3%)) p=0.7; Relative Risk 1.18 (text reports 14.3%, p=0.2) • 84% reduction in OASIS in nulliparous SVDs (1/98 (1%)) compared with 2014 (13/208 (6.25%)) (p=0.04) (text reports a p=0.003) • 84% reduction in OASIS in nulliparous		

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
				SVDs given episiotomy compared to those not given episiotomy (1% versus 6.9%) in 2015 p=0.001 • 18% reduction in OASIS in nulliparous (SVD+OVD) vaginal deliveries (49/838 (5.8%)) overall compared with 2014 (159/2238 (7.1%)), p=0.22. User Feedback 84% of users rated Episcissors as 'good' to 'very good' (55% rated it very good).		
Mohiudin (2018) UK	Before and After Study Intervention: Episcissors-60	2 NHS hospitals Nulliparous women (n=2566) Hospital 1: n=936 Hospital 2: n=1630	Number of OASIS Cases	Hospital 1 (Royal Free) Primiparous OVD • OASIS decreased by 33% from 5.6% to 4.2% (p=0.4) • OASIS rate in episiotomy group was 2.6% versus 42% in	None	Results presented separately for each hospital and only combined where possible due to a change in data management systems at one hospital during the study.

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
	Comparator: No details			the no episiotomy group following introduction of episcissors (p=0.000) Primiparous SVD • OASIS rate decreased by 51% from 4.7% to 2.3% (p=0.24) • OASIS rate was 0% in the episiotomy group versus 4.7% in the no-episiotomy group group following introduction of episcissors (p=0.03) Hospital 2 (Barnett) Primiparous OVD • 73% proportional decrease in OASIS from 9.6% to 2% (p=0.001) • 8% proportional increase in episiotomy numbers from 86% to 91% • 83% reduction in OASIS in the episiotomy group in the before period		Note that this study introduced a number of measures to reduce OASIS at the time of introducing Episcissors-60 and the results may reflect the impact of these measures combined.

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
				compared with the after period (6.3% versus 0.6%; p=0.01) • OASIS rated declined in the no episiotomy group (31% versus 17%; p=0.24) Primiparous SVD • OASIS decreased by 51% from 5.5% to 2.3% (p=0.03) • 43% increase in number of episiotomiesfrom 16.2% to 23.2% (p=0.005) • OASIS rate decreased from 6.6% to 0% (p=0.006) in women given episiotomies 44% reduction in OASIS in women not given episiotomy from 5.4% to 3% (p=0.12)		
Included studies	**Design and intervention(s)**	**Participants and setting**	**Outcomes**	**Results**	**Withdrawals**	**EAC Comments**

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
Unpublished Studies						
Condell et al (2017) UK	No details reported Intervention: Episcissors-60	N=179 instrumental deliveries performed between December 2016 and February 2017 (n=165 episiotmies; 67 with Episcissors-60)	Rate of OASIS	*Episcissor-60* No 4th degree tears 1 3b tear *Standard Scissors* 1 3b tear 1 3c tear	None reported	Unpublished abstract with limited information available.
Farnworth et al (2019) UK	No details reported Intervention: Episcissors-60	Eight NHS trusts (one midwifery and one medical contact in each)	Barriers to implementation	• Complex organisational procurement processes • Issues around storage/ sterilisation of Episcissors • Concerns about the strength of the evidence base about Episcissors	None reported	Unpublished abstract with limited information available.
Ayuk et al (2018) UK	Before and After Study 1 month 'wash-out' period (data not reported)	Nine Maternity Units invited to take part May 2017 to January 2018	• Rate of OASIS • Rate of Episiotomy • Blood Loss • Length of stay	• 6 maternity units agreed to take part • 1 excluded due to participation in RCOG OASI care bundle project	None reported	Unpublished 'before and after' project report

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
	4 month 'after' period			• Data from one unit excluded due to inconsistencies in the way Episcissors-60 was introduced. • No significant association between the introduction of Episcissors-60 and performance of episiotomy (p=0.94) • OASI rates were lower in women with an episiotomy than without (1.9% versus 2.8%; OR=0.67 95% CI 0.51-0.86, p=0.001) although this association was confined to the 'before' period (1.8% vs 2.9%; OR=0.63 [0.44-0.88]; p=0.002) and not after Episcissors-60 (2.0% vs 2.7%, OR=0.76 [0.51-1.13]; p=0.10) • In nulliparous women having an SVD, OASI		

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
				rates were lower in women who had an episiotomy (1.2%) compared with women who did not (3.8%) OR=0.29 [0.16-0.54], p<0.001. The number of episiotomies needed to prevent one OASI in nulliparous women with SVD was 37. • No significant association with the introduction of Episcissors-60 and the occurrence of OASIS in women who had an episiotomy (X^2=0.20, p=0.71) or in women who had an episiotomy with Episcissors-60 in the after period (X^2=0.013, p=0.99) • Mean delivery to discharge interval was 1.67±0.04 days before introduction of		

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
				Episcissors-60 and 1.58±0.04 days after introduction of Episcissors-60 (p=0.14) • Mean estimated delivery blood loss was 550.3±8.2ml before and 598.8±10.9ml after introduction of Episcissors-60 (p<0.001)		
Lou et al (2016) UK	Observational Study	Episcissors-60 used in 79 deliveries	OASIS Rate Operator Ratings	OASIS rate reduced from 5.6% to 3.2% during a 5 month period Operators reported a satisfaction rate of over 93% for ease of use of the instrument, sharpness of the instrument, length of blade and confidence about the episiotomy angle on a 5 point visual analogue scale 91% of the operators preferred using Episcissors-60 compared	Not Reported	The denominator population was not reported in the abstract. Divakova et al (2019) included unpublished data from the Lou study which indicated that the change in OASIS rate was across all births.

Included studies	Design and intervention(s)	Participants and setting	Outcomes	Results	Withdrawals	EAC Comments
				to normal episiotomy scissors.		

3.4 Overview of methodologies of all included studies

One study (Freeman et al, 2014) is a proof of concept study which investigated the ease of use of an Episcissors-60 prototype. Patient outcomes were not the primary outcomes in this study as it was designed to gain feedback from clinical staff in one NHS hospital on the functionality of Episcissors-60 when used in 17 deliveries requiring episiotomy.

One study (Patel et al, 2014) is a non-comparative case series study in a maternity unit in India assessing the post delivery suture angle in 25 women requiring an episiotomy when using Episcissors-60.

Two studies (van Roon et al, 2015 and Mohiudin et al, 2018) were before and after studies comparing outcomes following the introduction of Episcissors-60 with historical data using standard episiotomy scissors in a cohort of 3404 nulliparous women in 4 NHS hospitals in which there were approximately 1100 episiotomies. Full data for the number of episitomies using Episcissors-60 compared with standard scissors were not reported for all 4 hospitals making accurate comparisons of outcomes in the women getting episiotomies difficult.

One study (Sawant et al, 2015) was described as a randomized trial however the EAC have classified and assessed this study as a cohort study as no formal method of randomization has been described. The study compared outcomes in a maternity unit in India with one clinical team using Episcissors-60 and one clinical team using standard episiotomy scissors. The study included 63 nulliparous women undergoing episiotomy and was powered to detect a difference in mean post delivery suture angle.

Two studies were systematic reviews (Divakova et al, 2019; Cole et al, 2019), one with a meta-analysis (Divakova et al, 2019). Seaches in both reviews identified the same studies relating to Episcissors-60 (Freeman et al, 2014, Patel et al, 2014, van Hoon et al 2015, Sawant et al, 2015 and Mohuidin et al, 2018) however Divakova et al (2019) excluded two (Freeman et al, 2014 and Patel et al 2014) because there was no comparator. Divakova et al (2019) also included one abstract (Lou et al, 2016). Quality assessment tools and

risk of bias were assessed for all studies in each of the reviews. One review (Divakova et al, 2019) included a meta-analysis of data relating to rates of OASIS and post delivery suture angle. This is discussed in more detail in section 3.8.

3.5 Overview and critique of the company's critical appraisal

The company submission included critical appraisal tables for the individual studies included in the two systematic reviews as well as for two additional case series studies (Freeman et al 2014 and Patel et al 2015) which had not been included. No critical appraisal of the systematic reviews themselves has been included which the EAC considers to be a serious omission on the basis that the manufacturer appears to consider the systematic reviews to be the primary source of evidence of effectiveness for Episcissors-60. The EAC has included a critical appraisal of one systematic review and meta-analysis (Divakova et al, 2019) but did not include one for the second (Cole et al, 2019) as this review was a narrative description of the individual studies already assessed, most of which are also included in Divakova et al (2019).

The EAC noted two important issues in the critical appraisal provided by the manufacturer:

- Sawant et al (2015) is described as a randomized trial which the EAC disagrees with. Review of the study suggests that although the authors claim their study is similar to a prospective cluster randomized study design, it is clear that no formal randomization processes have been used. The EAC therefore considers that this study should be considered a comparative cohort study.

- The clinical submission states that Sawant et al (2015) included multiparous women. The EAC note that Sawant et al (2015) states all women included in the study were nulliparous.

The EAC conducted critical appraisals for one of the systematic reviews (Divakova et al, 2019) as well as for each of the individual studies included in the Assessment Report details of which can be found in Appendix B.

GRADE Assessment of the outcomes in each of the studies suggest that the quality of the evidence is very low (Appendix C). This is primarily due to the fact that there are no randomised trials; all studies are observation studies, two of which have no comparator group. There is a high risk of bias due to the the fact that outcomes are measured differently across the studies and most studies do not clearly report their 'before' data for accurate comparison. In addition, studies do not all report who carried out episiotomies and suturing post delivery.

3.6 Results

Results from the individual studies are presented in table 2 below. Pooled results from the meta-analysis (Divakova et al, 2019) are also presented and discussed in section 3.8.

Overall the results suggest that using Episcissors-60 when performing an episiotomy results in fewer OASIS and better post delivery suture angles compared with a standard episiotomy scissors.

The rate of OASIS when episiotomy was performed using Episcissors-60 versus standard episiotomy scissors was reported in three studies (Sawant et al, 2015, van Roon et al, 2015 and Mohiudin et al, 2018). Sawant et al (2015) reported no OASIS in the episcissors-60 group and one OASIS in the standard scissors group. Van Roon et al (2015) reported an 18% reduction in OASIS in nulliparous women requiring an episiotomy however this difference was not statistically significant (p=0.22). A statistically significant reduction in OASIS was reported for SVDs (84% reduction, p=0.04). This result is reflected in one before and after study (Mohiudin et al, 2018) which reported a statistically significant reduction in OASIS of 51% (p=0.03) in primiparous SVDs. Mohiudin et al (2019) also reported a statistically significant reduction in OASIS in primiparous OVDs (73% reduction, p=0.001) in one hospital but not in a second where OASIS reduced by 33% (p=0.4). The reduction in OASIS in Mohiudin et al (2019) was observed after the introduction of a range of measures including the use of Episcissors-60 therefore it is not clear what proportion of the reduction can be attributed to the Episcissors-60 alone. One

abstract (Lou et al, 2016) reported a reduction in OASIS rate during the Episcissors-60 study period from 5.6% to 3.2% compared with the preceding five months but did not report on episiotomy rates. One unpublished before and after study (Ayuk et al, 2018) reported no significant association between the introduction of Episcissors-60 and the occurrence of OASIS in women who had an episiotomy (1.8% vs 2%, X^2=0.2, p=0.71) nor was there any significant decrease in OASIS when considering all births (2.7% vs 2.5% X^2=0.6, p=0.46) following the introduction of Episcissors-60.

Two studies reported that the rate of episiotomy increased by 11% overall (van Roon et al, 2015) and 15% overall (Mohiudin et al, 2018) , while one unpublished study (Ayuk et al, 2018) reported no change in the rate of episiomties with the introduction of Episcissors-60. Two clinical experts suggested that it is possible that the introduction of Episcissors-60 might result in a behavior change with clinical staff, one clinical expert reported a small increase in episiotomities since the introduction of Episcissors and two clinical experts indicated that the introduction of Episcissors has increase awareness of the need for episotomies and appropriate technique.

The post delivery suture angle achieved when using Episcissors-60 is within the range recommended by the RCOG for reduced risk of OASIS. A total of four studies reported the post-delivery suture angle either as a mean or a median. One proof of concept study (Freeman et al, 2014) reported a median post delivery suture angle of 43° (95% CI 38.8-46). A second non-comparative study (Patel et al, 2014) reported a median post-delivery suture angle of 50° (range 45-55) which is within the recommended 40-60°.

One before and after study reported a significant difference in the mean post delivery suture angle between Episcissors-60 and standard scissors (p<0.0001) although the mean angle was 40.6° for Episcissors, the range was 30-50° however this did compare favourable to a mean of 28.3° (20-45°) with standard scissors.

One before and after study (van Roon et al, 2015) reported the post delivery suture angle for spontaneous vaginal deliveries and operative assisted

deliveries separately. The post suture angle was similar for both (53° for spontaneous vaginal deliveries and 52° for operative assisted deliveries). It is not reported whether this was a mean or a median, however standard deviations were reported therefore the EAC assume these were mean values.

One conference abstract (Lou et al, 2016) reported a mean post delivery suture angle of 50.7° when using Episcissors-60.

In one before and after study (van Roon et al, 2015) it was reported that 100% of midwives and 86% of doctors achieved a post delivery suture angle between 40-60° when using Episcissors however no comparable data were reported for the 'before' period so no comment can be made on whether this is a significant change.

Perineal body length (PBL) and episiotomy length were reported in one study each. Van Roon et al (2015) reported a mean PBL of 37mm in SVDs and 38mm in OVDs for the whole cohort. Sawant et al (2015) reported a mean epistiomy length of 47.2mm when using episcissors compared with 40mm when using standard scissors.

User feedback from one proof of concept study (Freeman et al, 2014) suggests that Episcissors-60 is easy to use based on 17 responses although it is not clear whether this represents a response from 17 different trainees or consultants as the study simply states the Episcissors-60 prototype was used in 17 women needing an episiotomy. One conference abstract reported that 91% of operators preferred Episcissors-60 and another abstract (Condell et al, 2017) reported that Episcissors helped to keep episiotomy angles to a safe 40-60°.

One conference abstract (Farnworth et al, 2019) reported a number of barriers to the implementation of Episcissors-60 as standard practice for epistiomy including lack of fiscal assistance and support from clinical leaders, complex organization procurement processes, storage and sterilisation issues and concerns about the strength of the evidence base.

Table 2: Results from Included Studies (Published and Unpublished)

Study	Rate of OASIS	Post Delivery Suture Angle	Length of Episiotomy	Perineal Body Length (PBL)	Ease of Use	Barriers to Use
Freeman et al (2014)	N=1 patient sustained an OASIS (grade 3a)	Mean post delivery angle: 42.4±7° Median post delivery angle: 43° (95% CI 38.8-46°)	Not Reported	Not Reported	Ease of use of the instrument as N=10 ‘strongly agree’ N=5 ‘tend to agree’ N=1 ‘neither agree nor disagee’ N=1 ‘strongly disagree’	Not Reported
Patel et al (2014)	N=0	Median post delivery angle: 50° (SD 3.5°)	Not Reported	Not Reported	Not Reported	Not Reported
Sawant et al (2015)	Episcissors-60=0 Standard Scissors=1 (grade 3)	Mean post-delivery suture angle was significantly different between the groups (p<0.0001) Episcissors-60: 40.6° (range 30-50; IQR 35-45;	Episcissors-60 47.2mm (95% CI±3.5) Standard Scissors: 40mm (95% CI±1.9)	Not Reported	Not Reported	Not Reported

Study	Rate of OASIS	Post Delivery Suture Angle	Length of Episiotomy	Perineal Body Length (PBL)	Ease of Use	Barriers to Use
		SD 5.7; 95% CI 38.6-42.6) Standard Scissors: 28.3° (range 20-45; IQR 25-30; SD 5.6; 95% CI 26.3-30.3)	P<0.001			
Van Roon et al (2015)	• 14.2% reduction in OASIS in nulliparous OVDs given episiotomies 12/223 (5.4%)) compared with 2014 (37/583 (6.3%)) p=0.7; Relative Risk 1.18 • 84% reduction in OASIS in nulliparous SVDs (1/98 (1%)) compared with 2014 (13/208 (6.25%)) (p=0.04)	• SVD: 53° (SD 6.5, 95% CI 50.7-55.8) • OVD: 52° (SD 9.6, 95% CI=49-54) • 100% of midwives and 86% of doctors achieved a post suture angle between 40° and 60°.	Not Reported	Mean PBL • SVD: 37mm (SD 8.3, 95% CI 34-39) • OVD: 38mm (SD 8, 95% CI 35-40) • PBL followed normal distribution and average length similar to other studies	84% of users rated Episcissors as 'good' to 'very good' (55% rated it very good).	Not Reported

Study	Rate of OASIS	Post Delivery Suture Angle	Length of Episiotomy	Perineal Body Length (PBL)	Ease of Use	Barriers to Use
	18% reduction in OASIS in nulliparous (SVD+OVD) vaginal deliveries (49/838 (5.8%)) overall compared with 2014 (159/2238 (7.1%)), p=0.22.					

Study	Rate of OASIS	Post Delivery Suture Angle	Length of Episiotomy	Perineal Body Length (PBL)	Ease of Use	Barriers to Use
Mohiudin et al (2018)	Primparous OVD Hospital 1: OASIS decreased by 33% from 5.6% to 4.2% (p=0.4) Hospital 2: 73% proportional decrease in OASIS from 9.6% to 2% (p=0.001) Primiparous SVD Hospital 1: OASIS decreased by 51% from 5.5% to 2.3% (p=0.03) Hospital 2: Not reported	Not Reported	Not Reported	Not Reported	Not Reported	Not Reported
Unpublished (Abstracts Only)						Not Reported

Study	Rate of OASIS	Post Delivery Suture Angle	Length of Episiotomy	Perineal Body Length (PBL)	Ease of Use	Barriers to Use
Lou et al (2016)	N=3 Reduction in OASIS rate during the study period from 5.6% to 3.2% compared with the preceding five months	• Mean post delivery suture angle was 50.7±3.4°			Operators rated ease of use of Episcissors-60, sharpness of the scissors, length of the blade and confidence about the episiotomy angle on a 5 point scale with a satisfaction rate of over 93% in each component 91% of operators preferred Episcissors-60	Not Reported
Condell et al (2017)	• No 4th degree tears were sustained during the study period with Episcissors-60 • One 3b tear was sustained using Episcissors-60 during a forceps delivery • 2 women sustained OASIS without episiotomy and 2 women sustained OASIS using standard scissors	Not Reported	Not Reported	Not Reported	• Operators reported that Episcissors-60 helped to keep the angle of episiotomy fixed to a safe 40-60°	Not Reported

Study	Rate of OASIS	Post Delivery Suture Angle	Length of Episiotomy	Perineal Body Length (PBL)	Ease of Use	Barriers to Use
Farnworth et al (2019)	Not Reported	Not Reported	Not Reported	Not Reported	Not reported	A number of bureaucratic, cultural and practical barriers to successful implementation and outcome evaluation were identified including: • Fiscal assistance and support from clinical leaders • Complex organisation procurement processes • Storage/sterilisation issues • Concerns about the strength of the evidence base

Study	Rate of OASIS	Post Delivery Suture Angle	Length of Episiotomy	Perineal Body Length (PBL)	Ease of Use	Barriers to Use
Ayuk et al (2018)	Standard Scissors: 38/2115 OASIS (1.8%) Episcissors-60: 30/1498 OASIS (2%) No significant association between the introduction of Episcissors-60 and OASIS in women who had an episiotomy.	Not reported	Not reported	Not reported	Not reported	Not reported

3.7 Description of the adverse events

The manufacturer states that no adverse events associated with using Episcissors-60 have been identified. The EAC have not identified any adverse events specifically related to the use of Episcissors-60. One clinical expert suggested that blunting of the Episcissors-60 was a a potential issue which could increase the risk of damage. The EAC note that the same clinical expert stated that Episcissors-60 were now sharpened after 20 uses and this has resolved the issue. The EAC note that blunting is an issue which might affect any reusable episiotomy scissors and therefore is not specific to Episcissors. This assumption was supported by three clinical experts who reported that all scissors become blunt over time. Two clinical expert stated that scissors are returned for sharpening when considered blunt by users and are unavailable for a period of two to three weeks.

It is useful to note that reusable Episcissors are being phased out and replaced with single use, disposable versions therefore the EAC consider this will not be an issue in the future.

3.8 Description and critique of evidence synthesis and meta-analysis

The clinical submission included evidence from a published systematic review and meta-analysis (Divakova et al 2019) and evidence from a second systematic review without a meta-anaysis (Cole et al 2019). There was significant overlap between the two reviews in terms of the individual studies included with both reviews including data from Sawant et al (2015), Van Roon et al (2015) and Mohiudin et al (2018) (table 3). Cole et al (2019) included two studies (Freeman et al, 2014 and Patel et al, 2014) which were excluded by Divakova et al (2019) on the grounds that neither study had a comparator group. A third study (Lou et al 2016) was not included in Cole et al (2019) and does not appear to have been identified during the searches. The EAC suggest that this might be due to the fact that the only available data is from a conference abstract. Divakova et al (2019) included Lou et al (2016) on the basis that is replaced a previous publication with more recent audit data however no details are provided as to what study it is updating therefore no

judgement can be made by the EAC on the appropriateness of including a conference abstract. In addition, review of the published abstract by the EAC identified significant discrepancy between the data in the published abstract compared with the data used in the meta-analysis.

The EAC reviewed the data in the meta-analysis (Divakoa et al, 2019) and noted some issues to be considered when interpreting the results:

- The data for Lou et al (2016) included in the meta-analysis suggest a total sample of 2,509. The EAC note that in the abstract referenced, the authors report Episcissors-60 was used in 79 deliveries and did not provide a comparable denominator for standard episiotomy scissors. The EAC noted however that the quality assessment table included in the publication scores Lou et al (2016) as having a sample size of <650 therefore it is unclear where the values in the meta-analysis have been obtained. The EAC contacted the author of the systematic review and received a response that indicated that the data included in the systematic review was personally communicated to them rather than being taken from the published abstract.

- Data from Mohiudin et al (2018) for the risk difference of OASIS in deliveries with Episcissors-60 compared with standard scissors is from one hospital only. This is due to the fact that Mohiudin et al (2018) does not report rate of OASIS in patients with episotomy for the before and after period in the second hospital. The study reports a total of 333 patients in the second hospital had an epsiotomy and of these 3 patients sustained an OASIS but does not state whether Episcissors was used in these cases. The rationale given for this omission is that reliable data were not available for the ‘before’ period.

- The reported outcomes included the risk difference for OASIS in all vaginal deliveries with or without episiotomy when using Episcissors-60 or standard episiotomy scissors. The population in the scope for this Assessment Report is women with a clinical indication for episiotomy therefore the EAC consider when interpreting the results, consideration

should be given to the population when considering the OASIS rate reduction.

- The rate of episiotomy before and after the introduction of Episcissors was also reported. This outcome was not listed in the scope as a relevant outcome, however the EAC has reported these results where included in the individual studies as information from the clinical experts suggests that the introduction of Episcissors-60 may have an impact on the rate of episiotomies performed, possibly due to increased confidence that safe angles can be achieved.

- The EAC identified one additional abstract (Condell et al, 2017) and one additional unpublished report (Ayuk et al, 2018) which reported rates of OASIS for Episcissors-60 and comparator standard scissors. These data were not included in the systematic review. The EAC acknowledges that although one abstract (Lou et al, 2016) appears to be included in the meta-analysis, the authors of the review received more comprehensive patient level data from the the authors which enabled it to be included.The EAC have included the data relating to episiotomies reported in Condell et al, 2017 and Ayuk et al, 2018 with the caveat that these are not peer reviewed publications and the abstract (Condell et al) cannot be assessed for quality as it does not provide enough detail. A critical appraisal of Ayuk et al (2018) has been included (Appendix B) however the EAC suggest that although this publication is publically available, it has not been through a standard peer review process.

Due to the overlap between the two systematic reviews (Divakova et al 2019 and Cole 2019), the EAC has reviewed the individual studies (See section 3.3) and conducted meta-analysis for outcomes of interest where there was enough data available.

Table 3: Studies included in meta-analysis

Study	Freeman (2014)	Patel (2014)	Sawant (2015)	Van Roon (2015)	Lou (2016)	Condell (2017)	Mohiudin (2018)	Ayuk et al (2018)
Divakova 2019	x	x	✓	✓	✓	x	✓	x
Cole 2019	✓	✓	✓	✓	x	x	✓	x
EAC	x	x	✓	✓	x	✓	✓	✓
EAC Comment	Non comparative study – not appropriate to include in a meta-analysis	Non comparative study – not appropriate to include in a meta-analysis	Included the data for OASIS in episiotomy with Episcissors-60 versus OASIS in episiotomy with standard scissors	Included data for OASIS in nulliparous births (SVD+OVD) given episiotomy with Episcissors-60 versus OASIS in nulliparous births (SVD+OVD) given episiotomy with standard scissors	The published abstract does not report a denominator for the period of time that standard episiotomy scissors was used which means that the data cannot be included in a meta-analysis. (2019) comparing OASIS rates in episiotomy patients with and without Episcissors-60	Abstract Only – cannot comment on the quality of the data or methodology. Not included in either systematic review, not clear whether it was identified and excluded or whether it was not identified.	Only data from one hospital was included as the data from the second hospital in the study was not available for Episcissors-60 versus standard scissors	Unpublished data identified by the EAC. This was included by the EAC as it provides additional data for the meta-analysis specifically comparing outcomes in women who had an episiotomy using Episcissors-60 and standard scissors.

From five studies (Mohiudin et al 2018, Ayuk et al, 2018, Condell et al 2017, Sawant et al 2015 and van Roon et al 2015) there were a total of 46 OASIS in 2362 patients who had episiotomy with Episcissors-60 (1.95%) compared with 110 OASIS in 3335 patients who had an episiotomy with other scissors (3.30%).

Table 1 includes the results from additional outcomes reported in the systematic review (Divakova et al, 2019). The EAC note that when considering the impact of Episcissors-60 on OASIS rates, there is a statistically significant decrease in OASIS rates across the whole birth cohort (RD= -0.02 (-0.04 to -0.01); p=0.002). Confining the results to the episiotomy patients only, Divakova et al (2019) also reported a statistically significant reduction in OASIS rates following introduction of Episcissors-60 (RD= -0.04 (-0.07 to -0.01); p=0.005).

The EAC noted that two of the included studies (Mohiudin et al, 2018 and van Roon et al, 2015) state that other factors were introduced with the aim of reducing OASIS at the same time as Episcissors-60. For this reason, the EAC conducted a pooled analysis using a random effects model to calculate the risk difference in rates of OASIS between Episcissors-60 and standard scissors in women who had an episiotomy. Pooled analysis (Figure 1) shows no significant risk difference between episiotomies performed using Episcissors-60 and standard scissors (RD= -0.02; 95% CI -0.05-0.01; p=0.14) however there was significant heterogentity between the studies (I^2=80%). Removing the two studies from the pooled analysis (Mohiudin et al, 2018 and van Roon et al, 2015) which introduced bundle measures to reduce OASIS (of which Episcissors-60 was a part), results in a risk difference of 0.0 [-0.0-0.01]; p=0.77; I^2=0% (Figure 2).

Pooled analysis of the results from Mohiudin et al (2018) and van Roon et al (2015) alone shows a significiant reduction in risk of OASIS for the Episcissors-60 group (RD= -0.04 [-0.08 to -0.00]; p=0.03) though the heterogeneity between the studies remained high (I^2=70%) (Figure 3). This

suggests that for women who have an episiotomy, there are potentially a number of factors which may reduce the risk of an OASIS.

When pooling the results from 3 studies, Divakova et al (2019) reported that rate of episiotomy did not change significantly following introduction of Episcissors-60 (RD=0.03 (-0.04 to 0.1), p=0.44). The EAC added the data from Ayuk et al (2018) and similarly reported no significant difference in the rate of episiotomy before and after the introduction of Episcissors-60; RD=0.01 (-0.02 to 0.04), p=0.35, I^2=83% (Figure 4).

Pooled analysis was not possible for any other outcome of interest as the outcomes were not reported in more than one study each.

Figure 1: Obstetric Anal Sphincter Injuries in deliveries with episiotomy performed with Episcissors-60 versus standard scissors including all studies with reportable data

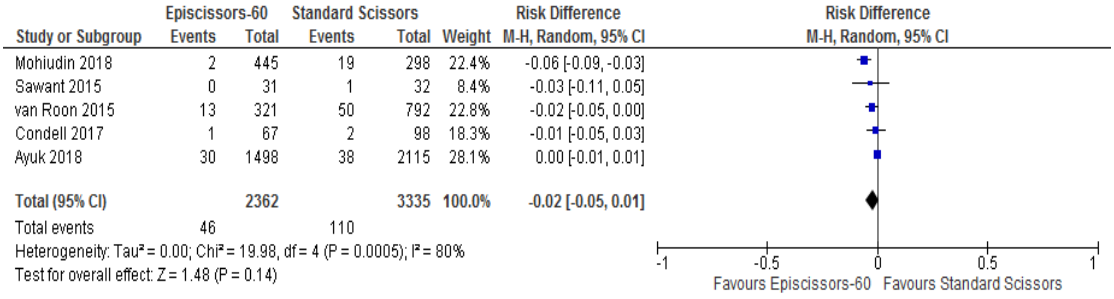


Figure 2: Obstetric Anal Sphincter Injuries in deliveries with episiotomy performed with Episcissors-60 versus standard scissors excluding studies which reported including other measures to reduce OASIS

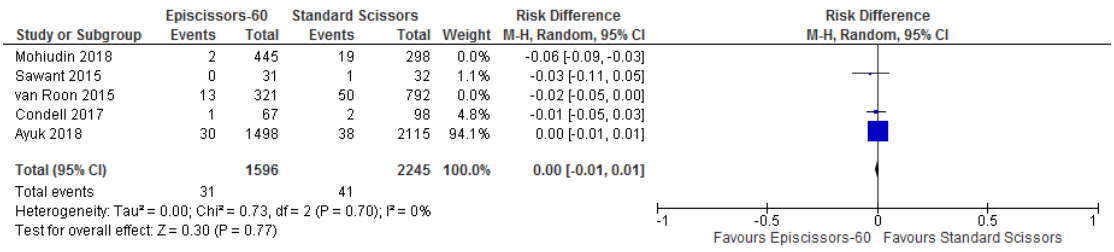


Figure 3: Obstetric Anal Sphincter Injuries in deliveries with episiotomy performed with Episcissors-60 versus standard scissors including only studies which reported including other measures to reduce OASIS

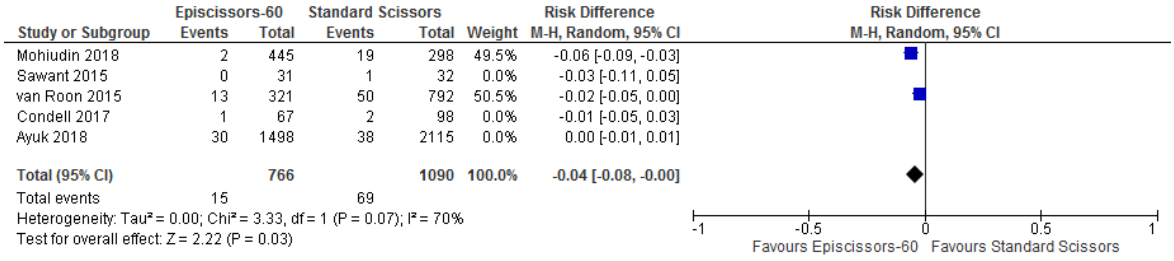
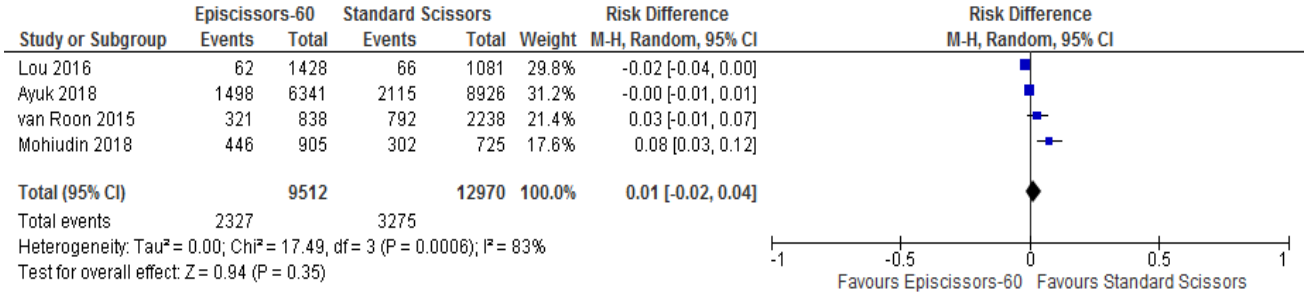


Figure 4: Rates of Episiotomy before and after the introduction of Episcissors-60



3.9 Ongoing studies

The EAC did not identify any ongoing studies of relevance. This may be due to the fact that there are ethical concerns with conducting a randomized trial in this patient group due to the severity of the outcomes and the potential long-term impact for patients who experience an OASIS.

As part of the Innovation and Technology Payment Programme, NHS England have included Episcissors-60 in the technologies eligible for an innovative technology tariff (ITT) which removes the need for multiple local price negotiations and guarantees automatic reimbursement. As part of the process, audit data are being collected including details on:

- Number of mothers requiring surgical repair after obstetric anal sphincter injury for the previous quarter. This is only required for the first claim.

- Number of guided mediolateral episiotomies undertaken using the Episcissors or other approved device during this period of reporting. Providers will be paid based on this number.

- Number of mothers requiring additional surgical repair after undergoing guided mediolateral episiotomy during this period of reporting.

- Average discharge time of mothers who have received a guided mediolateral episiotomy using the Episcissors or other approved device.

4 Economic evidence

4.1 Published economic evidence

Critique of the company's search strategy

No search strategy for the economic evidence was provided.

The EAC did not develop a separate search strategy for economic literature as the search strategy was developed to incorporate both clinical and economic studies (Appendix A).

Critique of the company's study selection

The econominc submission states that health economic studies reporting on 3rd and 4th degree tears in any population with any intervention would be included. The EAC disagrees with these inclusion criteria and considers that only health economic studies reporting the use of Episcissors-60 and standard episiotomy scissors should be included.

Included and excluded studies

The company stated that 5 economic studies were identified in their search, but only one study Orlovic (2018) was relevant. However an additional study, YHEC (2017) was listed in the company's description of identified studies. It is unclear whether this was identified in the search or through another route. The excluded studies of the 5 identified in the search are not listed therefore the EAC cannot comment on whether they were excluded appropriately.

The Orlovic (2018) study is not a study of Episcissors-60, so it does not meet the criteria in the scope of this assessment and the EAC excluded it. It provides background information on the incidence and economic burden of third and fourth degree tears in the English NHS.

The YHEC (2017) publication is an economic impact evaluation case study of Episcissors-60. It does not appear in the peer-reviewed literature, but is available from the YHEC website.

The EAC did not identify any additional economic studies for inclusion.

Overview of methodologies of all included economic studies

The YHEC (2017) study is a simple return on investment calculation. The study is from the NHS perspective and considers the likely return on investment for an NHS Trust purchasing 3 pairs of Episcissors-60 for every 1,000 births. YHEC go on to calculate the return on the NHS's development investment in the product (estimated to be £500k) from the 50 NHS Trusts already using Episcissors-60. They calculate that the development costs would be more than recouped in 1 year.

Overview and critique of the company's critical appraisal for each study

The company completed a quality assessment of the YHEC (2017) return on investment, using an appropriate checklist. There was no further critical appraisal of the economic evidence.

Does the company's review of economic evidence draw conclusions from the data available?

The company concluded that the YHEC (2017) study did not include complete costs relating to OASIS, therefore a *de novo* model was required. The EAC agrees with this assessment.

4.2 Company de novo cost analysis

Patients

The company states that the population is NHS patients undergoing episiotomy as clinically indicated, which matches the scope. However the model includes all births. Only 15% of women giving birth will have an episiotomy therefore the EAC suggests that the population in the model should be confined to those having episiotomy (approximately 94,000/year) and not the all births (approx. 626,300/year) to match the scope.

One clinical expert indicated that while using the total birth population may not represent a true effect of Episcissors-60, clinicians are interested in the effect on overall obstetric practice. The EAC suggest that comparing the results from a model which looks at both scenarios (whole births and episiotomy only) may provide some useful additional detail about the impact of introduction

Episcissors-60, particularly as there is some suggestion that the rate of episiotomy changes when Episcissors-60 is introduced and that there are potentially different rates of OASIS when considering all births and episiotomy births only.

Technology

The technology is Episcissors-60 (reusable)

The EAC note that there is a current move towards disposable Episcissors-60. The company has indicated that the cost of a disposable scissors would be reflective of the cost per use of a resuable scissors.

Comparator(s)

The comparator in the company model is disposable standard episiotomy scissors. The scope did not limit between disposable and reusable scissors and the EAC suggest that there may be a difference in the cost. The EAC has included the cost of a reusable standard scissors in the model which has a lower cost per use than the disposable cost identified in the company base-case. The EAC could not identify a cost per scissors for a disposable standard scissors however the EAC acknowledge that the cost of a disposable standard scissors may be as high as that included by the company. Communication from the company suggest that disposable standard scissors are usually manufactured in a low-wage country, and shipped to the UK/EU. They are then cleaned in a MHRA certified clean room, packed with protective inserts, and then sterilised with gamma radiation or ETO. There is per unit cost of this process which involves the UK labour, equipment, regulatory compliance, and maintenance all of which could increase the cost of a disposable standard scissors.

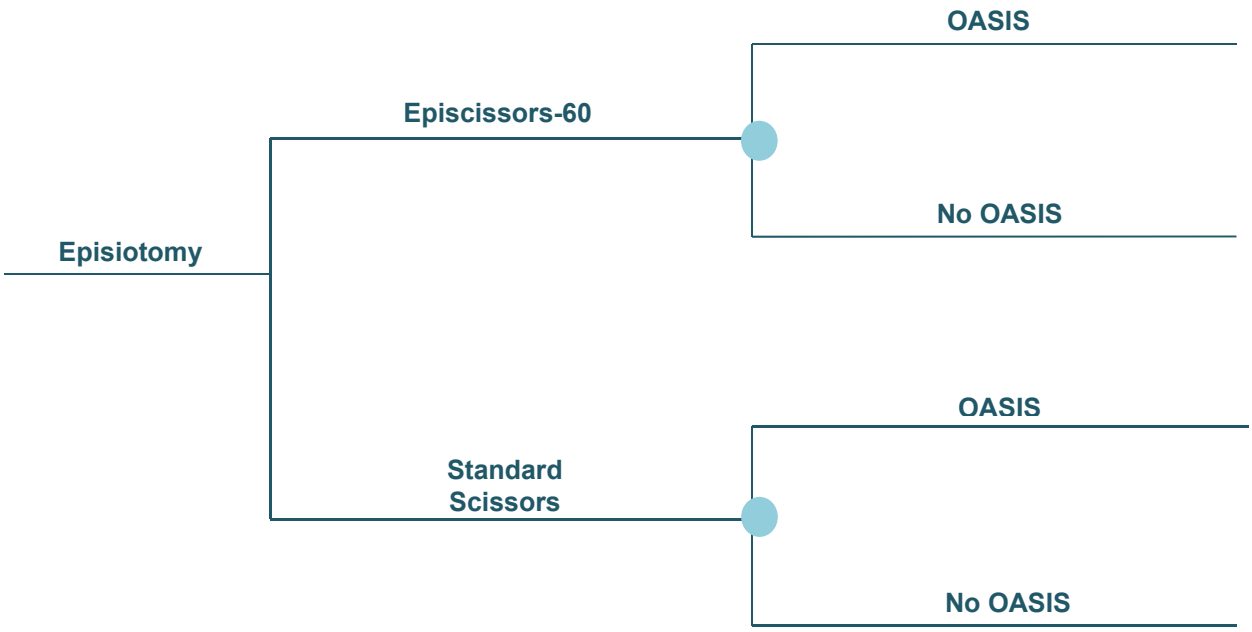
Model structure

The model structure is a simple decision tree with arms for Episcissors-60 and standard scissors. Each arm has branches for OASIS repair or no OASIS repair. As the care pathway is unaffected by the technology, this is an

appropriate structure. The time horizon is 1 year, so no discounting was applied and the perspective is NHS.

The model structure is simple because the introduction of Episcissors-60 is an exchange of one instrument for performing episitomy for another.

Figure 5: Model Schematic



The EAC checked that the model calulations performed as expected and they did so. Sensitvity Analysis in the model however was noted to vary the costs related to the intervention only, the EAC therefore conducted one way sensitivity analysis which included cost variations for both comparator and intervention.

Assumptions in the Model

The following assumptions were identified by the company:

Assumption	EAC Comment
The cost per use of standard episiotomy scissors is £2 giving a cost per birth of £0.30	The EAC note that the cost per use for an episiotomy scissors was obtained by the company from a clinical contact. The total cost for standard scissors was calculated (£2x94,000 episiotomies) and included in the model. The EAC identified the cost of two brands of resusable episiotomy scissors which are sold in packs of ten and used these figures to calculate an average cost per use for a standard episiotomy scissors. This means that the EAC base case is based on comparing reusable scissors in both arms.
The cost per use of Episcissors-60 is £16 giving a cost per birth of £2.40	The EAC made no changes to the cost of Episcissors-60.
The cost of OASIS repair is £1,538	The EAC agrees with the codes used to identify this cost however notes that the source used was the National Non Mandatory Tariff 2019/2020 without a market forces factor addition (MFF). Not adding the MFF is appropriate as this will be different for different providers. The EAC has used the 2017/2018 reference costs as this is more accurate reflection of the cost from the NHS perspective.
The cost of excess bed day is £665.20	The EAC have used the NHS reference costs 2017/2018 for the cost of an excess bed day. The company states that they are using NHS reference costs 2019/20 however these are not available.
The incidence of OASIS is 2.85% (2-4%) of all births	This value is the incidence of OASIS for all births (episiotomy plus no episiotomy births). The EAC note that the median OASIS rate reported in Thiagamoorthy et al, 2014 was 2.85% (0-8%). The company has used the rates reported in the base case for the comparator. The EAC disagrees with this as the rate relates to OASIS in both episiotomy and no episiotomy births. The EAC has therefore used the rate of OASIS in episiotomy births reported in RCOG 2016 (5.1%) for the base rate and used the results from the meta-analysis (section 3.8) for the reduction in OASIS

	following introduction of Episcissors-60 (2% absolute reduction, (range 5% reduction to 1% increase).
The reduction in OASIS using Episcissors-60 of 43%	This is the percentage difference between the rate of OASIS before Episcissors-60 and the rate after Episcissors-60. EAC considers this to be a misleading in the way it is presented as it suggests that Episcissors-60 will reduce OASIS by 43% when the absolute rate reduction is ~2%

The EAC has identified the following additional assumptions:

Assumption	EAC Comment
OASIS incidence in the population of women needing episiotomy may differ from the incidence in all births, whereas the model assumes they are the same	The EAC note that the OASIS rates used in the company model are the rates of OASIS for the whole birth population. Women who have clinical indications for an episiotomy will likely be at risk of a tear which could be as severe as a third or fourth degree tear. There is evidence to suggest that if the angle of episitomy is not within the safe range, there is a risk of OASIS resulting from the episiotomy. Therefore it is feasible that the incidence of OASIS may be different in different populations. Published data suggest that the rate of OASIS in nulliparous women who have an instrumental birth can be as high as 7.8% of women sustained OASIS in operative vaginal or instrumental deliveries (OVD) compared with 5.4% of nulliparous women and 1.6% of multiparous women with spontaneous vaginal deliveries. One study (van Roon et al, 2015) reported a rate of OASIS of 5% in all births before Episcissors-60 compared with 6.3% in the episiotomy population. After introduction of Episcissors-60 the rate in all births was 4.2% compared with 4% in the episiotomy group.

Summary of the base case

The results of the company base case are presented in table 4. The EAC noted that there was an error in the calculation for the cost of standard episiotomy scissors in the submitted model (table 5). The total cost of standard scissors based on £2 per standard scissors, given 94,000 episiotomies should be £188,000 (£2*94,000) however the cost has been entered into the model as £88,000. The EAC corrected this error and noted

that the change made little difference to the results with a slight increase in cost saving from £20.67 to £20.83 per patient.

The company economic model has calculated the cost savings based on a cost per birth basis for both the standard scissors and Episcissors-60. This substantially lowers the cost of Episcissors-60 in the model from £16 per use to £2.40 per birth. The company has used a higher cost for a standard scissors (£2) than that identified by the EAC. This cost has been assumed to be the cost of a single, disposable episiotomy scissors and has been included on a cost per birth basis at a cost of £0.30 per birth. The EAC did not identify any disposable episiotomy scissors on NHS Supply Chain and based their cost in the model on the cost of standard reusable scissors at a cost of £0.26 per use. The cost per birth of a standard episiotomy scissors using these figures would be £0.04 per birth. The lower cost per use of standard episiotomy scissors identified by the EAC suggests that the the cost savings with Episcissors-60 would decrease from £20.83 to £20.57 per patient

Table 4: Company's base case results

	Episcissors-60	Standard Episiotomy Scissors (company cost)	Cost saving per patient
Scissors (per birth)	£2.40	£0.14	-£2.26
OASIS Repair (per birth)	£24.98	£43.83	£18.85
Excess length of Stay (per birth)	£5.41	£9.49	£4.09
Total	£32.79	£53.47	**£20.67**

Table 5: EAC corrections to company base case

Parameter	Company Value	EAC Value	EAC Comment
Cost of standard scissors	£88,000	£188,000	Error in calculation or typing of value into the model. The total cost of the standard scissors based on the company assumption of £2 per use should be £188,000 (£2*94,000 episiotomies)

Cost of standard scissors	£188,000	£24,440	Once the initial error in calculation was corrected the EAC explored the impact of changing the cost of the episiotomy scissors to reflect the costs identified by the EAC.

Table 6: Results following EAC corrections to company base case

	Episcissors-60	Standard Episiotomy Scissors (company cost)	Cost saving per patient
Scissors (per birth)	£2.40	£0.04	-£2.36
OASIS Repair (per birth)	£24.98	£43.83	£18.85
Excess length of Stay (per birth)	£5.41	£9.49	£4.09
Total	£32.79	£53.36	**£20.57**

Sensitivity analysis

The company submission bases the best and worst case scenarios on data reported in the YHEC case study (YHEC, 2017) which reported a best case reduction of 50% and worst case reduction of 20% which was reported in Lou et al (2016).

The EAC noted that the results presented by the company indicate that that the worst case scenario for Episcissors-60 was more cost saving per patient than the best case scenario.

The EAC noted that the values used by the company did not accurately represent the best and worst case OASIS rates. The rates of OASIS for the best case and worst case when using standard scissors were 2% and 4% respectively (based on Thiagamoorthy et al, 2014) and the corresponding best and worst rates of OASIS when using Episcissors-60 were 1.4 % and 2.3% respectively which correspond with a 30% reduction and 43% reduction respectively (Table 6). In addition, the lowest and highest rates of OASIS reported by Thiagamoorthy et al (2014) were 0% and 8% respectively, not 2% and 4% as included in the company submission.

The EAC has made these corrections to the best and worst case scenarios (table 7) in the company submission and the new lowest and highest estimates are presented in table 8.

Table 7: EAC corrections to company sensitivity analysis

Lowest rate of OASIS reported in Thiagmoorthy et al (2014)	2%	0%	Thiagmoorthy et al reported a lower rate value of 0%
Highest rate of OASIS reported in Thiagmoorthy et al (2014)	4%	8%	Thiagmoorthy et al reported an upper rate of 8%
Probability Intervention – Worst Case	2.3% (rate reduction of 43% from comparator value)	0% (based on 20% reduction)	Using lower rate, the worst case scenario would be that Episcissors-60 reduces OASIS by 20% from the lowest rate of OASIS prior to Episcissors-60. In this situation, the lowest rate of OASIS reported in Thiagmoorthy et al was 0%, therefore the worst case scenario is that the introduction of Episcissors-60 has no impact (cannot reduce 0% by 20%).
Probability Intervention – Best Case	1.4% (rate reduction of 30% from comparator value)	4% (based on 50% reduction)	Using upper rate, the best case scenario would be that Episcissors-60 reduces OASIS by 50% from the highest rate of OASIS reported prior to Episcissors-60. In this case, the best case scenario is that the introduction of Episcissors-60 reduces the rate of OASIS from 8% to 4%.

Table 8: Company lowest and highest estimate of cost savings

	Base-case	Lowest estimate	Highest estimate
Range of cost-savings with device	£20.67	£29.92	£8.50

Range of cost-savings with device (EAC Corrections)	£20.57	-£2.36	£72.48

The company submission included one way sensitivity analysis which explored the impact of changing input parameters in the intervention arm only. The EAC noted that there were no low or high values included in the model for any parameters other than OASIS rates.

The EAC conducted one way sensitivity analysis to explore the impact of changing inputs in both the intervention and comparator arm. When varying the cost of Episcissor-60, cost of standard scissrors and the cost of OASIS repair and excess length of stay sensitivity analysis shows the model is cost saving in all cases.

The key driver in the model is the OASIS rate in the comparator (standard scissors) arm. The lower the rate of OASIS in the baseline, the less impact the introduction of Episcissors-60 can have on rates of OASIS therefore the potential for cost savings is reduced and there is a possibility that Episcissors-60 could be cost incurring (Figure 6).

Figure 6: Senstivity Analysis: Corrected Company Base Case

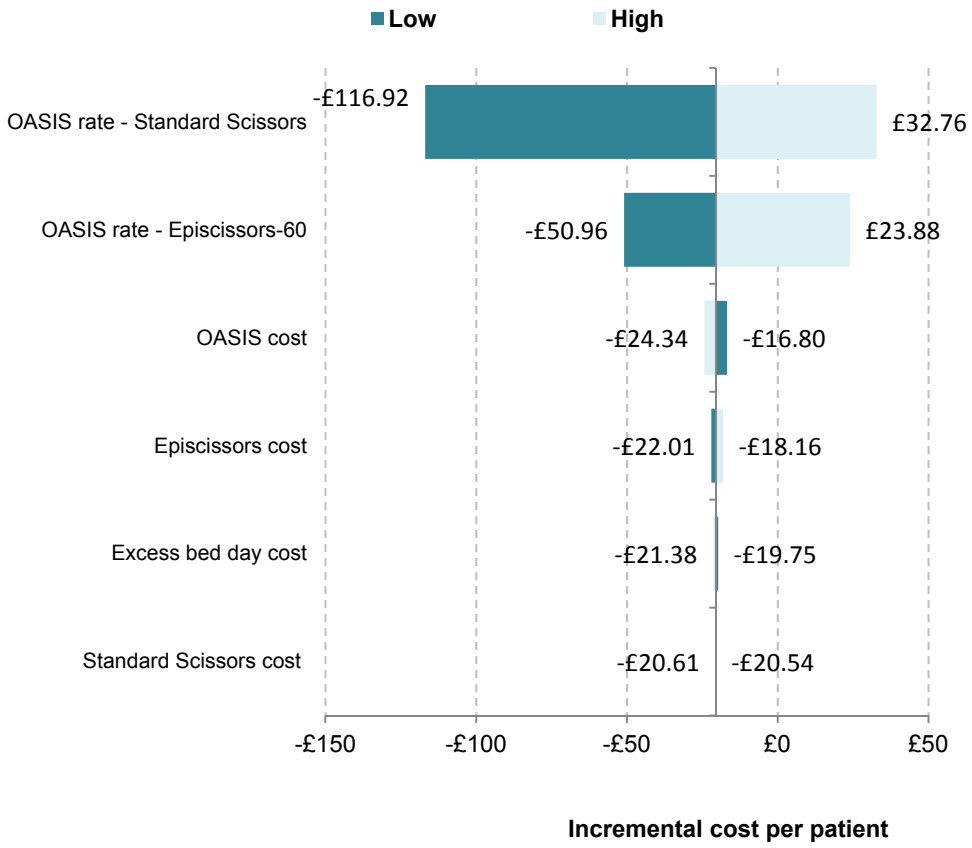


Table 9: Low and High Values in Sensitivy Analysis

Variable	High	Result	Low	Result	EAC Comment
OASIS rate - Standard scissors	0.08	£116.92	0.00	-£32.77	High and low values based on the rates reported in the literature
OASIS rate – Episcissors-60	0.04	-£23.88	0.00	£50.96	High and low values based on the rates reported in the literature
OASIS cost	£1845.60	£24.34	£1230.40	£16.80	High and low values based on a 20% variation in costs
Episcissors-60 cost - intervention	£32.00	£18.16	£6.40	£22.01	High value based on scissors being used only 10 times, low value based on scissors being used 50 times.
Excess bed day cost	£399.60	£21.38	£266.40	£19.75	High and low values based on a 20% variation in costs
Standard cost - intervention	£0.52	£20.60	£0.10	£20.54	High value based on scissors being used only [redacted], low value based on scissors being used [redacted].

Clinical parameters and variables

The company assumes a 43% reduction in OASIS from using Episcissors-60 based on the results reported in the Lou (2016) abstract. The EAC notes that the 43% is the difference between the rate of OASIS before Episcissors-60 (5.6%) and the rate of OASIS after the introduction of Episcissors-60 (3.2%) and reporting a 43% reduction in OASIS in isolation could be misleading and report the absolute rate reduction of 1.9% alongside the percentage rate reduction for clarity.

Resource identification, measurement and valuation

The EAC agrees with the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures (OPCS) codes used by the company to identify the most approapriate codes for the repair of third and fourth degree obstetric lacerations. The corresponding Healthcare Resource Group (HRG) code was used to identify the cost of an OASIS repair using the 2019/20 National Non-Mandatory Tariff without the market forces factor (MFF). The EAC agree with the classification (NZ27Z) but has used the costs in the NHS Reference Costs 2017/18.

Technology and comparators' costs

The technology (Episcissors-60) cost included in the company model is £320 (excluding VAT) giving a cost of £16 per use (based on 20 uses). The EAC has used this value in the base case. If Episcissors-60 was used 50 times the cost per use would be £6.40.

The comparator cost was assumed to be £2 per use as commercially sensitive data was not available to the company from NHS supply chain. The EAC has searched NHS supply chain and found actual purchase costs for standard reusable episiotomy scissors [redacted] from the catalogue (excluding VAT), giving a per patient use cost of £0.26 for [redacted] or £0.10 for [redacted].

EAC changes to the model

The EAC does not agree with the use of the total births as the population for the analysis. The scope relates specifically to women who have an episiotomy therefore the EAC has used this population. This change means that the incremental cost savings are spread over the episiotomy population rather than the total birth population.

The EAC has used NHS Reference costs to identify costs for OASIS repair and excess length of stay rather than the National Non Mandatory Tariffs.

No costs for sterilisation have been included in the model, because both are based on costs of reusable scissors, and the cost of sterilisation will be the same for both Episcissors-60 and standard episiotomy scissors. In addition, sterilisation costs will vary depending on whether hospitals perform sterilisation in-house or whether the process is outsourced.

The costs in the model for the technology and comparator are based on a cost per use for reusable scissors. The assumption is that the cost of a disposable scissors will be priced according to the cost per use of a reusable. The manufacturer of Episcissors-60 confirmed this will be the case for the disposable Episcissors.

Table 10: EAC revisions to the company's model (Base Case)

Parameter	Company base-case	EAC value	Source	Cumulative Impact
Population	626,203	94,000	Episiotomy population only	Episcissors-60 remains cost saving though the cost saving has reduced from £20.84 per episiotomy to £8.93 per episiotomy.
Standard Episiotomy Scissors	£2	£0.26	Standard reusable Episcissors-60 cost [redacted] on NHS Supply Chain.	Episcissors-60 remains cost saving though the cost saving reduces from £8.93 per episiotomy to £7.19 episiotomy.
OASIS Repair	£1538 exc MFF	£1956	NZ27Z National Reference Costs 2017-2018	Episcissors-60 remains cost saving with an increase in saving from £7.19 per

Parameter	Company base-case	EAC value	Source	Cumulative Impact
				episiotomy to £12.31 per episiotomy.
Excess length of stay	£333	£366	Non-Elective Excess Bed Days NZ27Z National Reference Costs 2017-2018 Cost is £731 per day. The cost in the model is based on 0.5 excess days (Orlovic et al 2017).	Episcissors-60 remains cost saving with an increase in saving from £12.31 per episiotomy to £12.72 per episiotomy.
Rate of OASIS before Episcissors-60 reported in Thiagmoorthy et al (2014)	2.85%	5.1%	Mean rate of OASIS among vaginal deliveries in primiparous women (RCOG 2016) The EAC could not identify any published literature which provided sufficient data to use a base rate of OASIS in women with episiotomy only. Primiparous women (1st birth) are higher risk for OASIS therefore the EAC have used the rates reported RCOG 2016. The EAC note that van Roon et al (2015) report a rate of OASIS of 6.3% in the episiotomy population bu there is not enough data reported in this study to report low and high values.	
Percentage Rate Reduction in OASIS between standard episiotomy scissors and	43%	2% (absolute reduction) 39% rate reduction	The EAC meta-analysis showed an absolute reduction of 2% in OASIS with Episcissors-60. The EAC has used this rate in their base case. This	Episcissors-60 remains cost saving (£30.70 per episiotomy).

Parameter	Company base-case	EAC value	Source	Cumulative Impact
Episcissors-60 (reported in Lou et al, 2016)			gives a probablity of OASIS in the Episcissors-60 arm of 3.1%. This rate reduction is very similar to the rate used by the company (1.9%)	

4.3 Interpretation of economic evidence

The EAC identified no published literature relevant to this topic.

4.4 EAC Interpretation of economic evidence

The EAC accept that the model functions as expected but disagrees with some of the assumptions regarding the data input in particular with relation to the population and the rates of OASIS in the model.

4.5 Results of EAC analysis

The EAC made some changes to the data input (table 10) in the company base case and the results are presented below (table 11).

Table 11: EAC Base-case analysis results

	Episcissors-60	Standard Episiotomy Scissors	Cost saving per patient
Scissors (per episiotomy)	£16	£0.26	-£15.74
OASIS Repair (per episiotomy)	£60.64	£99.76	£39.13
Excess length of Stay (per episiotomy)	£11.35	£18.67	£7.31
Total	£87.98	£118.68	**£30.70**

Sensitivity analysis results

Table 12: EAC revisions to the company's model

Parameter	Company base-case	EAC value	Source
Highest rate of OASIS before Episcissors-60 (Probability Comparator: Worst Case)	8%	6.5%	Highest rate (mean) of OASIS among vaginal deliveries in primiparous women (RCOG, 2016 The EAC could not identify any published literature which provided sufficient data to use a base rate of OASIS in women with episiotomy only. Primiparous women (1st birth) are higher risk for

Parameter	Company base-case	EAC value	Source
			OASIS therefore the EAC have used the rates reported in the Maternity Indicators Report.
Lowest rate of OASIS before Episcissors-60 (Probability Comparator: Best Case)	0%	3.7%	Lowest rate of OASIS among vaginal deliveries in primiparous women (RCOG 2016) The EAC could not identify any published literature which provided sufficient data to use a base rate of OASIS in women with episiotomy only. Primiparous women (1st birth) are higher risk for OASIS therefore the EAC have used the rates reported in the Maternity Indicators Report.
Lowest rate reduction in OASIS after Episcissors-60 (Probability Intervention: Worst Case)	20%	7.5% (27% increase)	Based on 1% absolute increase from meta-analysis (section 3.8, figure 1, confidence intervals).
Highest rate reduction in OASIS after Episcissors-60 (Probability Intervention: Best Case)	50%	0% (100% decrease)	Based on 5% absolute reduction from meta-analysis section 3.8, figure 1, confidence intervals). In this case the rate cannot be reduced from 3.7% by 5% therefore the best case scenario is that Episcissors-60 reduces the rate of OASIS in women with episiotomy to 0.

Table 13: EAC lowest and highest estimate

	Base-case	Lowest estimate	Highest estimate
Range of cost-savings with device	£30.70	-£38.96	£70.17

One way sensitivity analysis indicates that the main driver in the model is the OASIS rate. The lower the rate of OASIS in the baseline, the less impact the introduction of Episcissors-60 can have on rates of OASIS therefore the potential for cost savings is reduced and there is a possibility that Episcissors-60 could be cost incurring (Figure 7).

Figure 7: Sensitivity Analysis: EAC Base Case

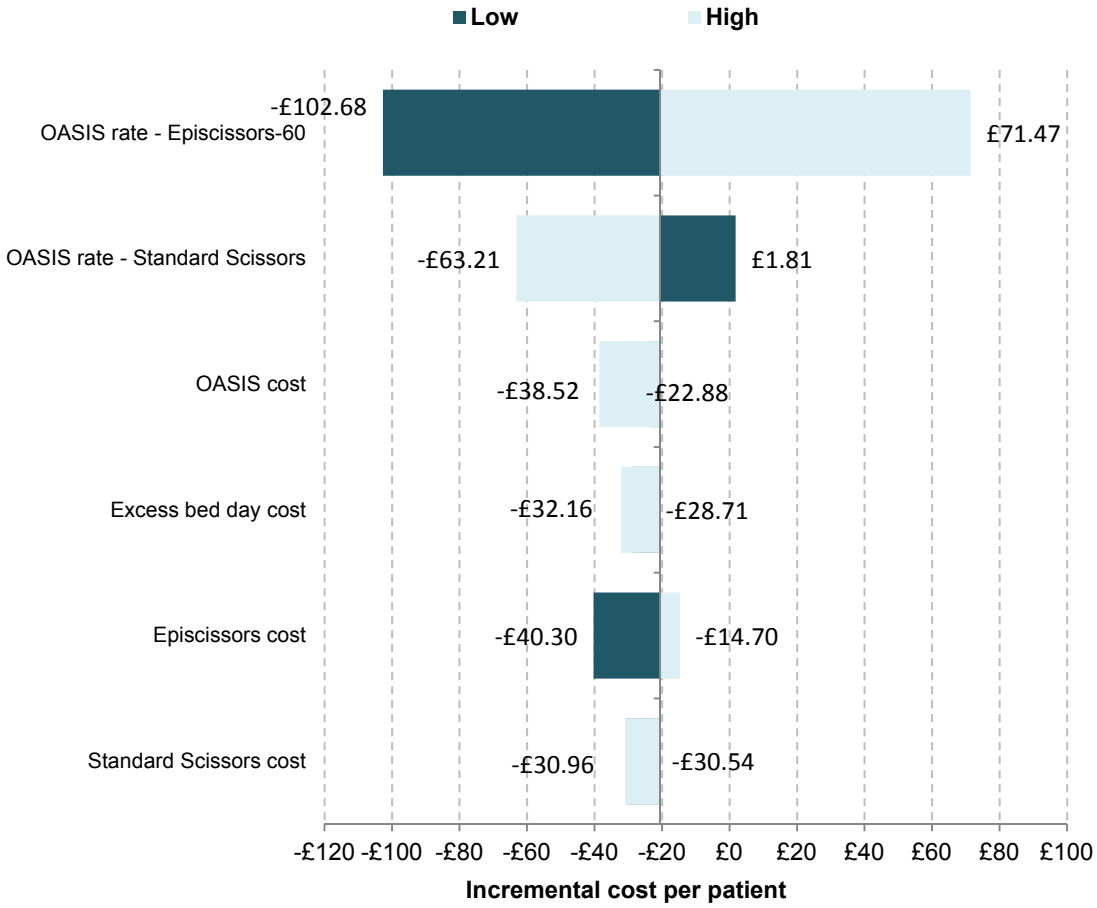


Table 14: Low and high values in Sensitivity Analysis

Variable	High	Result	Low	Result	EAC Comment
OASIS rate - intervention	0.08	-£71.47	0.00	102.682	High value based on 1% increase from meta-analysis, low value based on 5% decrease from meta-analysis
OASIS rate - comparator	0.07	£63.21	0.04	-£1.81	High and low values based on rate used in model (Published literature)
OASIS cost	£2347.20	£38.52	£1564.80	£22.88	High and low values based on a 20% increase or decrease in costs
excess bed day cost	£439.20	£32.16	£266.40	£28.71	High and low values based on a 20% increase or decrease in costs
Episcissors-60 cost - intervention	£32.00	£14.70	£6.40	£40.30	High value based on Episcissors-60 being used only 10 times, low value based on Episcissors-60 being used 50 times
standard cost - intervention	£0.52	-£30.96	£0.1	-£30.54	High value based on scissors being used only [redacted], low

					value based on scissors being used [redacted].

4.6 Scenario analysis

The EAC conducted a number of analyses to assess the impact of possible clinical scenarios.

Table 15: EAC Scenario Analyses

Scenario	Justification	Model Change	Impact
Episcissors-60 may be used up to 50 times	There is a suggestion that resusable Episcissors-60 could be used up to 50 times before being disposed of. If this reflects clinical practice, this would reduce the cost of Episcissors-60 per use.	The cost of Episcissors-60 reduces from £16 per use to £6.40 per use	Incremental cost saving increases from £30.70 to £40.30
Availability of Episcissors-60 increases the rate of episiotomy	There is some evidence that the availability of Episcissors-60 increases the rate of Episiotomy, possibly due to an increase in confidence of the clinical staff to achieve a safe angle.	The population was changed to reflect the whole birth population The cost of Episcissors-60 was increased to reflect a higher rate of episiotomies.	Incremental cost saving is £41.05
Cost of a disposable standard scissors is £4.00	There is some indication that due to manufacturing processes, the cost of a disposable scissors will be higher than the cost per use of a reusable scissors	The cost of the standard scissors was increased to £4	Incremental cost saving is £34.44

Cost of reusable epsicissors reduces based on increased number of uses

The company suggested that the cost of a disposable scissors may be based on the per use cost of a reusable scissors. Using cost based on [redacted] might result in a disposable scissors being less cost saving than a reusable scissors. The EAC acknowledges that this is based on the assumption that a) a reusable standard scissors is not used up to 50 times and b) that the cost of a standard disposable scissors in the model is an accurate reflection of the true cost of a disposable scissors.

The EAC modelled a reduction in the cost of reusable Episcissors-60 in the episiotomy population (EAC base case) and noted that the incremental cost savings increased from £30.70 to £40.30 per patient.

Table 16: Reduced cost of reusable Episcissors-60 based on 50 uses

	Base Case	Lowest estimate	Highest estimate
Range of cost savings with device	£40.30	-£34.00	£44.94

Rate of Episiotomy Increases following introduction of Episcissors-60

There is some evidence that the introduction of Episcissors-60 results in a change in the rates of episiotomy. Two studies reported an increase in the rate of Episiotomies by 11% (van Roon et al, 2015) and 15% (Mohiudin et al, 2018) respectively following the introduction of Episcissors-60. Although not statistically significant, there was an increase in the rate of episiotomies in the EAC meta-analysis (absolute increase 1% (Figure 4). The EAC modelled an increase in the episitomy rates in the total birth population (company base case, corrected version) and the incremental cost saving reduced very slightly from £20.47 to £20.41. The meta-analysis results indicate an absolute reduction of 2% as the best case and an absolute increase of 4% in the worst case. The impact of costing Episcissors-60 based on these estimates is presented below (table 17).

The results indicate that a small change in episiotomy rates does not have a large impact on the incremental cost savings.

Table 17: Increased Episiotomy rate and reduced OASIS rate with Episcissors-60

	Base Case	Lowest estimate	Highest estimate
Range of cost savings with device	£20.41	£19.93	20.89

Disposable scissors

The model structure is suitable for comparing a disposable version of Episcissors-60 with disposable standard episiotomy scissors with few changes. Instead of the cost per use in each arm we substitute the cost of each disposable Episcissors-60 and disposable standard episiotomy scissors. We are advised by the company to use a cost of £16 for the disposable Episcissors-60, which is the same as the cost per use of reusable scissors. We can take the same approach for standard disposable scissors and use the cost per use of 26p. This yields the same model results as in the EAC base case for reusable scissors, a cost saving of £30.70.

The model result is very insensitive to the cost of disposable standard scissors. In the worst case if we use a cost for disposable standard scissors of just 1p, the model remains cost saving at £30.45. Any higher cost of disposable standard scissors increases the cost saving for Episcissors-60. For example, there is some indication that due to manufacturing processes, the cost of a disposable scissors will be higher than the cost per use of a reusable scissors. If the cost of a standard scissors is increased to £4 per scissors, incremental cost savings increase to £34.44.

Model validation

There were no other health economic studies found in the literature to validate the structure of the de novo model. However it is a simple structure and the EAC considers the structure appropriate for the decision problem. Key

uncertainties relate to the rate of OASIS in the baseline and the impact of Episcissors-60 on the rate of OASIS.

Impact on the cost difference between the technology and comparator of additional clinical and economic analyses undertaken by the External Assessment Centre

The EAC made a number of changes to the model submitted by the company. Many of the changes were corrections to calculations or minor changes to rates used in the model and overall there was a small impact on the base case.

The main change made by the EAC was to include only the episiotomy population in the base case and a change in the base rates of OASIS to reflect the fact that the rate of OASIS may higher in episiotomy patients. This resulted in an increase in the cost savings from £20.57 to £30.70 per patient.

5 Conclusions

5.1 Conclusions on the clinical evidence

The clinical submission states that the evidence 'proves the claims in the scope...' suggesting that two independent systematic reviews endorsing their use is testament to the efficacy of Episcissors-60 however the EAC consider that the evidence has not been adequately reviewed, appraised and summarized.

Following appraisal of the included studies the EAC conclude that overall, the current clinical evidence suggests that there are potentially some benefits to using Episcissors-60 over standard episiotomy scissors.

Specifically, evidence suggests that using Episcissors-60 for episiotomy results in reliable post delivery suture angles within the recommended 40-60° to reduce the risk of OASIS.

Pooled analysis suggests no significant risk difference in favour of Episcissors-60 (RD= -0.02; 95% CI -0.05 to 0.01; p=0.14) for OASIS rates in women who had an epistiomy with Episcissors-60 compared with standard episiotomy scissors, though there is evidence from the pooled results of two studies, that Episcissors-60 as part of a bundle of care may significantly reduce OASIS rates in women who have an episiotomy (RD= -0.04 [-0.08 to -0.00]; p=0.03).

The evidence base is limited to a small number of non-comparative studies and before and after studies. There are no randomised trials and it is unlikely that it would be possible to conduct an RCT as there would be serious ethical concerns around including people in a trial.

There is some evidence that the introduction of Episcissors-60 may result in behaviour change and an increase in the number of episiotomies performed. Pooled analysis suggest that the rates of episiotomies could increase by 1% (absolute increase) as much as 4% (absolute increase) however the data are poor quality the result was not statistically significant.

5.2 Conclusions on the economic evidence

The deNovo cost model included data from a number of sources to the determine the incremental cost savings of Episcissors-60.

The OASIS rates for the baseline (before Episicssors-60) used in the company model were based on the rate in the total births reported in published literature (Thiagmoorthy et al, 2014). The reduction in rate of OASIS was also taken from published literature (YHEC).

The EAC did not identify any more appropriate source of OASIS rate data for a total birth population however as the scope related to patients with a clinical indication for episiotomy and the EAC did not consider that rates of OASIS in the whole birth population were reflective of the rates in the episiotomy population. The EAC therefore confined the base case to the episiotomy population using OASIS rates in nulliparous women reported in the Maternity Indicators Report (RCOG) for the baseline and the results from meta-analysis to calculate the change in rates following introduction of Episcissors-60 in episiotomy patients only.

There are a number of factors which can increase the risk of an OASIS including nulliparity, Asian ethnicity and instrument assisted births. OASIS rates are additionally likely to be impacted by a number of interventions such as episiotomy, manual perineal support or perineal massage. The baseline rate of OASIS may differ in different settings, impacted by factors such as the patient case mix, whether it is a midwife or consultant led setting, what protocols are in place for prevention of OASIS. One study reports rates of OASIS varying between 2% and 9.3% across individual NHS trusts (RCOG 2016). As a result, in a setting where the baseline rate of OASIS is high, if the introduction of Episcissors-60 reduces OASIS, then it is likely to be cost saving and cost savings will increase the more Episcissors-60 reduces OASIS.

There is a suggestion that the reusable Episcissor-60 could be used up to 50 times before replacement. If the cost of the disposable scissors is priced to

reflect a possible 50 uses then a shift to the disposable scissors may increase the cost savings associated with Episcissors-60.

The EAC acknowledge that their base case represents a small subset of women giving birth and one clinical expert has suggested that clinicians are interested in overall impact on obstetric practice and in this case, the total births population may be more useful.

The model does not include any of the potential long-term costs associated with OASIS and no comment can be made on how this might impact the results.

Litigation costs are a major factor associated with OASIS, costing an estimated 31.2 million over a ten year period. If the introduction of Episcissors-60 was to reduce the rate of OASIS, then it would be expected that these costs would also reduce.

6 Summary of the combined clinical and economic sections

The EAC concludes that the baseline rate of OASIS is likely to differ across the NHS and will be dependent on a number of factors including setting, individual patient risk factors and local protocols in place to prevent OASIS.

The EAC concludes that the introduction of Episcissors-60 appears to be both clinically effective and cost saving and that if Episcissors-60 reduces OASIS compared with standard scissors, then there will be cost savings to the NHS. The extent of the cost savings depends on how much of a difference the introduction of Episcissors-60 makes to baseline OASIS rates.

It is likely that Episcissors-60 makes episitomies safer and as a result will reduce the rate of OASIS however it is less clear whether the introduction of Episcissors-60 results in an increase in episiotomies and if this is the case, the reason for this increase should be investigated and the possibility that an increase in episiotomies may result in an increase risk of OASIS.

The EAC notes that as some of the clinical evidence is drawn from studies which introduced other measures at the same time as Episcissors, it is

possible that Episcissors-60 alone may be responsible in part for any reduction in OASIS rates, or whether improvements are the result of the combined effect of interventions and approaches.

The EAC accept that achieving zero OASIS as reported in Thiagmoorthy et al (2014) may not be clinically possible for all hospitals or trusts and would certainly not be realistic for the NHS, however the published literature suggests variability in the basline rates of OASIS and possible reduction in rates using Episcissors-60 and the scenarios presented by the EAC are meant to provide clinicians with an oversight of how the difference in OASIS rates both before and after the introduction of Episcissors-60 will impact on the possible cost savings.

7 Key Considerations

The EAC have identified some key areas for discussion and consideration (table 18)

Key Point for Consideration	Consider
Randomised controlled trials are generally considered to represent the best quality evidence however the EAC agrees with the company that an RCT would be unethical in this scenario.	Although, critical appraisal tools and GRADE Assessment have highlighted a number of potential issues which lead to a 'low quality evidence' assessment. The EAC highlights that these results are not definitive, can be subject to interpretation and in no way are meant to over-ride clinical judgement.
Rates of OASIS appear to be variable across the published literature.	Are there subgroups which drive the OASIS rates and may be worth investigating further (e.g. instrument births). Statistically significant differences may not represent a clinically significant difference. Clinicains should consider their own clinical experience when determining what basline rates of OASIS and what reductions might be achievable and the degree to which Episcissors-60 might contribute to a reduction.

Some studies introduced a number of different measures to protect against perineal tears at the same time as introducing Episcissors-60 but did not report any data on these other measures	Consider what these other measures might be and to what extent they may impact the results.
Introduction of Episcissors-60 may result in an increase in the rate of episiotomy	What are the reasons for such a behavior change and how might this impact the rates of OASIS? How could the possible behaviour change be assessed?

8 Implications for research

A study investigating the impact of Episcissors-60 in patients with episiotomy only should is recommended. This could be done using currently collected data as all maternity units should collect data on whether a patient was given an epistiomtomy and whether they sustained an OASIS. A detailed audit study would also provide data on whether the rates of episiotomy change following introduction of Episcissors-60 and what other factors are being implemented to prevent OASIS. This study could be done as a 'before and after' study with prospectively defined before and after period or it could be done as a prospective observational study identifying units not using Episcissors-60 and comparing outcomes with units using Episcissors-60. Outcomes of interest will include rate of episiotomy, post-suture angle of episiotomy, rate of OASIS and patient reported outcomes.

References

Ayuk et al (2018) Obstetric anal sphincter injuries (OASIS) before and after the introduction of the Episcissors-60: A multi-centre time series analysis. Accessed Online at: http://www.ahsn-nenc.org.uk/wp-content/uploads/2019/03/Episcissors-Project-Report-Dec-2018.pdf [last accessed: 25/07/2019]

Cole, J., et al. (2019). "The use of Episcissors-60 to reduce the rate of Obstetric Anal Sphincter Injuries: A systematic review." European Journal of Obstetrics, Gynecology, & Reproductive Biology **237**: 23-27.

Condell, A., et al. (2017). "Episcissors-reducing obstetric anal sphincter injuries (OASIS) in instrumental delivery." Neurourology and Urodynamics **36 (Supplement 3)**: S236-S237.

Davies-Tuck et al (2015) Maternal Asian ethnicity and the risk of anal sphincter injury. *ACTA Obstetricia et Gynecologica Scandinavica* 94;308-315

Divakova, O., et al. (2019). "Episcissors-60TM and obstetrics anal sphincter injury: a systematic review and meta-analysis." International Urogynecology Journal **02**: 02.

Farnworth, A., et al. (2019). "A pragmatic evaluation of barriers and facilitators to the implementation of an obstetric innovation (Episcissors) across maternity units in the North East and North Cumbria." BJOG: An International Journal of Obstetrics and Gynaecology **126 (Supplement 1)**: 108.

Freeman, R. M., et al. (2014). "Cutting a mediolateral episiotomy at the correct angle: evaluation of a new device, the Episcissors-60." Medical Devices Evidence and Research **7**: 23-28.

HES (2018) NHS Maternity Statistics, England 2017-2018. Available online at https://digital.nhs.uk/data-and-information/publications/statistical/nhs-maternity-statistics/2017-18 [last accessed 29/07/2019]

Lou YY et al (2016) Does Episcissors-60 reduce the incidence of obstetric anal sphincter injuries (OASIS)? BJOG: An International Journal of Obstetrics and Gynaecology 123 (S2); 51

Mohiudin, H., et al. (2018). "Implementation of the RCOG guidelines for prevention of obstetric anal sphincter injuries (OASIS) at two London Hospitals: A time series analysis." European Journal of Obstetrics, Gynecology, & Reproductive Biology **224**: 89-92.

Ness W (2017) Obstetric anal sphincter injury: causes, effects and management. Accessed online at: https://www.nursingtimes.net/clinical-archive/womens-health/obstetric-anal-sphincter-injury-causes-effects-and-management/7017458.article [last accessed on 25/07/2019]

NHS Litigation Authority (2012) Ten years of maternity claims: An analysis of NHS Litigation Authority Data. Accessed online at https://resolution.nhs.uk/resources/?fwp_resources_service=claims-management&fwp_resources_themes=maternity [Last accessed 30/07/219]

Orlovich et al (2018) Estimating the incidence and the economic burden of third and fourth degree obstetric tears in the English NHS: an observational study using propensity score matching *BMJ Open* 7:e015463. doi:10.1136/bmjopen-2016-015463

Patel, R. P. and S. M. Ubale (2014). "Evaluation of the angled Episcissors-60() episiotomy scissors in spontaneous vaginal deliveries." Medical Devices Evidence and Research **7**: 253-256.

Ramm et al (2018) Risk factors for the development of obstetric anal sphincter injuries in modern obstetric practice *Obstet Gynecol* 131;290-296

RCOG (2015) The management of Third and Fourth Degree Perineal Tears *Green-top Guideline 29* Online at https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg29/ [last accessed: 25/07/2019]

RCOG (2017) National Maternity and Perinatal Audit – Clinical Report. Accessed online at: https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/nmpa/ [last accessed: 25/07/2019]

RCOG (2016) Patterns of maternity care in English NHS Trusts Online at https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/clinical-indicators-programme/maternity-care/ [last accessed 25/07/2019]

Sawant, G. and D. Kumar (2015). "Randomized trial comparing episiotomies with Braun-Stadler episiotomy scissors and EPISCISSORS-60()." Medical Devices Evidence and Research **8**: 251-254.

Thiagamoorthy, G., et al. (2017). "Does episiotomy reduce the risk ofOASIS? multivariate logistic regression analysis of risk factors for OASIS." International Urogynecology Journal **28 (1 Supplement 1)**: S10-S11.

van Roon, Y., et al. (2015). "Comparison of obstetric anal sphincter injuries in nulliparous women before and after introduction of the EPISCISSORS-60() at two hospitals in the United Kingdom." International Journal of Women's Health **7**: 949-955.

YHEC (2017). Economic Impact Evaluation Case Study: Episcissors-60, YHEC.

Appendix A: EAC search strategy and study selection

Database: Ovid MEDLINE(R) ALL <1946 to May 24, 2019>

Search Strategy:

---

1 Episiotomy/is, mt [Instrumentation, Methods] (265)

2 (episiotom* adj5 ("60" or scissor* or instrument*)).tw. (138)

3 1 or 2 (386)

4 Obstetric Labor Complications/pc [Prevention & Control] (1629)

5 Perineum/in [Injuries] (1655)

6 ((Prevent* or reduc*) adj5 ("obstetric anal sphincter injur*" or OASI*)).tw. (81)

7 4 or 5 or 6 (3180)

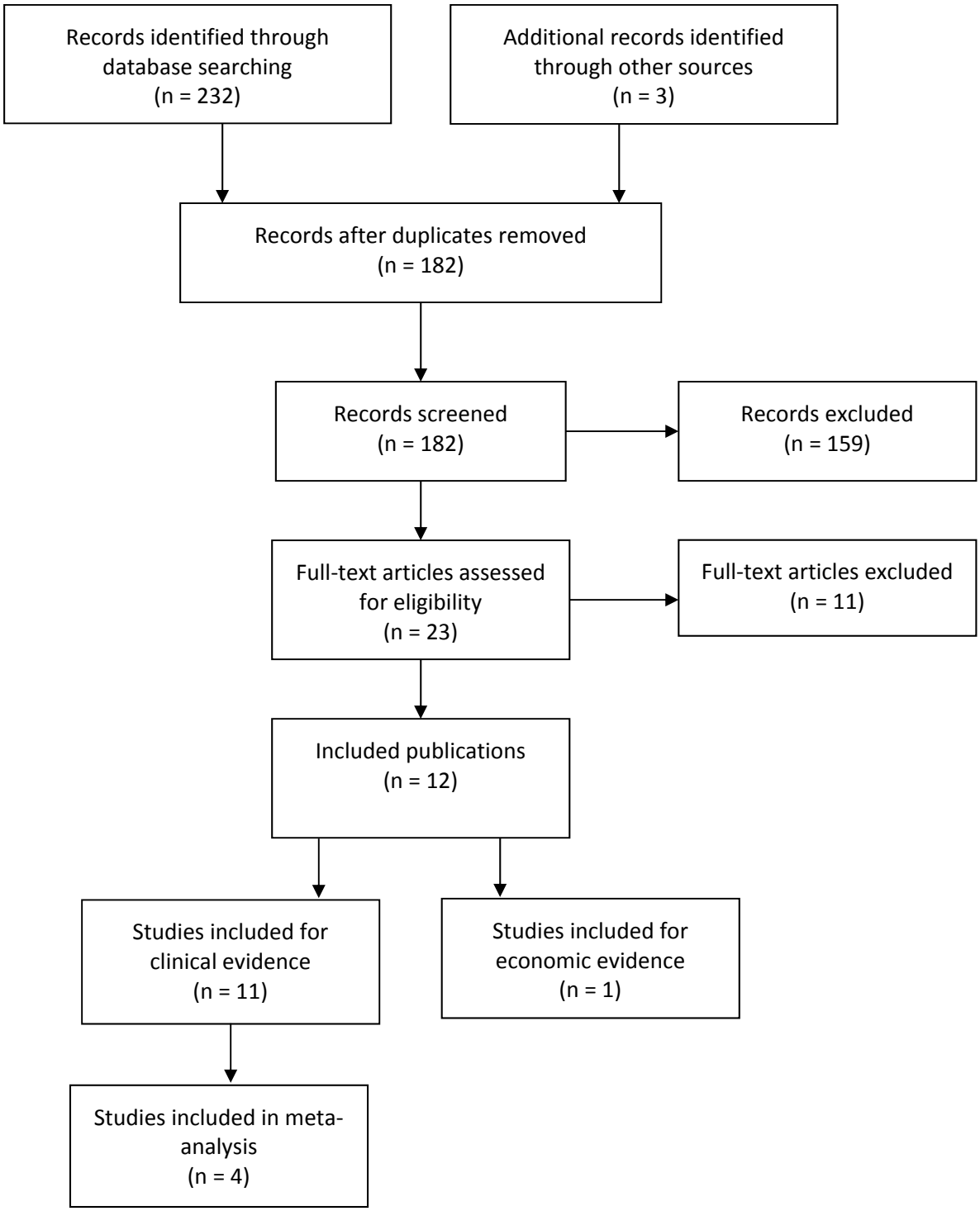
8 3 and 7 (149)

9 episcissors.tw. (9)

10 8 or 9 (154)

11 limit 10 to (english language and yr="2010 -Current") (57)

EAC Study Selection



Appendix B: Critical Appraisal Checklists

Systematic Review

AMSTAR 2 Results for Divakova, O. et al. (2019) DOI: 10.1007/s00192-019-03901-4

Divakova, O. et al. (2019) DOI: 10.1007/s00192-019-03901-4 is a Critially Low quality review

1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	No
3. Did the review authors explain their selection of the study designs for inclusion in the review?	No
4. Did the review authors use a comprehensive literature search strategy?	Partial Yes
5. Did the review authors perform study selection in duplicate?	Yes
6. Did the review authors perform data extraction in duplicate?	No
7. Did the review authors provide a list of excluded studies and justify the exclusions?	No

8. Did the review authors describe the included studies in adequate detail?	Partial Yes
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	
NRSI	No
10. Did the review authors report on the sources of funding for the studies included in the review?	Yes
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	
NRSI	Yes
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	No
13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?	No
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	No
15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	No
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes

To cite this tool: Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, Moher D, Tugwell P, Welch V, Kristjansson E, Henry DA. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017 Sep 21;358:j4008.

Observational Studies

Study name: Freeman et al (2014)		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Y	As this was a proof of concept study, the small sample size and no comparator group are appropriate
Was the exposure accurately measured to minimise bias?	Y	
Was the outcome accurately measured to minimise bias?	Y	A blinded investigator measured the post-suture angle
Have the authors identified all important confounding factors?	N	Proof of concept study, no analysis on confounders
Have the authors taken account of the confounding factors in the design and/or analysis?	N	Proof of concept study
Was the follow-up of patients complete?	N/A	No patient follow-up
How precise (for example, in terms of confidence interval and p values) are the results?	Not Clear	No statistical analyses performed. Outcome was clinician reported satisfaction with the device. Some changes made as a result of the feedback from clinicians
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Study name: Patel et al 2014		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Y	
Was the exposure accurately measured to minimise bias?	Y	
Was the outcome accurately measured to minimise bias?	Not Clear	Outcome measurement not blinded
Have the authors identified all important confounding factors?	Not Clear	No comparator but authors discuss possible reasons why results differ from other studies
Have the authors taken account of the confounding factors in the design and/or analysis?	N	
Was the follow-up of patients complete?	N/A	No follow-up
How precise (for example, in terms of confidence interval and p values) are the results?	Not Clear	No confidence intervals or p-values as no comparator. Results presented as a median with range and standard deviation
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Study name: Sawant et al (2015)		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Y	The study describes itself as similar to block cluster randomised study however as there is no clear details around the randomisation process and the study appears to compare the outcomes of two time periods on a ward, this is considered to be an observational study. For an observational study the cohort was recruited in an acceptable manner
Was the exposure accurately measured to minimise bias?	Y	
Was the outcome accurately measured to minimise bias?	Not Clear	Outcome measure not blinded
Have the authors identified all important confounding factors?	N	No mention/discussion of possible confounders
Have the authors taken account of the confounding factors in the design and/or analysis?	N	No analysis investigating possible confounders
Was the follow-up of patients complete?	N/A	No patient follow-up
How precise (for example, in terms of confidence interval and p values) are the results?	Precise	Results can be considered precise for the primary outcome (post delivery distance from midline); two tailed t-tests performed and p value presented. Study was not powered for rate of OASIS therefore results presented as a number of OASIS with each type of scissors (no p values, statistical analysis)
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Study name: Van Roon et al (2015)		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Y	
Was the exposure accurately measured to minimise bias?	Y	
Was the outcome accurately measured to minimise bias?	Unclear	Comparison was made with historical data however the dates (length of time) this historical data was compared with is not clear. It seems as though 6 months Episcissors data was compared with 12 months historical data. Not clear as to who conducted outcome measurements.
Have the authors identified all important confounding factors?	N	No discussion as to how the different length of time for the intervention and historical data might impact results. No discussion on whether there might be a short term impact following introduction of Episcissors due to training/greater awareness Not clear if practices differ at each hospital
Have the authors taken account of the confounding factors in the design and/or analysis?	N	
Was the follow-up of patients complete?	N/A	No patient follow-up
How precise (for example, in terms of confidence interval and p values) are the results?	Unclear	p-values reported for comparisons however some of the results are not clearly reported and there appears to be some selective reporting of statistical results in the text of the paper.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Study name: Mohiudin et al (2018)		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Y	
Was the exposure accurately measured to minimise bias?	Y	
Was the outcome accurately measured to minimise bias?	Unclear	The outcome data were compared with date from a 'before' period (historical controls) however no details were provided about the historical data. Dates not clear for before or after
Have the authors identified all important confounding factors?	Y	The authors highlight the introduction of other measures to prevent OASIS at the same time as Epcissors
Have the authors taken account of the confounding factors in the design and/or analysis?	N	The authors assume that these interventions would be practiced equally between episiotomy and non-episiotomy groups which seems reasonable.
Was the follow-up of patients complete?	N/A	No follow-up
How precise (for example, in terms of confidence interval and p values) are the results?	Precise	p- values reported
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Study name: Ayuk et al (2018)		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Y	Nine maternity units invited to participate.
Was the exposure accurately measured to minimise bias?	Y	Objective measures
Was the outcome accurately measured to minimise bias?	Unclear	The outcome data were compared with date from a 'before' period. The times periods of data collection for before and after are not clear.
Have the authors identified all important confounding factors?	Unclear	The authors mention confounding variables in the discussion but other than parity not stated which factors were considered.
Have the authors taken account of the confounding factors in the design and/or analysis?	Y	The authors designed the study to account for the impact of EpiScissors alone and excluded any units that had introduced other measures.
Was the follow-up of patients complete?	N/A	No patient follow-up.
How precise (for example, in terms of confidence interval and p values) are the results?	Unclear	No confidence intervals presented only p-values
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Appendix C: GRADE Assessment

Episcissors-60 compared to Standard Episiotomy Scissors for women requiring an episiotomy

Certainty assessment						
№ of participants (studies) Follow-up	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall certainty of evidence**
Rate of Obstetric Anal Sphincter Injuries						
5697 (5 observational studies[1-5])	serious [a]	not serious	not serious	not serious	none	⨁◯◯◯ VERY LOW
Post Delivery Suture Angle						
188 (5 observational studies[1-2, 6-7, 9]) [b]	serious [c]	serious [d]	not serious	not serious	none	⨁◯◯◯ VERY LOW
Episiotomy Length						
63 (1 observational study[2])	serious [e]	not serious	not serious	not serious	none	⨁◯◯◯ VERY LOW
Perineal Body Length						
100 (1 observational study[1])	serious [f]	not serious	not serious	serious [g]	none	⨁◯◯◯ VERY LOW

CI: Confidence interval

Explanations

a. Some of the included studies assessed a bundle of interventions, some were abstracts only and could not be quality assessed, one is a project report that has not been published
b. Numbers reported in the published literature are not clear in all studies. Comparator data from the 'before' periods are not always provided in detail. Care should be taken when interpreting these results.
c. None of the studies were randomised trials. Two of the studies were non-comparative. The studies did not detail who performed the episiotomy (midwife, consultant etc) or level of experience.
d. Reported as means or medians. Cannot pool the results based on the different methods of reporting the same outcome. This might make it more difficult to compare results across the studies.
e. Described as a randomised trial however this is an observational 'before-and-after' study
f. Not a randomised trial, no comparison with the 'before' period
g. Data were collected from two hospitals however each hospital used different reporting systems and results are presented for a subset of patients (n=100) who had episiotomy with Episcissors-60 with no comparator.

References

1. vanRoon (2015)
2. Sawant (2015)
3. Mohiudin (2018)
4. Ayuk (2018)
5. Condell (2017)
6. Freeman (2014)
7. Patel (2014)
8. Farnworth (2018)
9. Lou (2016)

Appendix D Model Changes

Table 1: Model Checks

Model checks were made on the corrected company base case

Sheet Title	Cell	Parameter	Test	Impact	Results
Intervention costs	E15	Cost of Episcissors	Increase the cost of Episcissors to £320 per use	Episcissors-60 would not be expected to be cost saving in the scenario	Cost of Episcissors for 94,000 Episiotomies increases to £30,080,000 Incremental cost: Episcissors becomes cost incurring in the base case (-£25.07)
Intervention costs	E15	Cost of Episcissors	Cost of Episcissors is equal to cost of standard scissors	Episcissors-60 should be more cost saving in this scenario as the rates of OASIS are lower in the Episcissors-60 group	Cost of Episcissors is £24,400 Incremental cost saving is £22.93 compared with £20.57.
Resource use intervention	E28	Cost of excess LOS	Length of stay increases by 5 days for an OASIS repair	There is a lower rate of OASIS in the Episcissors-60 arm, therefore fewer patients incurring the excess length of stay. Incremental cost savings should increase	Cost in the model increases to £3330 Incremental cost saving is £57.29
Probabilities Intervention	I15	Rate of OASIS repair	Increase the rate of OASIS in the Episcissors arm to reflect no change	If the introduction of Episcissors-60 makes no difference to the rate of OASIS then it should be cost incurring to introduce it as the cost of Episcissors-60 is greater than the cost of standard scissors	Rate in the model increases to 2.9% Episcissors becomes cost incurring (-£2.36)

Table 2: Corrections to company model

Sheet Title	Cell	Company Value	EAC Value	Comment
Standard Episiotomy Scissors				
Comparator Costs	E15	£88,000	£188,000	The EAC note that the cost value the manufacturer has input into the model (£88,000) does not correspond to a cost per scissors or per birth. The value is entered into the model as a total cost therefore the EAC cannot check the calculation that resulted in the £88,000. The EAC assume this is an error in input as the cost of standard scissors would be £188,000 (£2*94000)
Sensitivity Analysis				
Probabilities Comparator (worst case)	J15	2%	0%	Thiagmoorthy et al reported a lower rate value of 0%

Probabilities Comparator (best case)	K15	4%%	8%	Thiagmoorthy et al reported an upper rate of 8%
Probabilities Intervention (worst case)	J15	2.3%	0%	Using lower rate, the worst case scenario would be that Episcissors-60 reduces OASIS by 20% from the lowest rate of OASIS prior to Episcissors. In this situation, the lowest rate of OASIS reported in Thiagmoorthy et al was 0%, therefore the worst case scenario is that the introduction of Episcissors-60 has no impact (cannot reduce 0% by 20%).
Probabilities Intervention (best case)	K15	1.4%	4%	Using upper rate, the best case scenario would be that Episcissors-60 reduces OASIS by 50% from the highest rate of OASIS reported prior to Episcissors. In this case, the best case scenario is that the introduction of Episcissors reduces the rate of OASIS from 8% to 4%.

Table 3: Changes to company model

Sheet Title	Cell	Company Value	EAC Value	Comment
Population in the Model				
Model Set-up	E12	626,203	94,000	The company value represents the total births in one year (England only). The scope for the Assessment Report is women with a clinical indication of episiotomy therefore the EAC have used a value representing the proportion of women who will have an episiotomy (15% of total births) as the patient cohort in the model
Probabilities in the Model				
Probabilities Intervention	I15	1.6%	3.1%	Represents the a 2% absolute reduction as identified in the meta-analysis
Probabilities Comparator	I15	2.85%	5.1%	Represents the rate of OASIS in nulliparous women (Maternity Indicators report)
Standard Episiotomy Scissors				
Comparator Costs	E15	£2 per episiotomy £0.30 per birth	[redacted] £0.26 per episiotomy	The EAC identified a cost per reusable episiotomy scissors on NHS Supply chain.
OASIS Repair				
Resource Use Intervention	E27	£1538 exc Market Forces Factor (MFF)	£1956	The EAC used Reference Costs 2017/18 (NZ27Z)
Excess Bed Days				
Resource Use Intervention	E28	£333	£366	The EAC used Non-Elective Excess Bed Days. NZ27Z National Reference Costs 2017-2018 Cost is £731 per day. The cost in the model is based on 0.5 excess days (Orlovic et al 2017).
Sensitivity Analysis				
Probabilities Comparator (worst case)	J15		6.5%	High rate of OASIS reported in nulliparous women in the maternity indicators report

Probabilities Comparator (best case)	K15		3.7%	Low rate of OASIS reported in nulliparous women in the maternity indicators report
Probabilities Intervention (worst case)	J15		7.7%	Based on a possible absolute increase of 1% (meta-analysis confidence intervals)
Probabilities Intervention (best case)	K15		1.5%	Based on a possible absolute decrease of 5% (meta-analysis confidence intervals)

Addendum to the Assessment Report: Episcissors-60 for guided mediolateral episiotomy

Additional Study, published after submission of the Assessment Report

Searches for the Assessment Report identified a study document which reported the results of a study investigating the impact of Episcissors-60 on rates of OASIS, however this report, although published and publically available, had not been peer reviewed at the time of submission.

The EAC however considered it to be an important study which included detailed information on the number of women who underwent and episiotomy. The EAC therefore critically appraised the study report (see Assessment Report) and included the results from the study in the table of included and excluded studies (section 3.3). In addition, the EAC used the episiotomy data in the meta-analysis (section 3.8). Following submission, a Pre-Proof version of the peer reviewed article was made available online (Ayuk et al, 2019) and the EAC considered that is would be appropriate to present a full discussion of the outcomes and results reported.

Ayuk et al investigated the impact of Episcissors-60 in isolation (no other interventions) on the rates of OASIS in a cohort of 19256 women (11,192 before Episcissors-60 and 8,064 after Episcissors-60) and reported no significant association with Episcissors-60 and performance of an episiotomy (X^2=0.006, p=0.94). No significant association was reported between the introduction of Episcissors-60 and the rates of OASIS in all women (X^2=0.6, p=0.46) or in women who had an episiotomy (X^2=0.20, p=0.71).

Three way log linear analysis indicated that the third order interaction (Episcissors-60 introduction/Episiotomy/OASI) was not significant, nor was the two way interaction (Episcissors-60 introduction/OASI) whereas the two way interaction between performance of an episiotomy and OASI was significant. This suggests that the performance of an episiotomy reduces the occurrence of an OASI but that this effect is not impacted by the introduction of Episcissors.

Although not an outcome for the study, increased blood loss was reported by clinicians using Episcissors-60 and so study investigaotrs requested data on delivery blood loss. There was a small but statistically significant increase in blood loss in women who had an episiotomy after the introduction of Episcissors-60. One centre modified practice to facilitate rapid repair of Episcissors-60 episiotomies as a result of their experience. Possible reasons put forward by the authors for the increased blood loss include

- Episiotomies with Episcissors-60 are longer than with standard scissors
- Episcissors-60 are recognized to be sharper than other scissors and sharp dissection in associated with greater blood loss
- Angle of Episcissors-60 may result in cutting of major blood vessels

It should be noted that it is recognized that clinicians underestimate blood loss and blood loss was not an a priori outcome therefore these results should be interpreted with caution.

Cost Results using the Divakova meta-analysis results

Ayuk et al (2018) and Condell et al (2017) are both studies which although published and available in the public domain, have not been through a formal peer review process as with articles published in journals. Excluding these two studies essentially replicates the results of the systematic review (Divakova et al, 2019) and suggests an absolute reduction of OASIS of 4% following introduction of Episcissors (-0.04 (-0.07 to -0.01); p=0.005). The EAC has included the results of the cost analysis using the results of the meta-analysis without these two studies. Episcissors-60 is cost saving in all scenarios (table 1).

Figure 1: Meta-analysis results excluding Ayuk and Condell

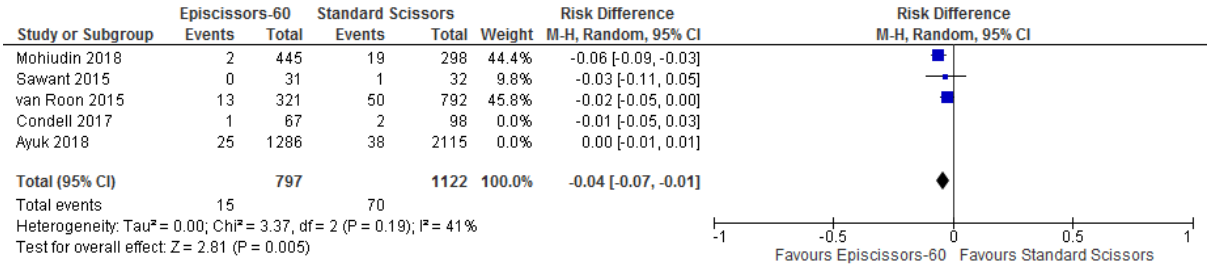


Table 1: Comparison of cost savings using EAC meta-analysis results compared with Divakova (2019) meta-analysis results

	Base-case	Lowest estimate*	Highest estimate*
Range of cost-savings with device (EAC meta-analysis including Ayuk and Condell)	£30.70	-£38.96	£70.17
Range of cost-savings with device (Divakova)	£77.14	£7.48	£70.17
*Based on the upper and lower confidence intervals			

Cost Results using the Ayuk results only

Although Ayuk et al (2018) has not been published in a peer reviewed journal, the study represents the largest study available. Conducted across 9 maternity units in the UK, the study reported data from 19,256 women including 3401 (17.6%) who had an episiotomy. Ayuk et al (2018) reported no significant difference in OASIS rates between episiotomy with Episcissors-60 and standard scissors (absolute reduction of 0% (-1% to 1%), p=0.76).

Using these rates in the EAC base case Episcissors-60 becomes cost incurring in the base case and worst case scenarios suggesting that when Episcissors-60 makes no change to OASIS rates or leads to a possible increase in OASIS rates, Episcissors-60 will be cost incurring. In the best case scenario in which there is a reduction in OASIS rates, Episcissors-60 is cost saving (£7.48)

Table 2: Comparison of cost savings using EAC meta-analysis results compared with Ayuk results only

	Base-case	Lowest estimate*	Highest estimate*
Range of cost-savings with device (EAC meta-analysis including Ayuk and Condell)	£30.70	-£38.96	£70.17
Range of cost-savings with device (Ayuk only)	-£15.74	-£38.96	£7.48
*Based on the upper and lower confidence intervals			

Cost Results without Excess Length of Stay

NHS reference cost NZ27Z includes some costs related to length of stay. It is not clear whether there is an excess length of stay over and above what is already factored into the cost 'Post-natal therapeutic procedures'.

Excluding the cost of an excess length of stay from the model results in a reduction in the cost savings associated with Episcissors-60.

Table 3: Impact of excess length of stay on cost savings

	Base-case	Lowest estimate	Highest estimate
Range of cost-savings with device (EAC base case with 0.5 days excess length of stay	£30.70	-£38.96	£70.17
Range of cost-savings with device (EAC base case no excess length of stay)	£23.38	-£35.30	£56.63
Range of cost-savings with device (Company base case with 0.5 days excess length of stay	£20.57	-£2.36	£72.48
Range of cost-savings with device (Company base case no excess length of stay)	£16.49	-£2.36	£59.16

Threshold Analysis

Threshold analysis shows how the rate of OASIS in both the standard scissors arm and the Episcissors-60 arm impacts the cost savings. The higher the rate of OASIS in the standard scissors arm and the greater the impact of Episcissors-60 in reducing the rate of OASIS, the more cost saving Episcissor-60 is likely to be. If Episcissor-60 does not reduce the rate of OASIS or if there is any increase in the rate of OASIS compared with standard scissors, then Episcissors-60 would be cost incurring.

Figure 2: Threshold Analysis using Company Base Case

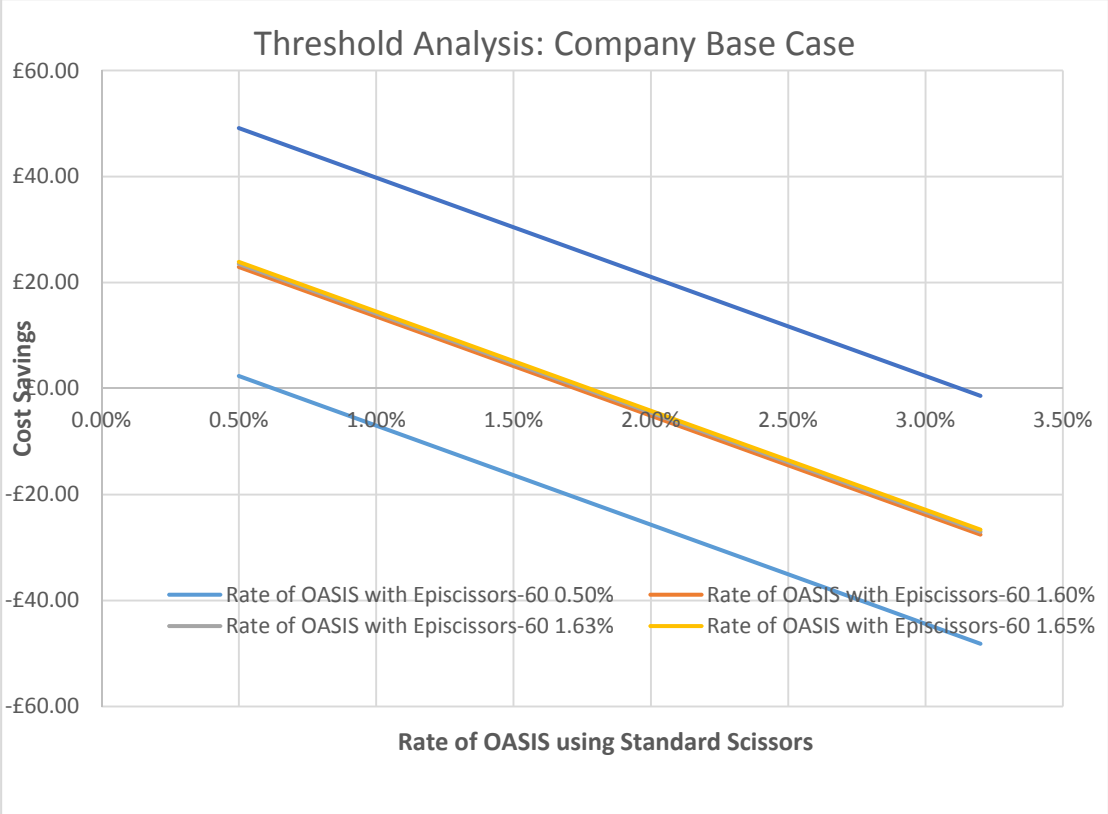
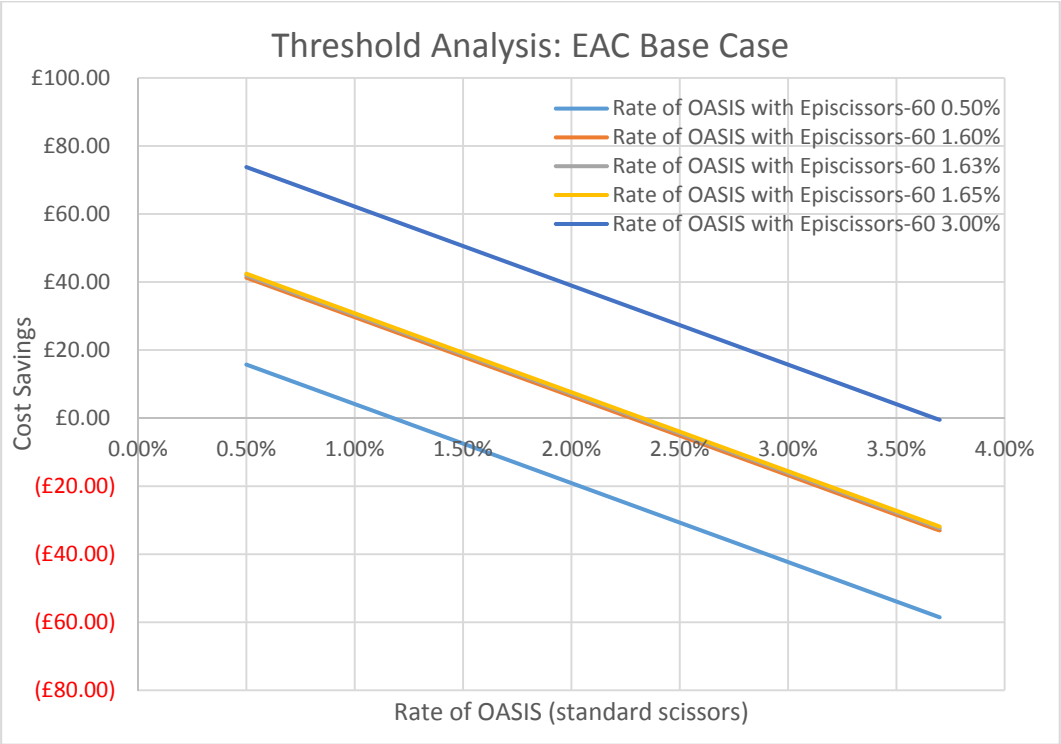


Figure 3: Threshold Analysis using EAC Base Case



NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

Assessment report overview

Episcissors-60 for guided mediolateral episiotomy

This assessment report overview has been prepared by the Medical Technologies Evaluation Programme team to highlight the significant findings of the External Assessment Centre (EAC) report. It includes **brief** descriptions of the key features of the evidence base and the cost analysis, any additional analysis carried out, and additional information, uncertainties and key issues the Committee may wish to discuss. It should be read along with the company submission of evidence and with the EAC assessment report. The overview forms part of the information received by the Medical Technologies Advisory Committee when it develops its recommendations on the technology.

Key issues for consideration by the Committee are described in section 6, following the brief summaries of the clinical and cost evidence.

This report contains information that has been supplied in confidence and will be redacted before publication. This information is highlighted in [redacted]. This overview also contains:

- Appendix A: Sources of evidence
- Appendix B: Comments from professional bodies
- Appendix C: Comments from patient organisations
- Appendix D: Additional analyses carried out by External Assessment Centre
- Appendix E: Decision problem from scope

1 The technology

Episcissors-60 are adapted surgical scissors made from stainless steel used to perform an incision for mediolateral (that is, a cut from the vagina at an angle off to one side of the anus) episiotomies. There are reusable and single use versions. The reusable version is being phased out and replaced with a single use version. Both versions are being considered within the scope of this evaluation, but evidence was only available for the reusable version. The scissors have 5-centimetre long blades with a guide-limb mounted at the blade pivot point and angled at 60 degrees from the blades. A cutting angle of 60 degrees is ensured by positioning the guide limb pointing towards the anus in the vertical perineal midline. The aim of Episcissors-60 is to prevent inaccurate visual estimation of the cutting angle and so reduce the incidence of obstetric anal sphincter injuries (OASIS).

Episcissors-60 was CE-marked as a Class I medical device in March 2014. The single use version is planned to launch in the NHS in June 2019 after which the reusable version will be phased out. Episcissors-60 are currently made by 2 manufacturers under license from MEDINVENT LTD.

2 Proposed use of the technology

2.1 Disease or condition

15.2% of all births in England between 2011 to 2012 required an episiotomy (HES online). Between April 2015 and March 2016, out of 325,816 women in England who had a vaginal birth of a singleton cephalic baby at term (a single baby presenting head-first), 21.6% had an episiotomy. In those delivering spontaneously, 8.5% had an episiotomy. In those requiring instrumental delivery, 85.5% had an episiotomy (National Maternity and Perinatal Audit, RCOG 2017). OASI is a major complication of vaginal births. It is a tear that extends into the anal sphincter and/or anal mucosa. Between April 2015 and March 2016, 7.8% of nulliparous women and 4.8% of multiparous women sustained OASIS in operative vaginal or instrumental deliveries in England (National Maternity and Perinatal Audit, RCOG 2017). In the UK, all OASIS

are repaired as soon as possible after birth, with the aim of reducing long term incontinence. However, the risk of complications remain high despite repair (National Maternity and Perinatal Audit, RCOG 2017). A meta-analysis found that 30% of women who had an OASI still had symptoms 1 year after childbirth (Oberwalder et al. 2003). Symptoms include faecal urgency, inability to control wind and uncontrolled bowel movements (Dudding et al. 2008).

2.2 Patient group

Nulliparous women (women who have not given birth before) are more likely to sustain an OASI. Instrumental births in nulliparous women also increases the risk of OASIS. Ethnicity is a relevant subgroup identified, since some women of Asian family origin may be more at risk of OASIS. It has been suggested that this may be due to a short perineal body length (Patel et al. 2014).

2.3 Current management

NICE clinical guideline on intrapartum care for healthy women and babies recommends that an episiotomy should only be performed if there is a clinical need, such as an instrumental birth or suspected fetal compromise. Routine episiotomy is not indicated during spontaneous vaginal birth or after third or fourth-degree tears from previous childbirth. An episiotomy should be mediolateral, originating at the vaginal fourchette and directed towards the right side. The angle of the cut to the vertical axis at the time of episiotomy is recommended to be 45 to 60 degrees. Tested effective analgesia should be provided before carrying out an episiotomy, except in emergency cases such as acute fetal compromise. A routine episiotomy should not be offered during spontaneous vaginal birth or at vaginal birth after previous third- or fourth-degree trauma.

Similarly, the Royal College of Obstetricians and Gynaecologists' (RCOG) guidance on The Management of Third and Fourth Degree Tears recommends that an episiotomy should be mediolateral and should only be performed if clinically indicated. The cutting angle is advised to be 60 degrees from the midline at the time of episiotomy. In 2017, an OASI care bundle was

piloted with the aim of reducing rates of OASIS. The care bundle includes raising awareness, use of manual perineal protection, perineal examination and episiotomy when indicated at 60 degrees at crowning. More information can be found here: The OASI Care Bundle Project, RCOG.

The NICE clinical guideline on faecal incontinence in adults: management recommends that women with OASIS are identified as high risk for faecal incontinence. Women should be treated with condition-specific interventions as well as general measures for faecal incontinence. General measures include coping strategies, incontinence pads, anti-diarrhoeal medicines and pelvic floor muscle training.

2.4 Proposed management with new technology

Episcissors-60 are designed to achieve a mediolateral cut at 60 degrees to the perineal midline, so preventing inaccurate visual estimation of the cutting angle. The device aims to reduce the incidence of OASIS. Episcissors-60 are an alternative to current standard episiotomy scissors where visual estimation of the cutting angle is required.

3 Company claimed benefits and the decision problem

Table 1 Changes to the decision problem

Decision problem	Variation proposed by company	EAC view of the variation
Population – women who have a clinical need for an episiotomy such as for instrumental deliveries or in cases of suspected fetal compromise	No variation	-
Intervention – Episcissors-60	No variation	The published evidence relates to the reusable version of episcissors-60 only. The reusable version is currently being phased out and replaced with a disposable version.
Comparator – standard episiotomy scissors	No variation	This will include both reusable and disposable standard episiotomy scissors.

Outcomes – Procedural outcomes • Device related adverse events • Incidence and severity of OASIs • Complication rates (wound breakdown, wound infection, anal incontinence, and post-partum haemorrhage • Ease of use of instrument including handedness • Operator learning curve • Cost of complications (including OASI repair) Duration of follow-up should be sufficient to capture all relevant complications • Post delivery suture angles • Length of episiotomy • Post delivery distance from midline Patient Outcomes • Length of stay • Quality of life	No variation	-
Cost analysis - Comparator(s): • Standard reusable episiotomy scissors • Standard disposable episiotomy scissors Costs will be considered from NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	No variation	Long term costs associated with OASIS were not included in the model.

Subgroups – ethnicity	Results for subgroups were not reported	The evidence did not include any information on subgroups but did include studies in India. Women of Indian subcontinent origin may be more at risk of OASIS.

4 The evidence

4.1 Summary of evidence of clinical benefit

The company submitted 2 systematic reviews (Divakova et al, 2019 and Cole et al, 2019) which included data from 5 observational studies (Freeman et al, 2014; Patel et al, 2014; Sawant et al, 2015; van Roon et al, 2015; Mohiudin et al 2018). They also submitted an additional observational study (van Roon et al, 2016), 1 conference abstract (Lou et al, 2016) and data from one unpublished study was provided academic in confidence, (Koh et al). The observational studies included in the systematic reviews consisted of 1 proof of concept study (Freeman et al, 2014), 1 comparative cohort study (Sawant et al, 2015), 1 non-comparative case-series study (Patel et al, 2014) and 2 before and after studies (van Roon et al, 2015 and Mohiudin et al, 2018).

The EAC undertook their own literature search, identifying a total of 11 studies for inclusion. This encompassed 7 published studies, and 4 publicly available but non peer-reviewed studies for inclusion, including two abstracts (Condell et al. 2017 and Farnworth et al. 2019), a before and after study (Ayuk et al. 2018) and an observational study (Lou et al. 2016). The study by Ayuk et al. has since been peer reviewed and published. Van Roon et al, 2016 was excluded by the EAC as this compared clinicians' ability to cut episiotomies at the recommended 60° angle with standard episiotomy scissors compared with Episcissors-60 in a birth simulation model and did not include patients. The rationale for the study selection is described in section 3.2 and 3.3 of the assessment report. The EAC noted that the clinical evidence base is limited to a small number of non-comparative studies and before and after studies.

Table 2 Included studies

Studies included by both EAC and company	
Publication and study design	8 studies included by both (2 before and after studies, 1 cohort study, 1 case series, 1 proof of concept study, 1 conference abstract, 1 systematic review, 1 systematic review with meta-analysis)
Reference	Before and after studies: Van Roon 2015, Mohiudin 2018 Cohort study: Sawant 2015 Case series: Patel 2014 Proof of concept study: Freeman 2014 Observational study (publicly available, non peer-reviewed): Lou 2016 Systematic review: Cole 2019 Systematic review with meta-analysis: Divakova 2019
Studies in submission excluded by EAC	
Publication and study design	1 observational study and 1 unpublished study
Reference	1 observational study: Van Roon 2016 1 unpublished study: Koh 2019
Additional studies not in submission included by EAC	
Publication and study design	2 abstracts and 1 before and after project report
Reference	Abstracts (publicly available, non peer-reviewed): Condell 2017, Farnworth 2019 Before and after project report: Ayuk 2018

A comparative cohort study (Sawant et al, 2015) and a non comparative case series study (Patel et al, 2014) were both conducted in Indian hospitals. These have been included as the company states that Asian women may be more at risk of OASIS and these studies provide evidence of the possible benefit of Episcissors-60 in this patient group which may be applicable to the UK setting. However, the EAC noted 2 important issues raised in the company submission with the Sawant et al, 2015 study. It is described as a randomised trial, which the EAC disagrees with since no formal randomisation processes were used. The company submission states that Sawant et al, 2015 included multiparous women, however the EAC note that all women in the study were nulliparous.

Two before and after studies (Van Roon et al, 2015 and Mohiudin et al, 2018) were conducted in 4 UK hospitals in which there were approximately 1100 episiotomies, providing directly applicable evidence related to the use of Episcissors-60 in an NHS setting. However, full data for the number of

episiotomies using Episcissors-60 compared with standard scissors were not reported for all 4 hospitals making accurate comparisons of outcomes in the women getting episiotomies difficult.

The company submission included 2 systematic reviews (Divakova et al, 2019 and Cole et al, 2019) and one unpublished study (Koh et al). The EAC could not identify an overall summary, discussion or interpretation of evidence beyond text drawn from the systematic reviews. The EAC noted that both systematic reviews used quality assessment tools and assessed risk of bias for all studies. However, the authors of the reviews highlight that the currently available data is limited and low quality and should be interpreted with caution. The EAC note that there is a high risk of bias due to the fact that outcomes are measured differently across the studies and most studies do not clearly report their 'before' data for accurate comparison. In addition, studies do not all report who carried out episiotomies and suturing post-delivery. The EAC state that their additional identified studies did not change the conclusion in the quality of evidence.

Table 3 Summary of key studies

Study and design	Participants/ population	Intervention & comparator	Outcome measures	Results	Withdrawals	EAC Comments
Divakova (2019) Systematic review and meta-analysis. Searches up to September 2018. Studies Included: Van Roon (2015) Sawant (2015) Lou (2016) Mohiudin (2018)	Pregnant women who underwent mediolateral or lateral episiotomy with episcissors-60 or standard episiotomy scissors.	Episcissors-60 compared with standard episiotomy scissors	Rate of OASIs, episiotomy rate, post-delivery suture angle	Only Meta-analysis results are presented. *Rate of OASIs (3 studies):* Risk of OASIs is significantly lower with Episcissors-60 compared with standard episiotomy scissors in women who have an episiotomy • Episcissors-60: 15/797 • Standard Scissors: 70/1122 • RD = -0.04 (-0.07 to -0.01), p=0.005, I^2=41%. NNT=25 Risk of OASIs in all births (the denominator includes the total number of vaginal deliveries i.e. those who have had an episiotomy and those who have not had an episiotomy) is significantly reduced with Episcissors-60 (3 studies). • Episcissors-60: 125/3483 • Standard scissors: 295/4668 • RD = -0.02 (-0.04 to -0.01), p=0.002, I^2=59% *Episiotomy Rate before and after Episcissors-60 (3 studies)* There was no significant difference in episiotomy rate following introduction of Episcissors-60	None	Quality Assessment for each individual study was performed using a tool designed and tailored by the authors. There are no details on validation of the modified tool, though it was based on the national Heart, Lungs and Blood Institute tool for assessing before and after studies. It was modified to provide an overall score which is not recommended (Cochrane Collaboration). The review included data from one abstract (Lou et al, 2016) however the data in the abstract and the data used in the meta-analysis are different. The EAC have contacted the author of

				• Before (standard scissors): 29% (1160/4044) • After (Episcissors-60): 26% (829/3171) • RD: 0.03 (-0.04 to 0.10), p=0.44, I^2=92% *Post delivery suture angle (1 study)* • 12° difference in post delivery suture angles with Episcissors-60 closer to the recommended 40-60° • Episcissors-60 mean: 40.6° • Standard scissors mean: 28.3° • Mean Difference: 12.30 [9.51-15.09], p<0.00001		the review for clarification. There is a transcription error for van Roon 2015, before total events should be 791 not 792 in figure 2.
Cole (2019) Systematic Review. Searches up to May 2018. Studies Included: Freeman (2014) Patel (2014) Van Roon (2015) Sawant (2015) Mohiudin (2018)	Pregnant women who underwent mediolateral or lateral episiotomy with episcissors-60	Episcissors-60 compared with standard episiotomy scissors or no comparator (Freeman 2014, Patel 2014)	Rate of OASIs, episiotomy rate, post-delivery suture angle	No meta-analysis carried out. The results are presented narratively for each study. Results for the relevant studies are presented for each study individually below.	None	Quality assessments of individual studies were done using the Newcastle-Ottawa Scale and risk of bias was assessed using the Cochrane Risk of Bias tool.

Non-comparative studies were included.						
Freeman (2014) Case series proof of concept study. October 2011 to February 2012.	Women (n=17) giving birth via instrumental vaginal delivery requiring an episiotomy in 1 NHS hospital. Location: UK	Episcissors-60 prototype, no comparator	Ease of use of the Episcissors-60 prototype, clinical staff experience, rate of OASIS, post-delivery episiotomy angle	Ease of use of Episcissors-60: n=10 ‘strongly agree’ n=5 ‘tend to agree’ n=1 ‘neither agree nor disagree’ n=1 ‘strongly disagree’ Reasons for ‘tend to agree’ related to the length of the cut (e.g. the incision could not be extended because the blades were too short) Reason for ‘strongly disagree’ was that the user was left handed and unable to orientate herself into a position to align the scissors. N=1 patient sustained OASI (grade 3a) Mean post delivery angle: 42.4±7°. Median post delivery angle: 43° (95% CI 38.8-46°)	None	No details on the number of trainees or consultants providing feedback. It is not clear whether the feedback is provided on a per episiotomy basis or whether each response was from a unique trainee/consultant. Patient population represents a subset of relevant population as study population only involved women giving birth via instrumental delivery. The EAC note that small sample size with no comparator in a partially applicable population means potentially limited generalisability to wider population.

Patel (2014) Case series	Women (n=25) giving birth by spontaneous vaginal delivery requiring episiotomy in 2 maternity hospitals in India	Episcissors-60, no comparator	Pre suturing examination for OASI, post-delivery angle measured by obstetrician.	Median post-delivery suture angle: 50° (SD 3.5; IQR 48-54; range 45-55). No cases of OASI were reported.	None	Patient population represents a subset of relevant population as study population only involved women giving birth via spontaneous vaginal delivery. Small sample size with no comparator in a partially applicable population means potentially limited generalisability to wider population.
Sawant (2015) Cohort study. May 2014 to October 2014.	n=63 nulliparous women undergoing episiotomy for indications such as prolonged second stage of labour, instrumental delivery and foetal distress Location: India	Intervention: Episcissors-60 (n=31) Comparator: Braun-Stadler episiotomy scissors (n=32)	Post-delivery suture angle, Length of episiotomy, Distance from the caudal end of the episiotomy to the anus	Mean post-delivery suture angle was significantly different between the groups (p<0.0001): *Episcissors-60:* 40.6° (range 30-50; IQR 35-45; SD 5.7; 95% CI 38.6-42.6) *Standard Scissors:* 28.3° (range 20-45; IQR 25-30; SD 5.6; 95% CI 26.3-30.3) Post delivery distance from midline was significantly different between the groups (p<0.0001) *Episcissors-60:* 35mm (95% CI ±2.2; IQR 30-39mm; SD 6.29 *Standard Scissors:* 19.6mm (95% CI ±1.3; IQR 14.75-22.5; SD 6.6)	None	Small sample size with no comparator in a partially applicable population means potentially limited generalisability to wider population. The EAC noted that there were some discrepancies in the paper related to reporting between text and tables.

				Length of episiotomy was significantly different between the groups (p<0.0001) *Episcissors-60:* 47.2mm (95% CI±3.5) *Standard Scissors:* 40mm (95% CI±1.9) OASIs *Episcissors-60:* 0 *Standard Scissors:* 1 (grade 3)		Described in paper as randomised, however the EAC has classified this as a cohort study as no method of randomisation has been described. Powered to detect a difference in mean post delivery suture angle but not in rates of OASIs.
Van Roon (2015) Before and After Study. January 2015 to May 2015.	Nulliparous women (n=838) giving birth by SVD (n=589) or OVD (n=249) in 2 NHS hospitals. Hospital 1: n=197 Hospital 2: n=641 Location: UK	Intervention: Episcissors-60 Comparator: No details given, historical data using standard episiotomy scissors	Perineal Body Length (PBL), uptake of episiotomy, post suturing angles, effect on OASIS, user feedback	Data collection forms were completed for 100 nulliparous vaginal deliveries and these formed the basis for PBL measurements, post-episiotomy suturing angles and user feedback. Mean PBL • SVD: 37mm (SD 8.3, 95% CI 34-39) • OVD: 38mm (SD 8, 95% CI 35-40) • PBL followed normal distribution and average length similar to other studies Episiotomy Angles • SVD: 53° (SD 6.5, 95% CI 50.7-55.8) • OVD: 52° (SD 9.6, 95% CI=49-54)	None	The EAC noted some discrepancies in the reporting between text and tables. The EAC contacted the author of this study to seek clarification on how the figures were reported.

				• 100% of midwives and 86% of doctors achieved a post suture angle between 40° and 60°. Episiotomy Usage • Hospital 1: 16.5% increase in the number of episiotomies (59/60) in nulliparous OVDs after the introduction of Episcissors-60 compared with year 2014 (203/239) (p=0.003) • Hospital 2: 47% increase in the number of episiotomies (74/452) in nulliparous SVDs after the introduction of Episcissors-60 compared with year 2014 data (122/1084) (p=0.007) • Overall: 11% increase in episiotomy numbers (321/838) in nulliparous vaginal deliveries after the introduction of Episcissors-60 compared with year 2014 (667/3156) (p=0.08) OASIS Incidence • 14.2% reduction in OASIS in nulliparous OVDs given episiotomies (12/223, 5.4%) after the introduction of Episcissors-60 compared with year 2014 (37/583, 6.3%) p=0.7; RR 1.18 (discrepancy between study results table and text. Text reports 14.3%, p=0.2) • 84% reduction in OASIS in nulliparous SVDs (1/98, 1%) after the introduction of Episcissors-60 compared with year 2014 (13/208, 6.25%) (p=0.04) (text reports a p=0.003)		

				• 84% reduction in OASIS in nulliparous SVDs given episiotomy compared to those not given episiotomy (1% versus 6.9%) in 2015 p=0.001 • 18% reduction in OASIS in nulliparous (SVD+OVD) vaginal deliveries (49/838, 5.8%) overall after the introduction of Episcissors-60 compared with year 2014 (159/2238, 7.1%), p=0.22. User Feedback • 84% of users rated Episcissors-60 as 'good' to 'very good' (55% rated it very good).		
Mohiudin (2018) Before and After Study	Nulliparous women (n=2566) giving birth by SVD or OVD in 2 NHS hospitals Hospital 1: n=936 Hospital 2: n=1630 Location: UK	Intervention: Episcissors-60 Comparator: No details, historical data using standard episiotomy scissors	Number of OASIS cases	Hospital 1 (Royal Free) In *primiparous OVD* after implementation of the RCOG guidelines for the prevention of OASIS (including introduction of Episcissors-60): • OASIS rate decreased by 33% from 5.6% to 4.2% (p=0.4) • OASIS rate in episiotomy group was 2.6% versus 42% in the no episiotomy group (p=0.000) In *primiparous SVD* after implementation of the RCOG guidelines for the prevention of OASIS (including introduction of Episcissors-60): • OASIS rate decreased by 51% from 4.7% to 2.3% (p=0.24) • OASIS rate was 0% in the episiotomy group (using Episcissors-60) versus 4.7% in the no-episiotomy group (did not have an episiotomy so did not use Episcissors-60) (p=0.03)	None	Results presented separately for each hospital and only combined where possible due to a change in data management systems at one hospital during the study. Note that this study introduced a number of measures to reduce OASIS at the time of introducing Episcissors-60 and the results may reflect the impact of

				Hospital 2 (Barnett) In *primiparous OVD* after implementation of the RCOG guidelines for the prevention of OASIS (including introduction of Episcissors-60): • 73% proportional decrease in OASIS from 9.6% to 2% (p=0.001) • 8% proportional increase in episiotomy numbers from 86% to 91% • 83% reduction in OASIS in the episiotomy group in the before period compared with the after period (6.3% versus 0.6%; p=0.01) • OASIS rated declined in the no episiotomy group (31% versus 17%; p=0.24) In *primiparous SVD* after implementation of the RCOG guidelines for the prevention of OASIS (including introduction of Episcissors-60): • OASIS decreased by 51% from 5.5% to 2.3% (p=0.03) • 43% increase in number of episiotomies from 16.2% to 23.2% (p=0.005) • OASIS rate decreased from 6.6% to 0% (p=0.006) in women given episiotomies • 44% reduction in OASIS in women not given episiotomy from 5.4% to 3% (p=0.12)		these measures combined.

The EAC reviewed the individual studies included in the systematic reviews (Divakova et al, 2019 and Cole et al, 2019) and conducted a meta-analysis for outcomes of interest where there was enough data available. Table 3 outlines the studies included in the meta-analysis and the EAC's rationale for inclusion or exclusion.

The EAC excluded the study by Farnworth et al, 2019 since this is an implementation study and a companion report to Ayuk et al, 2018. The EAC also excluded van Roon et al, 2016 from their meta-analysis since this study is a simulation study.

The EAC included 2 publicly available but non peer-reviewed studies in their meta-analysis (a report by Ayuk et al, 2018 and an abstract by Condell et al, 2017) which reported rates of OASIS for Episcissors-60 and comparator standard scissors. The EAC were not able to assess Condell et al, 2017 for its quality as it does not provide enough detail. Ayuk et al, 2018 has since been published. A critical appraisal of Ayuk et al, 2018 was conducted (appendix B in the assessment report). The EAC state that the cohort in the Ayuk et al, 2018 study was recruited in an acceptable way, with 9 maternity units invited to participate. Objective measures were used, but the outcome data were compared with date from a "before" period. The time periods of data collection for before and after are not clear. The EAC also state that the authors mention confounding variables, including parity, but did not state which other factors were considered. The study looked at the intervention of Episcissors-60 alone, and excluded any units that had introduced other measures. Limitations of the study included lack of patient follow up and no reporting of confidence intervals (only p-values reported).

Table 4 Studies included and excluded in meta-analysis

Study	Freeman (2014)	Patel (2014)	Sawant (2015)	Van Roon (2015)	Lou (2016)	Condell (2017)	Mohiudin (2018)	Ayuk et al (2018)
Divakova 2019	x	x	✓	✓	✓	x	✓	x
Cole 2019	✓	✓	✓	✓	x	x	✓	x
EAC	x	x	✓	✓	x	✓	✓	✓
EAC Comment	Non comparative study – not appropriate to include in a meta-analysis	Non comparative study – not appropriate to include in a meta-analysis	Included the data for OASIS in episiotomy with Episcissors-60 versus OASIS in episiotomy with standard scissors	Included data for OASIS in nulliparous births (SVD+OVD) given episiotomy with Episcissors-60 versus OASIS in nulliparous births (SVD+OVD) given episiotomy with standard scissors	The published abstract does not report a denominator for the period of time that standard episiotomy scissors was used which means that the data cannot be included in a meta-analysis. (2019) comparing OASIS rates in episiotomy patients with and without Episcissors-60	Abstract Only – cannot comment on the quality of the data or methodology. Not included in either systematic review, not clear whether it was identified and excluded or whether it was not identified.	Only data from one hospital was included as the data from the second hospital in the study was not available for Episcissors-60 versus standard scissors	Unpublished data identified by the EAC. This was included by the EAC as it provides additional data for the meta-analysis specifically comparing outcomes in women who had an episiotomy using Episcissors-60 and standard scissors.

The EAC noted that two of the included studies (Mohiudin et al, 2018 and van Roon et al, 2015) state that other factors were introduced with the aim of reducing OASIS at the same time as Episcissors-60. For this reason, the EAC conducted a pooled analysis using a random effects model to calculate the risk difference in rates of OASIS between Episcissors-60 and standard scissors in women who had an episiotomy. Pooled analysis was also conducted for rate of episiotomy. Pooled analysis was not possible for any other outcome of interest as the outcomes were not reported in more than one study each. Figures 1 to 4 below indicate results from the pooled analysis.

Figure 1: Obstetric Anal Sphincter Injuries in deliveries with episiotomy performed with Episcissors-60 versus standard scissors including all studies with reportable data

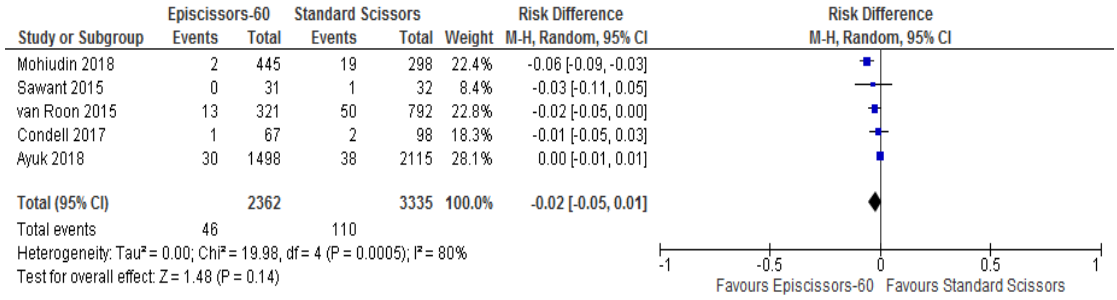


Figure 2: Obstetric Anal Sphincter Injuries in deliveries with episiotomy performed with Episcissors-60 versus standard scissors excluding studies which reported including other measures to reduce OASIS

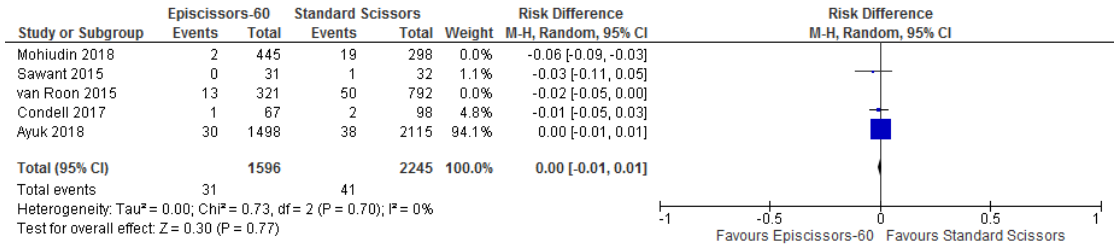


Figure 3: Obstetric Anal Sphincter Injuries in deliveries with episiotomy performed with Episcissors-60 versus standard scissors including only studies which reported including other measures to reduce OASIS

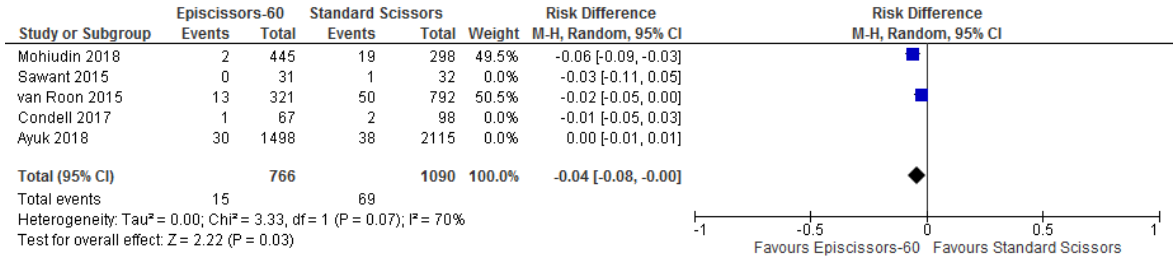
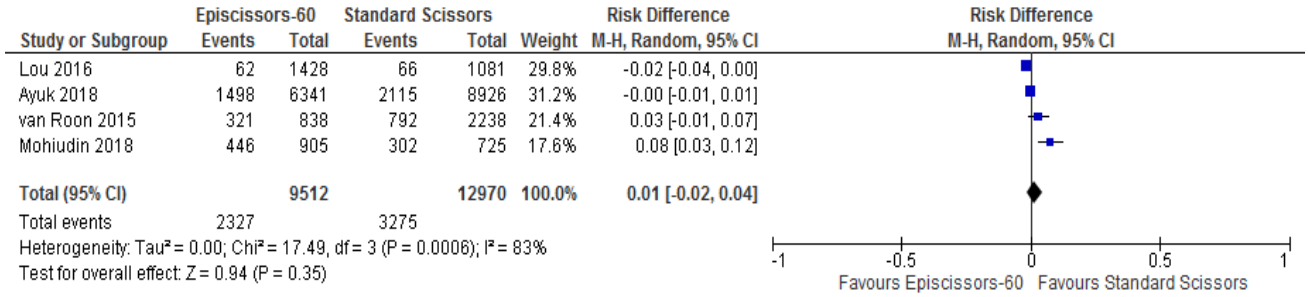


Figure 4: Rates of Episiotomy before and after the introduction of Episcissors-60



4.2 Summary of economic evidence

The company submission identified 5 economic studies from their search, excluding 4 of them. The excluded 4 studies were not listed, therefore the EAC were unable to comment on whether they were excluded appropriately. The EAC disagreed with the remaining company-identified study by Orlovic 2018, as it is not a study of Episcissors-60 and not relevant to the scope. The EAC excluded this study. The company listed an additional study by YHEC (2017), however the EAC noted that it is unclear whether this was identified in the search or another route. The EAC agreed with the inclusion of this study. The EAC did not identify any additional economic studies for inclusion.

De novo analysis

The company created a de novo cost analysis using a simple decision tree model with arms for Episcissors-60 and standard scissors. Each arm has 2 endpoints: OASI repair or no OASI repair. The time horizon is 1 year, so no discounting was applied and the perspective is the NHS. As the care pathway

is unaffected by the technology, the introduction of Episcissors-60 is an exchange of one instrument for performing an episiotomy for another, the EAC considered the structure of the company model to be appropriate. The model structure is demonstrated in section 8.1.4 in the company submission, and figure 5 in the assessment report.

The EAC disagreed with some of the inputs in the model. The EAC suggest that the population should be confined to those having an episiotomy (as in the scope), as opposed to all births. The EAC also suggest that the incidence of OASIS should be that for episiotomy births and not all births. The EAC checked the model calculations, with all performing as expected. Sensitivity analysis in the company's model was noted to vary the costs related to the intervention only. The EAC therefore varied costs in both the intervention and comparator in their one way sensitivity analysis.

The model includes a number of assumptions, as described in table 5.

Table 5 Model assumptions

Assumptions identified by the company	
Assumption	**EAC Comment**
The cost per use of standard episiotomy scissors is £2 giving a cost per birth of £0.30	The EAC note that the cost per use for standard episiotomy scissors was obtained by the company from a clinical contact. The total cost for standard scissors was calculated (£2x94,000 episiotomies) and included in the model. The EAC identified the cost of two brands of reusable episiotomy scissors which are sold in packs of ten and used these figures to calculate an average cost per use for a standard episiotomy scissors. This means that the EAC base case is based on comparing reusable scissors in both arms.
The cost per use of Episcissors-60 is £16 giving a cost per birth of £2.40	The EAC made no changes to the cost of Episcissors-60.

The cost of OASIS repair is £1,538	The EAC agrees with the codes used to identify this cost, however notes that the source used was the National Non Mandatory Tariff 2019/2020 without a market forces factor addition (MFF). Not adding the MFF is appropriate as this will be different for different providers. The EAC has used the 2017/2018 reference costs as this is more accurate reflection of the cost from the NHS perspective. The reference cost represents a range of post-natal therapeutic procedures of which OASIS repair is one.
The cost of excess bed day is £665.20	The EAC have used the NHS reference costs 2017/2018 for the cost of an excess bed day. The company states that they are using NHS reference costs 2019/20 however these are not available.
The incidence of OASIS is 2.85% (2-4%) of all births	This value is the incidence of OASIS for all births (episiotomy plus no episiotomy births). The EAC note that the median OASIS rate reported in Thiagamoorthy et al, 2014 was 2.85% (0-8%). The company has used the rates reported in the base case for the comparator. The EAC disagrees with this as the rate relates to OASIS in both episiotomy and no episiotomy births. The EAC has therefore used the rate of OASIS in episiotomy births reported in RCOG 2016 (5.1%) for the base rate and used the results from the meta-analysis (section 3.8) for the reduction in OASIS following introduction of Episcissors-60 (2% absolute reduction, range 5% reduction to 1% increase)
The reduction in OASIS using Episcissors-60 of 43%	43% is the percentage difference between the rate of OASIS before Episcissors-60 and the rate after Episcissors-60. The EAC considers the absolute rate reduction of ~2% as the best way of presenting this reduction and have used this figure.
Additional assumptions identified by the EAC	
OASIS incidence in the population of women needing episiotomy may differ from the incidence in all births, whereas the model assumes they are the same	The EAC note that the OASIS rates used in the company model are the rates of OASIS for the whole birth population. Women who have clinical indications for an episiotomy will likely be at risk of a tear which could be as severe as a third or fourth degree tear. There is evidence to suggest that if the angle of episiotomy is not within the

	safe range, there is a risk of OASIS resulting from the episiotomy. Therefore, it is feasible that the incidence of OASIS may be different in different populations. Published data suggest that the rate of OASIS in nulliparous women who have an instrumental birth can be as high as 7.8% of women sustained OASIS in operative vaginal or instrumental deliveries (OVD) compared with 5.4% of nulliparous women and 1.6% of multiparous women with spontaneous vaginal deliveries. One study (van Roon et al, 2015) reported a rate of OASIS of 5% in all births before Episcissors-60 compared with 6.3% in the episiotomy population. After introduction of Episcissors-60 the rate in all births was 4.2% compared with 4% in the episiotomy group.

The company base case results are presented in table 6.

Table 6 Company base case results

Cost category	**Company's base-case**		
	Episcissors-60	**Standard Episiotomy Scissors**	**Cost saving per patient**
Scissors (per birth)	£2.40	£0.14	-£2.26
OASI repair (per birth)	£24.98	£43.83	£18.85
Excess length of stay (per birth)	£5.41	£9.49	£4.09
Total	£32.79	£53.47	**£20.67**
Sensitivity analysis	**£29.92 (lowest)**		**£8.50 (highest)**

Costs and resource use

The comparator in the company model is disposable standard episiotomy scissors. The scope did not limit between disposable and reusable scissors and the EAC suggest that there may be a difference in the cost. The EAC has

included the cost of reusable standard scissors in the model which has a lower cost per use than the disposable cost identified in the company base-case. The EAC acknowledge that the cost of disposable standard scissors may be as high as that included by the company.

The costs in the EAC model for the technology and comparator are based on a cost per use for reusable scissors. The EAC assume that the cost of disposable scissors will be priced according to the cost per use of a reusable. The company confirmed this will be the case for the disposable Episcissors-60.

The EAC noted that there was an error in the calculation for the cost of standard episiotomy scissors in the submitted model. The total cost of standard scissors based on £2 per standard scissors, given 94,000 episiotomies should be £188,000 (£2*94,000) however the cost was entered into the model as £88,000. The EAC corrected this error and noted that the change made little difference to the results with a slight increase in cost saving from £20.67 to £20.83 per patient.

The company economic model has calculated the cost savings based on a cost per birth basis for both the standard scissors and Episcissors-60. This substantially lowers the cost of Episcissors-60 in the model from £16 per use to £2.40 per birth. The company has used a higher cost for standard scissors (£2) than that identified by the EAC. This cost has been assumed to be the cost of a single, disposable episiotomy scissor and has been included on a cost per birth basis at a cost of £0.30 per birth. The EAC did not identify any disposable episiotomy scissors on NHS Supply Chain and based their cost in the model on the cost of standard reusable scissors at a cost of £0.26 per use. The cost per birth using standard episiotomy scissors would be £0.04 per birth. The lower cost per use of standard episiotomy scissors identified by the EAC suggests that the cost savings with Episcissors-60 would decrease from £20.83 to £20.57 per patient. The corrected company base case was used when making comparisons with the model updated by the EAC.

Results

The EAC made a number of changes to the model submitted by the company. Many of the changes were corrections to calculations or minor changes to rates used in the model and overall there was a small impact on the base case.

The main change made by the EAC was to include only the episiotomy population (as opposed to all births) in the base case and a change in the base rates of OASIS to reflect the fact that the rate of OASIS may be higher in episiotomy patients. This resulted in an increase in the cost savings from £20.57 to £30.70 per patient. The EAC corrections for clinical variables and costs are summarised in table 7 and 8. The results of the EAC base-case are shown in table 8.

Table 7: EAC clinical corrections to company model

Item	Figure used in company base-case	Figure used by EAC	Source (those different from submission are highlighted)
Population	626,203	94,000	Episiotomy population only
Rate of OASIS before Episcissors-60	2.85%	5.1%	The company used the figures reported in Thiagamoorthy et al (2014). The EAC could not identify any published literature which provided sufficient data to use a base rate of OASIS in women with episiotomy only. Primiparous women (1st birth) are higher risk for OASIS therefore the EAC have used the mean rate of OASIS among vaginal deliveries in primiparous women reported in RCOG 2016 The EAC note that van Roon et al (2015) report a rate of OASIS of 6.3% in the episiotomy population but there is not enough data reported in this study to report low and high values.
Percentage Rate Reduction in OASIS in standard episiotomy scissors and Episcissors-60 (reported in Lou et al, 2016)	43%	2% (absolute reduction) 39% rate reduction	The EAC meta-analysis showed an absolute reduction of 2% in OASIS with Episcissors-60. The EAC has used this rate in their base case. This gives a probability of OASIS in the Episcissors-60 arm of 3.1%. This rate reduction is very similar to the rate used by the company (1.9%)

Table 8: EAC cost corrections to company model

Item	Cost used in company base-case	Cost used by EAC	Source (those different from submission are highlighted)
Standard Episiotomy Scissors	£2	£0.26	Standard reusable episiotomy scissors cost [redacted] on NHS Supply Chain.
OASIS Repair	£1538 exc MFF	£1956	NZ27Z National Reference Costs 2017-2018
Excess length of stay	£333	£366	Non-Elective Excess Bed Days NZ27Z National Reference Costs 2017-2018 Cost is £731 per day. The cost in the model is based on 0.5 excess days (Orlovic et al 2017).

Table 9 EAC base case results

Cost category	EAC's base-case		
	Episcissors-60	Standard Episiotomy Scissors	Cost saving per patient
Scissors (per birth)	£16	£0.26	-£15.74
OASI repair (per birth)	£60.64	£99.76	£39.13
Excess length of stay (per birth)	£11.35	£18.67	£7.31
Total	£87.98	£118.68	**£30.70**
Sensitivity analysis	**-£38.96 (lowest)**		**£70.17 (highest)**

The EAC noted that the values used by the company did not accurately represent the best and worst case OASIS rates. The lowest and highest rates of OASIS reported by Thiagamoorthy et al (2014) were 0% and 8% respectively, not 2% and 4% as included in the company submission. The EAC also noted that the company submission included one way sensitivity analysis which explored the impact of changing input parameters in the intervention arm only, and the only included parameter was OASIS rates.

The EAC made corrections to the best and worst case scenarios and conducted one-way sensitivity analysis to explore the impact of changing inputs in both the intervention and comparator arm, and varying other input parameters in addition to OASIS rates. The model was cost saving in all

cases when varying the cost of Episcissor-60, cost of standard scissors, cost of OASIS repair and excess length of stay. The key driver in the model was the OASIS rate in the comparator (standard scissors) arm. The lower the baseline OASIS rate, the less of an impact Episcissors-60 can have on OASIS rates, therefore the potential for cost savings is reduced and there is a possibility that Episcissors-60 could be cost incurring. The results from the EAC sensitivity analysis is presented in table 10. Key uncertainties relate to the rate of OASIS at baseline and the impact of Episcissors-60 on the rate of OASIS.

Table 10: Low and high values in EAC Sensitivity Analysis

Variable	High	Result	Low	Result	EAC Comment
OASIS rate - intervention	0.08	-£71.47	0.00	102.682	High value based on 1% increase from meta-analysis, low value based on 5% decrease from meta-analysis
OASIS rate - comparator	0.07	£63.21	0.04	-£1.81	High and low values based on rate used in model (Published literature)
OASIS cost	£2347.20	£38.52	£1564.80	£22.88	High and low values based on a 20% increase or decrease in costs
excess bed day cost	£439.20	£32.16	£266.40	£28.71	High and low values based on a 20% increase or decrease in costs
Episcissors-60 cost - intervention	£32.00	£14.70	£6.40	£40.30	High value based on Episcissors-60 being used only 10 times, low value based on Episcissors-60 being used 50 times
standard cost - intervention	£0.52	-£30.96	£0.1	-£30.54	High value based on scissors being used only [redacted], low value based on scissors being used [redacted].

The EAC modelled 3 additional clinical scenarios for Episcissors-60. The EAC modelled a reduction in cost of reusable Episcissors-60 in the episiotomy population (EAC base case) and noted an incremental cost saving increase from £30.70 to £40.30 per patient. This was based on a suggestion that reusable Episcissors-60 could be used up to 50 times before being disposed of, which would reduce the cost of Episcissors-60 from £16 per use to £6.40 per use.

The EAC also modelled an increase in episiotomy rate in the total birth population (company base case, EAC corrected version), since there is some evidence that the availability of Episcissors-60 increases the rate of episiotomy. The population was changed to reflect the whole birth population and the cost of Epsicssors-60 was increased to reflect a higher rate of episiotomies. The EAC noted a slight reduction in incremental cost saving from £20.47 to £20.41.

The third modelled scenario looked at a higher cost of standard scissors of £4, as there is some indication that due to manufacturing processes, the cost of disposable scissors will be higher than the cost per use of reusable scissors. This increased the incremental cost saving to £34.44. The EAC noted that the model is very insensitive to the cost of disposable standard scissors.

5 Ongoing research

The company identified one ongoing, unpublished study by Koh et al. The EAC are not aware of any ongoing research on Episcissors-60.

As part of the Innovation Technology Programme, NHS England have included Episcissors-60 in the technologies eligible for an innovative technology tariff and are collecting audit data, including details on:

- Number of mothers requiring surgical repair after obstetric anal sphincter injury for the previous quarter. This is only required for the first claim.
- Number of guided mediolateral episiotomies undertaken using the Episcissors-60 or other approved device during this period of reporting. Providers will be paid based on this number.
- Number of mothers requiring additional surgical repair after undergoing guided mediolateral episiotomy during this period of reporting.
- Average discharge time of mothers who have received a guided mediolateral episiotomy using Episcissors-60 or other approved device.

The EAC recommend that there should be further research in the form of a study investigating the impact of Episcissors-60 in patients with episiotomy only. This could be done using currently collected data as all maternity units should collect data on whether a patient was given an episiotomy and whether they sustained an OASIS. A detailed audit study would also provide data on whether the rates of episiotomy change following introduction of Episcissors-60 and what other factors are being implemented to prevent OASIS. This study could be done as a 'before and after' study with prospectively defined before and after period or it could be done as a prospective observational study identifying units not using Episcissors-60 and comparing outcomes with units using Episcissors-60. The EAC suggest that outcomes of interest would include rate of episiotomy, post-suture angle of episiotomy, rate of OASIS and patient reported outcomes.

6 Issues for consideration by the Committee

Clinical evidence

The clinical evidence, including the additional studies identified by the EAC, is limited in both the number of studies and also the quality of studies. The authors of the published reviews highlight that the currently available data is limited and low quality.

The EAC has completed an additional analysis, excluding Ayuk et al. 2018 and Condell et al. 2017 from their meta-analysis. They have also presented associated cost analysis. The committee need to consider which meta-analysis is most appropriate.

Rates of OASIS appear to be variable across the published literature. The EAC suggest further investigation of subgroups, such as instrumental births, and their associated OASIS rates. A further point for consideration highlighted by the EAC includes whether Episcissors-60 increases the rate of episiotomy. It may be important to consider the reasons for such a behaviour change, how this behaviour change may be assessed, and how this might impact the rates of OASIS. Furthermore, some studies introduced a number of different

measures to protect against OASIS at the same time as introducing Episcissors-60, but did not report any data on these measures. The committee may wish to consider what these other measures may be and to what extent they may impact the results.

The clinical evidence is based on the reusable version of Episcissors-60 which is being phased out and no studies include the new disposable version. It may be important to consider whether the clinical evidence is transferable to the new disposable version.

Cost evidence

The EAC were unable to identify a cost for disposable standard scissors. However, the EAC did not consider this an issue, as the cost of the comparator did not affect the cost case for Episcissors-60.

The model does not include any potential long-term costs associated with OASIS, and the EAC were unable to comment on how this might impact results. The model is sensitive to the OASI rate and the excess length of stay resulting from an OASI, the committee needs to decide if these figures are robust.

7 Authors

Faye Sheldon, analyst

Lizzy Latimer, technical adviser

NICE Medical Technologies Evaluation Programme

August 2019

Appendix A: Sources of evidence considered in the preparation of the overview

A Details of assessment report:

- O'Connell S, Morgan H, Carolan-Rees G, Episcissors-60 for guided mediolateral episiotomy, July 2019

B Submissions from the following sponsors:

- MEDINVENT LIMITED

C Related NICE guidance

NICE Clinical Guidelines

- Intrapartum care for healthy women and babies. NICE clinical guideline 190 (2014, updated 2017). Available from https://www.nice.org.uk/guidance/cg190
- Faecal incontinence in adults: management. NICE clinical guideline 49 (2007). Available from https://www.nice.org.uk/guidance/cg49

NICE Pathways

- Faecal incontinence. NICE pathway (2013, updated 2019). Available from https://pathways.nice.org.uk/pathways/faecal-incontinence
- Intrapartum care. NICE pathway (2011, updated 2019). Available from https://pathways.nice.org.uk/pathways/intrapartum-care
- Antenatal care for uncomplicated pregnancies. NICE pathway (2011, updated 2019). Available from https://pathways.nice.org.uk/pathways/antenatal-care-for-uncomplicated-pregnancies

D References

Ayuk et al (2018) Obstetric anal sphincter injuries (OASIS) before and after the introduction of the Episcissors-60: A multi-centre time series analysis. Accessed Online at: http://www.ahsn-nenc.org.uk/wp-content/uploads/2019/03/Episcissors-Project-Report-Dec-2018.pdf [last accessed: 25/07/2019]

Cole, J., et al. (2019). "The use of Episcissors-60 to reduce the rate of Obstetric Anal Sphincter Injuries: A systematic review." European Journal of Obstetrics, Gynecology, & Reproductive Biology **237**: 23-27.

Condell, A., et al. (2017). "Episcissors-reducing obstetric anal sphincter injuries (OASIS) in instrumental delivery." Neurourology and Urodynamics **36 (Supplement 3)**: S236-S237.

Davies-Tuck et al (2015) Maternal Asian ethnicity and the risk of anal sphincter injury. *ACTA Obstetricia et Gynecologica Scandinavica* 94;308-315

Divakova, O., et al. (2019). "Episcissors-60TM and obstetrics anal sphincter injury: a systematic review and meta-analysis." International Urogynecology Journal **02**: 02.

Farnworth, A., et al. (2019). "A pragmatic evaluation of barriers and facilitators to the implementation of an obstetric innovation (Episcissors) across maternity units in the North East and North Cumbria." BJOG: An International Journal of Obstetrics and Gynaecology **126 (Supplement 1)**: 108.

Freeman, R. M., et al. (2014). "Cutting a mediolateral episiotomy at the correct angle: evaluation of a new device, the Episcissors-60." Medical Devices Evidence and Research **7**: 23-28.

HES (2018) NHS Maternity Statistics, England 2017-2018. Available online at https://digital.nhs.uk/data-and-information/publications/statistical/nhs-maternity-statistics/2017-18 [last accessed 29/07/2019]

Lou YY et al (2016) Does Episcissors-60 reduce the incidence of obstetric anal sphincter injuries (OASIS)? BJOG: An International Journal of Obstetrics and Gynaecology 123 (S2); 51

Mohiudin, H., et al. (2018). "Implementation of the RCOG guidelines for prevention of obstetric anal sphincter injuries (OASIS) at two London Hospitals: A time series analysis." European Journal of Obstetrics, Gynecology, & Reproductive Biology **224**: 89-92.

Ness W (2017) Obstetric anal sphincter injury: causes, effects and management. Accessed online at: https://www.nursingtimes.net/clinical-archive/womens-health/obstetric-anal-sphincter-injury-causes-effects-and-management/7017458.article [last accessed on 25/07/2019]

NHS Litigation Authority (2012) Ten years of maternity claims: An analysis of NHS Litigation Authority Data. Accessed online at https://resolution.nhs.uk/resources/?fwp_resources_service=claims-management&fwp_resources_themes=maternity [Last accessed 30/07/219]

Orlovich et al (2018) Estimating the incidence and the economic burden of third and fourth degree obstetric tears in the English NHS: an observational study using propensity score matching *BMJ Open* 7:e015463. doi:10.1136/bmjopen-2016-015463

Patel, R. P. and S. M. Ubale (2014). "Evaluation of the angled Episcissors-60() episiotomy scissors in spontaneous vaginal deliveries." Medical Devices Evidence and Research **7**: 253-256.

Ramm et al (2018) Risk factors for the development of obstetric anal sphincter injuries in modern obstetric practice *Obstet Gynecol* 131;290-296

RCOG (2015) The management of Third and Fourth Degree Perineal Tears *Green-top Guideline 29* Online at

https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg29/ [last accessed: 25/07/2019]

RCOG (2017) National Maternity and Perinatal Audit – Clinical Report. Accessed online at: https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/nmpa/ [last accessed: 25/07/2019]

RCOG (2016) Patterns of maternity care in English NHS Trusts Online at https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/clinical-indicators-programme/maternity-care/ [last accessed 25/07/2019]

Sawant, G. and D. Kumar (2015). "Randomized trial comparing episiotomies with Braun-Stadler episiotomy scissors and EPISCISSORS-60()." Medical Devices Evidence and Research **8**: 251-254.

Thiagamoorthy, G., et al. (2017). "Does episiotomy reduce the risk of OASIS? multivariate logistic regression analysis of risk factors for OASIS." International Urogynecology Journal **28 (1 Supplement 1)**: S10-S11.

van Roon, Y., et al. (2015). "Comparison of obstetric anal sphincter injuries in nulliparous women before and after introduction of the EPISCISSORS-60() at two hospitals in the United Kingdom." International Journal of Women's Health **7**: 949-955.

YHEC (2017). Economic Impact Evaluation Case Study: Episcissors-60, YHEC.

Appendix B: Comments from professional bodies

Expert advice was sought from experts who have been nominated or ratified by their Specialist Society, Royal College or Professional Body. The advice received is their individual opinion and does not represent the view of the society.

Mr Abdul Sultan

Consultant Obstetrician and Gynaecologist, Croydon Health Services NHS Trust, British Society of Urogynaecology.

Dr Ranee Thakar

Consultant Urogynaecologist, Croydon University Hospital, Royal College of Obstetricians and Gynaecologists Council Member

Mr Ashish Pradhan

Consultant Urogynaecologist, Addenbrookes Hospital Cambridge, British Society of Urogynaecology and Royal College of Obstetricians and Gynaecologists

Dr Latha Vinayakarao

Consultant Obstetrician, Poole Hospital NHS Foundation Trust, Royal College of Obstetricians and Gynaecologists.

Kerry Barker-Williams

Research Midwife, Countess of Chester NHS Foundation Trust, Royal College of Midwives

Dr Bini Ajay

Consultant Obstetrician and Gynaecologist, Croydon University Hospital, Fellow of the Royal College of Obstetricians and Gynaecologists

Kylie Watson

Midwife Ward Manager, Manchester University Hospitals NHS Foundation Trust, Royal College of Midwives

Dr Allison Farnworth

Senior Research Midwife, Newcastle University, Nursing and Midwifery Council and Royal College of Midwives

Dr Paul Ayuk

Consultant Obstetrician, Newcastle-upon-Tyne Hospitals NHS Trust, Member of Royal College of Obstetricans and Gynaecologists

Please see the clinical expert statements included in the pack for full details.

Appendix C: Comments from patient organisations

The following patient organisations were contacted and no response was received.

- WellBeing of Women
- Baby Lifeline
- Disability, Pregnancy & Parenthood international (DPPi)
- Multiple Births Foundation
- National Childbirth Trust (NCT)
- Tommy's – The Baby Charity
- Twins and Multiple Births Association
- PANDAS Foundation
- MASIC Foundation

One response was received from Birth Trauma Association (BTA), please see the response in the pack for full details.

Appendix D: Additional analyses carried out by the External Assessment Centre

Additional analysis of the submitted evidence carried out after the External Assessment Report was initially submitted to NICE, considered relevant to fully address the issues in the scope.

Cost Results using the Divakova meta-analysis results

Ayuk et al (2018) and Condell et al (2017) are both studies which although published and available in the public domain, have not been through a formal peer review process as with articles published in journals. Excluding these two studies essentially replicates the results of the systematic review (Divakova et al, 2019) and suggests an absolute reduction of OASIS of 4% following introduction of Episcissors-60 (-0.04 (-0.07 to -0.01); p=0.005). The EAC has included the results of the cost analysis using the results of the meta-analysis

without these two studies. Episcissors-60 is cost saving in all scenarios (table 1).

Figure 1: Meta-analysis results excluding Ayuk and Condell

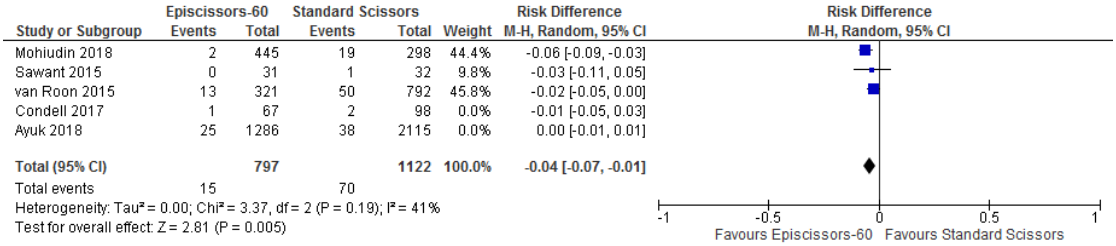


Table 1: Comparison of cost savings using EAC meta-analysis results compared with Divakova (2019) meta-analysis results

	Base-case	Lowest estimate*	Highest estimate*
Range of cost-savings with device (EAC meta-analysis including Ayuk and Condell)	£30.70	-£38.96	£70.17
Range of cost-savings with device (Divakova)	£77.14	£7.48	£70.17
*Based on the upper and lower confidence intervals			

Cost Results using the Ayuk results only

Although Ayuk et al (2018) has not been published in a peer reviewed journal, the study represents the largest study available. Conducted across 9 maternity units in the UK, the study reported data from 19,256 women including 3401 (17.6%) who had an episiotomy. Ayuk et al (2018) reported no significant difference in OASIS rates between episiotomy with Episcissors-60 and standard scissors (absolute reduction of 0% (-1% to 1%), p=0.76).

Using these rates in the EAC base case Episcissors-60 becomes cost incurring in the base case and worst case scenarios suggesting that when Episcissors-60 makes no change to OASIS rates or leads to a possible

increase in OASIS rates, Episcissors-60 will be cost incurring. In the best case scenario in which there is a reduction in OASIS rates, Episcissors-60 is cost saving (£7.48)

Table 2: Comparison of cost savings using EAC meta-analysis results compared with Ayuk results only

	Base-case	Lowest estimate*	Highest estimate*
Range of cost-savings with device (EAC meta-analysis including Ayuk and Condell)	£30.70	-£38.96	£70.17
Range of cost-savings with device (Ayuk only)	-£15.74	-£38.96	£7.48
*Based on the upper and lower confidence intervals			

Cost Results without Excess Length of Stay

NHS reference cost NZ27Z includes some costs related to length of stay. It is not clear whether there is an excess length of stay over and above what is already factored into the cost 'Post-natal therapeutic procedures'.

Excluding the cost of an excess length of stay from the model results in a reduction in the cost savings associated with Episcissors-60.

Table 3: Impact of excess length of stay on cost savings

	Base-case	Lowest estimate	Highest estimate
Range of cost-savings with device (EAC base case with 0.5 days excess length of stay	£30.70	-£38.96	£70.17
Range of cost-savings with device (EAC base case no excess length of stay)	£23.38	-£35.30	£56.63
Range of cost-savings with device (Company base case	£20.57	-£2.36	£72.48

with 0.5 days excess length of stay			
Range of cost-savings with device (Company base case no excess length of stay)	£16.49	-£2.36	£59.16

Threshold Analysis

Threshold analysis shows how the rate of OASIS in both the standard scissors arm and the Episcissors-60 arm impacts the cost savings. The higher the rate of OASIS in the standard scissors arm and the greater the impact of Episcissors-60 in reducing the rate of OASIS, the more cost saving Episcissor-60 is likely to be. If Episcissor-60 does not reduce the rate of OASIS or if there is any increase in the rate of OASIS compared with standard scissors, then Episcissors-60 would be cost incurring.

Figure 2: Threshold Analysis using Company Base Case

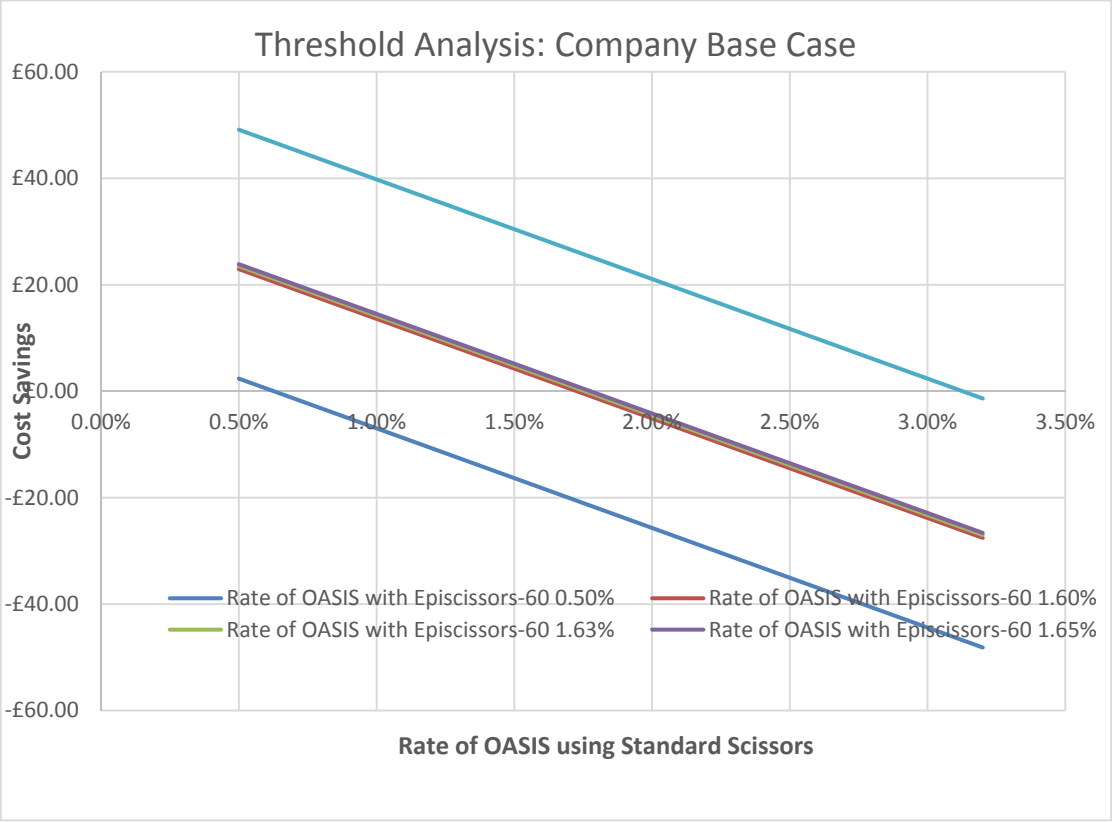
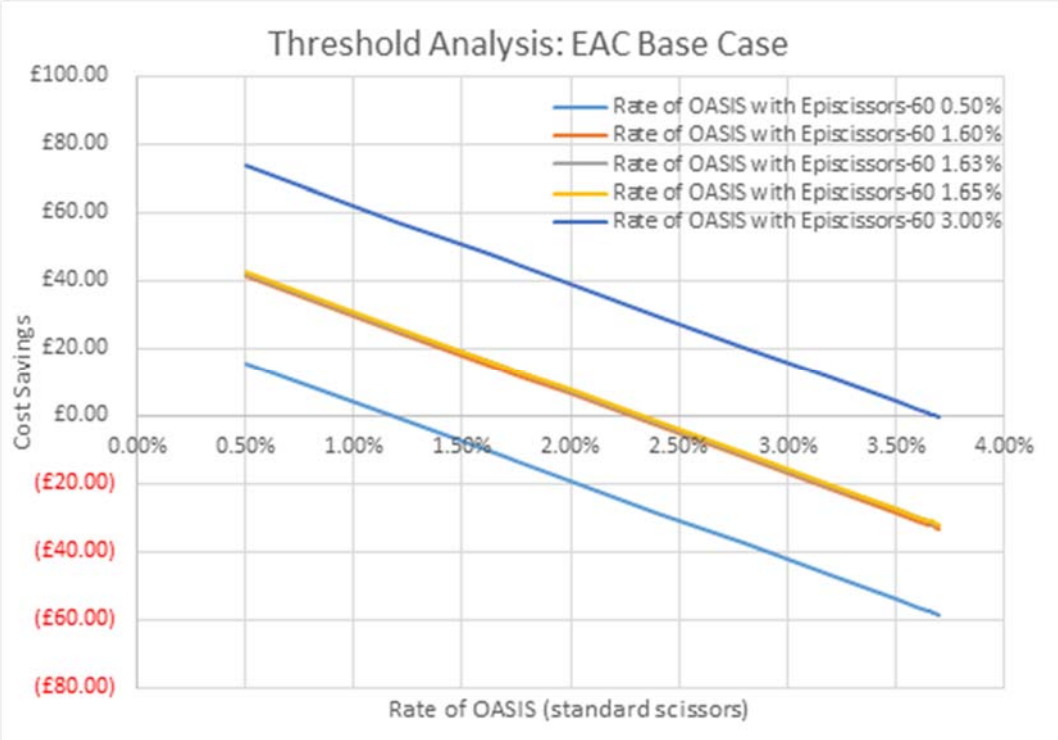


Figure 3: Threshold Analysis using EAC Base Case



Appendix E: decision problem from scope

	Scope issued by NICE
Population	Women who have a clinical need for an episiotomy, such as for instrumental deliveries or in cases of suspected fetal compromise.
Intervention	Episcissors-60
Comparator(s)	• Standard reusable episiotomy scissors • Standard disposable episiotomy scissors (see also 'Cost analysis' below)
Outcomes	The outcome measures to consider include: Procedural outcomes: • Device-related adverse events • Incidence and severity of OASIs • Complication rates, e.g. wound breakdown, infections, anal incontinence and postpartum haemorrhage • Ease of use of instrument, including handedness • Operator learning curve • Costs of any complications (including OASI repair). Duration of follow up should be sufficient to capture all relevant complications. • Post-delivery suture angles • Length of episiotomy

<table>
<tr><td></td><td>

- Post-delivery distance from midline

Patient outcomes:

- Length of stay
- Quality of life

</td></tr>
<tr><td>Cost analysis</td><td>Comparator(s):

- Standard reusable episiotomy scissors
- Standard disposable episiotomy scissors

Costs will be considered from an NHS and personal social services perspective.

The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared.

Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.</td></tr>
<tr><td>Subgroups to be considered</td><td>Ethnicity</td></tr>
<tr><td>Special considerations, including those related to equality</td><td>Episcissors-60 are intended for use in pregnant women during labour. Some women of Asian family origin may be more at risk of OASIs.
People with severe faecal incontinence may meet the criteria for disability under the Equality Act 2010.
Sex, pregnancy, race and disability are protected characteristics under the Equality Act 2010.
Consideration will be given to whether Episcissors-60 can easily be used by lefthanded people.</td></tr>
<tr><td rowspan="5">Special considerations, specifically related to equality issues</td><td colspan="2">Episcissors-60 are intended for use in pregnant women during labour. Some women of Asian family origin may be more at risk of OASIs. Those with severe faecal incontinence may meet the criteria for disability under the Equality Act 2010. Sex, pregnancy, race and disability are protected characteristics under the Equality Act (2010).</td></tr>
<tr><td>Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?</td><td>No</td></tr>
<tr><td>Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?</td><td>No</td></tr>
<tr><td>Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?</td><td>No</td></tr>
<tr><td colspan="2"></td></tr>
</table>

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

Episcissors-60 for guided mediolateral episiotomy

1 Technology

1.1 Description of the technology

Episcissors-60 are adapted surgical scissors made from stainless steel used to perform an incision for mediolateral episiotomies. There are reusable and single use versions. The scissors have 5-centimetre long blades with a guide-limb mounted at the blade pivot point and angled at 60 degrees from the blades. A cutting angle of 60 degrees is ensured by positioning the guide limb pointing towards the anus in the vertical perineal midline.

Evidence suggests that the cutting angle of a mediolateral episiotomy affects the incidence of OASIs (Stedenfeldt et al. 2012, Eogan et al. 2006). The aim of Episcissors-60 is to prevent inaccurate visual estimation of the cutting angle and so reduce the incidence of obstetric anal sphincter injuries (OASIs).

Two versions of Episcissors-60 are available based on operator preference: a straight version and an angled version. The straight version has blades in line with the handles, whereas the angled version has blades at 150 degrees to the handles. Both versions give an incision point 1 centimetre horizontally offset from the posterior vaginal fourchette.

The reusable version of Episcissors-60 can form part of a reusable equipment birthing pack following cleaning and sterilising between uses. They are intended for use in secondary care midwifery and obstetric units, primary care midwifery units and birth centres, and for home births. Episcissors-60 was included in the NHS Innovation and Technology Tariff (ITT) 2017/18.

1.2 Regulatory status

Episcissors-60 was CE-marked as a Class I medical device in March 2014. The single use version is planned to launch in the NHS in June 2019 after which the reusable version will be phased out. Episcissors-60 are currently made by 2 manufacturers under license from MEDINVENT LTD.

1.3 Claimed benefits

The benefits to patients claimed by the company through the use of Episcissors-60 for guided mediolateral episiotomy are:

- Cuts at a fixed 60 degree angle at crowning in line with the Royal College of Obstetricians and Gynaecologists' recommendation
- Prevention of OASIs
- Fewer complications such as wound breakdown, infections and anal incontinence

The benefits to the healthcare system claimed by the company are:

- Preferred by staff over normal scissors
- Cost-saving because of fewer OASIs
- Reduced costs associated with fewer complications
- Reduced length of stay

1.4 Relevant diseases and conditions

Episcissors-60 are intended for use in mediolateral episiotomy, which is recommended only when there is a clinical need, such as for instrumental deliveries or in cases of suspected fetal compromise. Routine episiotomy is not indicated during spontaneous vaginal birth or after third or fourth-degree tears from previous childbirth.

According to HES online, 15.2% of all births in England between 2011 to 2012 required an episiotomy. OASIs can be minimised by mediolateral episiotomies, but only if the correct cutting angle is achieved. OASIs occur in 2.9% of all vaginal births in the UK, 6.1% of first-time births and 1.7% of births in women who have given birth 2 or more times before (Thiagamoorthy et al.

2014). A meta-analysis found that 30% of women who had an OASI still had symptoms 1 year after childbirth (Oberwalder et al. 2003). Symptoms include faecal urgency, inability to control wind and uncontrolled bowel movements (Dudding et al. 2008).

Perineal trauma was the 4th highest reason for obstetric claims settlements. The compensation cost for perineal trauma across NHS organisations for the 10 years to March 2010 was £31.2 million according to the NHS Litigation Authority 2012. Perineal trauma was the 4th highest reason for obstetric claim settlements over this period of time.

1.5 Current management

Current clinical practice in the NHS for a woman requiring mediolateral episiotomy is described by several guidelines. NICE clinical guideline on intrapartum care for healthy women and babies recommends that an episiotomy should only be performed if there is a clinical need, such as an instrumental birth or suspected fetal compromise. An episiotomy should be mediolateral, originating at the vaginal fourchette and directed towards the right side. The angle of the cut to the vertical axis at the time of episiotomy is recommended to be 45 to 60 degrees. Tested effective analgesia should be provided before carrying out an episiotomy, except in emergency cases such as acute fetal compromise.

The Royal College of Obstetricians and Gynaecologists' guidance on The Management of Third and Fourth Degree Tears recommends in a similar way that an episiotomy should be mediolateral and should only be performed if clinically indicated. The cutting angle is advised to be 60 degrees from the midline at the time of episiotomy. Should an OASI occur during vaginal delivery, it should usually be repaired in an operating theatre under general or regional anaesthesia. Broad-spectrum antibiotics should be given following repair of OASIs. Follow up should involve 6-12 week review. Women with ongoing OASI symptoms should be referred to a specialist gynaecologist or a colorectal surgeon.

The NICE clinical guideline on faecal incontinence in adults: management recommends that women with OASIs are identified as high risk for faecal incontinence. Women should be treated with condition-specific interventions as well as general measures for faecal incontinence. General measures include coping strategies, incontinence pads, anti-diarrhoeal medicines and pelvic floor muscle training.

2 Statement of the decision problem

	Scope issued by NICE
Population	Women who have a clinical need for an episiotomy, such as for instrumental deliveries or in cases of suspected fetal compromise.
Intervention	Episcissors-60
Comparator(s)	• Standard reusable episiotomy scissors • Standard disposable episiotomy scissors (see also 'Cost analysis' below)
Outcomes	The outcome measures to consider include: Procedural outcomes: • Device-related adverse events • Incidence and severity of OASIs • Complication rates, e.g. wound breakdown, infections, anal incontinence and postpartum haemorrhage • Ease of use of instrument, including handedness • Operator learning curve • Costs of any complications (including OASI repair). Duration of follow up should be sufficient to capture all relevant complications. • Post-delivery suture angles • Length of episiotomy • Post-delivery distance from midline Patient outcomes: • Length of stay • Quality of life
Cost analysis	Comparator(s): • Standard reusable episiotomy scissors • Standard disposable episiotomy scissors Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared.

	Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	Ethnicity	
Special considerations, including those related to equality	Episcissors-60 are intended for use in pregnant women during labour. Some women of Asian family origin may be more at risk of OASIs. People with severe faecal incontinence may meet the criteria for disability under the Equality Act 2010. Sex, pregnancy, race and disability are protected characteristics under the Equality Act 2010. Consideration will be given to whether Episcissors-60 can easily be used by lefthanded people.	
Special considerations, specifically related to equality issues	Episcissors-60 are intended for use in pregnant women during labour. Some women of Asian family origin may be more at risk of OASIs. Those with severe faecal incontinence may meet the criteria for disability under the Equality Act 2010. Sex, pregnancy, race and disability are protected characteristics under the Equality Act (2010).	
	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No

3 Related NICE recommendations and NICE pathways

Published

NICE Clinical Guidelines

- Intrapartum care for healthy women and babies. NICE clinical guideline 190 (2014, updated 2017). Available from https://www.nice.org.uk/guidance/cg190
- Faecal incontinence in adults: management. NICE clinical guideline 49 (2007). Available from https://www.nice.org.uk/guidance/cg49

NICE Pathways

- Faecal incontinence. NICE pathway (2013, updated 2019). Available from https://pathways.nice.org.uk/pathways/faecal-incontinence
- Intrapartum care. NICE pathway (2011, updated 2019). Available from https://pathways.nice.org.uk/pathways/intrapartum-care
- Antenatal care for uncomplicated pregnancies. NICE pathway (2011, updated 2019). Available from https://pathways.nice.org.uk/pathways/antenatal-care-for-uncomplicated-pregnancies

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

- Antenatal care for uncomplicated pregnancies update. NICE clinical guideline. Publication expected December 2020.

4 External organisations

4.1 Professional organisations

4.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Royal College of Midwives
- Royal College of Obstetricians and Gynaecologists
- British Society of Urogynaecology

4.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Royal College of Midwives

- Royal College of Obstetricians and Gynaecologists
- British Society of Urogynaecology
- British Society of Psychosomatic Obstetrics, Gynaecology and Andrology

4.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Baby Lifeline
- Birth Trauma Association (BTA)
- Disability, Pregnancy & Parenthood international (DPPi)
- Multiple Births Foundation
- PANDAS Foundation
- Tommy's – The Baby Charity
- Twins and Multiple Births Association (TAMBA)
- WellBeing of Women

NICE National Institute for Health and Care Excellence

Adoption scoping report: MTG 457 Episcissors-60 for guided mediolateral episiotomy

Summary

Adoption levers

- Increases confidence in carrying out an episiotomy
- May reduce the risk of third and fourth degree perineal tears

Adoption barriers

- Cost of purchasing (and replacing) Episcissors-60
- Not included in pre-prepared birth packs and other scissors are
- Create an unnecessary large cut in some deliveries
- May cause an increase in episiotomy rates
- May be mistaken for single use and inadvertently discarded
- Re-use and decontamination concerns
- Perceived lack of training in episiotomies in general and with Episcissors-60

1. Introduction

This adoption scoping report includes some of the benefits and difficulties that may be faced by organisations when planning to adopt Episcissors-60 into routine NHS use. This report refers to both the straight and angled reusable version of Episcissors-60.

2. Contributors

Adoption information was gathered from the company and 7 NHS staff in 6 trusts:

- 1 consultant obstetrician
- 1 consultant in obstetrics and gynaecology
- 5 midwifes (2 delivery suite coordinators)

The angled version has been used by 2 contributors, a midwife and a consultant in obstetrics and gynaecology. The midwife has had access to the technology for 1 year and has used it on 2 patients, the consultant has used it on 9 patients in 5

Issue date: June 2019

years. Two contributors have observed the scissors in use by colleagues but not used themselves by choice.

3. Use of Episcissors-60 in practice

The company states Episcissors-60 is available in 70% of NHS hospitals in England in May 2019.

Users of the technology explained Episcissors-60 have been used in instrumental and non-instrumental deliveries.

Non-instrumental deliveries are usually carried out by a midwife. In this type of delivery a smaller episiotomy may be carried out when the baby is crowning. The perineum is stretched and pale in colour and there may be less blood loss.

Instrumental deliveries are usually carried out by a doctor. In this type of delivery a larger episiotomy may be required when the baby's position may be higher. The perineum may not be stretched and not as pale in colour and could result in a higher blood loss. Contributors reported more episiotomies are carried out in instrumental deliveries.

One user is left handed and would use Episcissors-60 with her right hand as they would any other episiotomy scissors. Thy have had no issues to report.

4. Reported benefits

The benefits of adopting Episcissors-60 as reported to the adoption team by the healthcare professionals either using the technology or with expertise in this area are:

- Increases confidence in carrying out an episiotomy
- Potentially reduces the risk of third and fourth degree perineal tears

5. Insights from the NHS

Care pathway

Birth packs are purchased from an external company containing single use items including disposable episiotomy scissors at 1 contributor's organisation. This is reported to be an adoption barrier particularly in an urgent delivery as staff prefer to use episiotomy scissors that are available nearby and that they are familiar with. As the packs contain sterile items and are sealed by an external company it is not possible to replace the scissors with the higher cost Episcissors-60.

Clinician acceptance

Contributors acknowledged the Episcissors-60 may reduce third and fourth degree perineal tears, although some said there was not enough high quality evidence to demonstrate this. Some contributors were concerned the Episcissors-60 may encourage staff to carry out episiotomies more routinely causing an unnecessary increase in episiotomy rates.

Resource impact

All contributors agreed the cost of purchasing and replacing Episcissors-60 is high and reported that reusable equipment often gets lost. At a contributor's organisation, 6 pairs were purchased and only 3 remain. It is suspected they are mistakenly discarded with other single use equipment.

Another contributor explained that due to the cost of the technology, their Episcissors-60 are labelled with a code. When staff use them, they are expected to record the code within the patient's notes so usage can be traced. Staff therefore feel uncomfortable using the high cost technology in case they go missing.

One contributor's organisation has a policy of not reusing reusable equipment to reduce infection rates within their unit.

Training

Episiotomy training is part of initial midwifery training and further formal on-the-job episiotomy training is generally not provided. The company have product demonstration videos on their website.

Most contributors agreed that episiotomy training generally could be improved and that this would increase staff confidence. Training should cover appropriate timing, the procedure and how to use episiotomy scissors.

Patient experience

Some contributors explained Episcissors-60 create a cut the full length of the blade and that this may create an unnecessary large cut. This can increase blood loss and require more sutures, and as a consequence may increase pain and prolong healing in some patients. Two contributors explained, as the incision is larger, the sutures required for the cut are deeper.

Maintenance

Sterilisation of the reusable Episcissors-60 was considered a barrier by some contributors due to turnaround time in CSSD (internal decontamination and sterilisation department) and concerns that they would go missing.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical Technologies Evaluation Programme

Sponsor submission of evidence:

Evaluation title: EPISCISSORS-60 for guided mediolateral episiotomy

Sponsor: MEDINVENT LIMITED

Date sections A and B submitted: 04-06-2019

Date section C submitted: 10-6-2019

August 2011 (Version 1.1)

Contents

Document key

Boxed text with a grey background provides specific and/or important guidance for that section. This should not be removed.

Information in highlighted black italic is to help the user complete the submission and may be deleted.

The user should enter text at the point marked ‘Response’ or in the tables as appropriate. ‘Response’ text may be deleted.

List of tables and figures

Please include a list of all tables and figures here with page references.

Glossary of terms

If a glossary of terms is required to inform the submission of evidence include in the table. Delete if not required.

Term	Definition
OASIS	Obstetric anal sphincter injuries; previously referred to as third/fourth degree tears
Nulliparous women	Women giving birth for the first time

Section A – Decision problem

Section A describes the decision problem, the technology and its clinical context. There is also information about ongoing studies, regulatory information and equality issues.

Sponsors should submit section A before the full submission (for details on timelines, see the NICE document 'Guide to the Medical Technologies Evaluation Programme process', available from www.nice.org.uk/mt

Statement of the decision problem

The decision problem is specified in the final scope issued by NICE. The decision problem states the key parameters that should be addressed by the information in the evidence submission. All statements should be evidence based and directly relevant to the decision problem.

Table A1 Statement of the decision problem

	Scope issued by NICE	Variation from scope	Rationale for variation
Population	Women who have a clinical need for an episiotomy, such as for instrumental deliveries or in cases of suspected fetal compromise		
Intervention	Episcissors-60		
Comparator(s)	Standard episiotomy scissors		
Outcomes	Procedural outcomes: • Device-related adverse events • Incidence and severity of OASIs • Complication rates, e.g. wound breakdown, infections, anal incontinence and postpartum haemorrhage • Ease of use of instrument, including handedness • Operator learning curve • Costs of any complications (including OASI repair). Duration of follow up should be sufficient to capture all relevant complications. • Post-delivery suture angles • Length of episiotomy • Post-delivery distance from midline Patient outcomes: • Length of stay • Quality of life		

Cost analysis	Comparator(s): • Standard reusable episiotomy scissors • Standard disposable episiotomy scissors	ROI; Cost avoidance	Sale price data is commercially confidential; we have no reliable sources to verifiably quote prices for standard episiotomy scissors. NHS Supply Chain have declined to share these prices.
Subgroups to be considered	Ethnicity	No information available in published literature	
Special considerations, including issues related to equality	Consideration will be given to whether Episcissors-60 can easily be used by lefthanded people	Not done	No data available in published literature

If the sponsor considers that additional parameters should be included in the submission, which are not stated in the decision problem, this variation from the scope and the rationale for it must be clearly described in the relevant columns in table A1.

1 Description of technology under assessment

1.1 Give the brand name, approved name and details of any different versions of the same device.

Response EPISCISSORS-60™ guided episiotomy scissors. Available in reusable and single use versions. Documents submitted, but please keep manufacturer names confidential as this is a commercially sensitive matter.

All different versions/prototypes of the technology listed here must be CE marked or have equivalent UK regulatory approval.

1.2 What is the principal mechanism of action of the technology?

Response They are guided episiotomy scissors with a unique flexible guide limb that points towards the anus. When the guide-limb is aligned correctly to the anus during crowning, the scissors ensure a fixed angle episiotomy cut at 60 degrees to the anal midline. The flexible nature of the guide allows it to remain in contact with the perineal skin at crowning when spherical distension of the perineum takes place. This avoids the errors of parallax that can ensue if the guide-limb is not in contact with the skin. The 60 degree episiotomy angle is recommended by the Royal College of Obstetricians and Gynaecologists for prevention of Obstetric Anal Sphincter Injuries (OASIS), also called as third/fourth degree tears in their green top guideline no GTG 29 (2015)

2 Clinical context

2.1 Provide a brief overview of the disease or condition for which the technology is being considered in the scope issued by NICE.

Response There are approximately 94,556 episiotomies (OPCS code R27) performed in England each year. EPISCISSORS-60 are usable in all these episiotomies. HES have changed their methodology for Maternity, and describe episiotomies being performed in 15.1% of births. The denominator of all births in England is 626,203 as per the HES maternity report 2017-18.

Episiotomies can cause OASIS if they are angled to close to the anal midline or too far away from the midline. If episiotomies are angled too close to the anal midline, they can cut into the anal sphincter muscles directly (Eogan 2006, Andrews 2006, Stedenfeldt 2012, Kalis 2008, Kalis 2011, El-Din 2014). If episiotomies are cut too far away from the anal midline, they fail to sufficiently unload the pressure on the central part of the posterior perineum. OASIS can result as a consequent (Stedenfeldt 2012).

A post-sutured episiotomy angle is safest within the 40-60 degree range, However, since the perineum distends during childbirth, to achieve this safe angle, the episiotomy should be cut at 60 degrees to the anal midline at the time of crowning of the fetal head (RCOG GTG29).

OASIS occurs in 5.9% of all first births (Gurol_Urganci 2013) and a national median rate of 2.85% (range 0-8%) was found in a questionnaire based study with 81% national response rate (Thiagamoorthy 2014). YHEC quoted a national rate of 4% in their analysis of the EPISCISSORS-60, which was done on NHS England's instructions. We could not identify any contemporaneous HES data on third and fourth degree tears.

The National Maternity and Perinatal Audit 2016-17 (http://www.maternityaudit.org.uk/pages/home) does not describe an overall rate of OASIS. It presents figures stratified by previous parity and type of birth. In nulliparous women, 5.4% sustained OASIS in spontaneous births and 7.8% sustained OASIS in Operative vaginal or instrumental deliveries (OVD). In parous women 1.6% sustained OASIS during spontaneous births (SVD) and 4.8% sustained OASIS during instrumental deliveries (OVD).

The disease or condition for which the technology is being considered in the scope must include an estimate of prevalence and/or incidence for the benefitting population. All estimates must be referenced.

2.2 Give details of any relevant NICE or other national guidance or expert guidelines for the condition for which the technology is being used. Specify whether the guidance identifies specific subgroups

and make any recommendations for their treatment. If available, these should be UK based guidelines.

Response The Royal College of Obstetricians and Gynaecologists (RCOG) Green Top Guideline no.29 (2015) is NICE accredited evidence. It recommends a 60 degree angled episiotomy to the midline at crowning of the fetus to prevent OASIS. It does not mandate episiotomy routinely in spontaneous births. It recommends that episiotomy as described above SHOULD be considered during operative vaginal deliveries OVD (forceps and vacuum). NICE intrapartum guideline CG190 has not been updated since 2007 about episiotomy angles, and recommends a 45-60 episiotomy angle but does not specify whether this is the cutting angle or suture angle. A 45 degree episiotomy cutting angle will likely lead to a sutured episiotomy angle of less than 30 degrees which is the danger zone for OASIS. A 40 degree episiotomy cutting angle has been associated with sutured episiotomy angles of 22 degrees (Kalis 2011) and has been shown to have significantly higher OASIS (Eogan 2006, Stedenfeldt 2012, El-Din 2014)

2.3 Describe the clinical pathway of care that includes the proposed use of the technology.

Response Maternity (childbirth); intrapartum care.

If a relevant NICE clinical guideline has been published, the clinical pathway of care should be consistent with the NICE guideline and described. If relevant, this should include comparator technologies.

2.4 Describe any issues relating to current clinical practice, including any uncertainty about best practice.

Response The current clinical practice is to ‘eyeball’ the episiotomy angles. It has been shown in several in vitro and in-vivo studies that doctors and midwives are unable to correctly and consistently estimate the episiotomy angles during the stressful time of childbirth (Tincello 2003, Andrews 2006, Silf 2014, Fodstad 2014, Naidu 2015). This makes it difficult to ethically justify a randomised trial comparing ‘eyeballing’ with a safety device like the

EPISCISSORS-60, which takes away the human error in estimating episiotomy angles. There is no uncertainty about best practice as the RCOG recommendation to cut an episiotomy at 60 degrees is now adopted by the ACOG, Canadian SOGC, French CNOG and Australian WHA.

If the clinical pathway of care described in response to question 3.3 is not consistent with the relevant NICE clinical guideline, this should be explained in response to question 3.4.

2.5 Describe the new pathway of care incorporating the new technology that would exist if the technology was adopted by the NHS in England.

Response The pathway of care does not change as a result of the EPISCISSORS-60. It simply removes the avoidable harm due to human error in estimating episiotomy angles during childbirth. It makes childbirth safer. Therefore, it is a patient safety device.

2.6 Describe any changes to the way current services are organised or delivered as a result of introducing the technology.

Response There are no changes.

2.7 Describe any additional tests or investigations needed for selecting or monitoring patients, or particular administration requirements, associated with using this technology that are over and above usual clinical practice.

Response None

2.8 Describe any additional facilities, technologies or infrastructure that need to be used alongside the technology under evaluation for the claimed benefits to be realised.

Response None

2.9 Describe any tests, investigations, interventions, facilities or technologies that would no longer be needed with using this technology.

Response No additional tests or investigations are required.

2.10 Describe how the NHS in England can disinvest from tests, investigations, interventions, facilities or technologies described in section 3.9 that would no longer be needed with using this technology.

Response NHSE will achieve savings from the reduction in OASIS repair costs, future elective caesarean sections and anal incontinence disease burden (OASIS is a leading cause of AI in women). Simple calculations suggest a saving of £25 million in direct OASIS repair costs per year. Using the EPISCISSORS-60 leads to Cost Avoidance for the NHS.

3 Regulatory information

3.1 Provide PDF copies of the following documents:

- instructions for use
- CE mark certificate or equivalent UK regulatory approval such as EC declaration of conformity
- quality systems (ISO 13485) certificate (if required).

PDF copies of these documents should be submitted at the same time as section A.

3.2 Does the technology have CE mark for the indication(s) specified in the scope issued by NICE? If so, give the date that authorisation was received. If not, state current UK regulatory status, with relevant dates (for example, date of application and/or expected approval dates).

Response The scissors belong to class 1 and class 2a medical devices group. Therefore, they are self-certified by the manufacturers (declaration of

conformity). There is no special “CE certificate” granted that we, or the manufacturers are aware of. The manufacturers have the declaration of conformity and ISO13485 certificates.

3.3 Does the technology have regulatory approval outside the UK? If so, please provide details.

Response The technology is approved in Australia, the EU, and via the 510K route in the USA. It is also being used in the Middle East.

3.4 If the technology has not been launched in the UK provide the anticipated date of availability in the UK.

Response N/A

3.5 If the technology has been launched in the UK provide information on the use in England.

Response EPISCISSORS-60 were first launched in England in 2014. According to data from the NHS Supply Chain and NHS England, they are used in over 70% of English Hospitals.

4 Ongoing studies

4.1 Provide details of all completed and ongoing studies on the technology from which additional evidence relevant to the decision problem is likely to be available in the next 12 months.

[redacted]

TITLE

[redacted]

This should include unpublished and ongoing studies, and studies awaiting publication. Also include post-marketing surveillance and register data.

4.2 If the technology is, or is planned to be, subject to any other form of assessment in the UK, please give details of the assessment, organisation and expected timescale.

Response NHS England will be monitoring the uptake of the EPISCISSORS-60 and analysing its impact of the OASIS rate from English Hospitals. We do not have any further details of this evaluation.

5 Equality

NICE is committed to promoting equality of opportunity and eliminating unlawful discrimination on the grounds of age, disability, gender reassignment, race, religion or belief, sex, and sexual orientation, and to comply fully with legal obligations on equality and human rights.

Equality issues require special attention because of NICE's duties to have due regard to the need to eliminate unlawful discrimination, promote equality and foster good relations between people with a characteristic protected by the equalities legislation and others.

Any issues relating to equality that are relevant to the technology under assessment should be described. This section should identify issues described in the scope and also any equality issues not captured in the final scope.

Further details on equality may be found in section 11.3 of this document.

5.1.1 Describe any equality issues relating to the patient population and condition for which the technology is being used.

Response There are no equality issues. We have repeatedly emphasised to NICE that there are no issues related to left handed users. We have received user reports describing left handed clinicians performing both a left and right sided mediolateral episiotomy without any problems. We have also challenged NICE to provide any evidence of custom-made left handed surgical scissors available for clinical practice in obstetrics. NICE have failed to provide any such evidence. Therefore, in the absence of a legitimate comparator, this is a non-issue. It maybe noted that the NICE MIB033 on the EPISCISSORS-60 highlighted left handed users as an issue despite our protestations.

5.1.2 Describe any equality issues relating to the assessment of the technology that may require special attention.

Response None that we are aware of. There are no comparator surgical scissors available specifically for left handed users.

5.1.3 How will the submission address these issues and any equality issues raised in the scope?

Response N/A

Section B – Clinical evidence

6 Published and unpublished clinical evidence

Section B requires sponsors to present published and unpublished clinical evidence for their technology.

Sponsors should read section 6 of the Medical Technologies Evaluation Programme methods guide on published and unpublished evidence, available from www.nice.org.uk/mt

All statements should be evidence-based and directly relevant to the scope. Reasons for deviating from the scope should be clearly stated and explained in table A1.

Sponsors are required to submit section B in advance of the full submission (for details on timelines, see the NICE document 'Guide to the Medical Technologies Evaluation Programme process', available from www.nice.org.uk/mt

6.1 Identification of studies

Please note: sections 7.1 and 7.2 of the submission are divided into published and unpublished data. Responses must be split accordingly.

The sponsor's review of the clinical evidence should be systematic and transparent, and a suitable instrument for reporting such as the PRISMA statement (http://www.prisma-statement.org/statement.htm) should be used and CRD should be referred to (www.york.ac.uk/inst/crd).

The strategies used to retrieve relevant clinical data from the published literature and unpublished sources should be clearly described. The methods used should be justified with reference to the scope. Sufficient detail should be provided to enable the methods to be reproduced (the External Assessment Centre must be able to reproduce the search), and the rationale for any inclusion and exclusion criteria regarding search terms should be given.

Published studies

6.1.1 Describe the strategies used to retrieve relevant clinical data from the published literature. Exact details of the search strategy used should be provided in section 10, appendix 1.

6.1.2 Response Since there are two recent peer-reviewed published systematic reviews including all hitherto published work, we used and reproduce their methodology. Divakova (2019) describe the Healthcare Databases Advanced Search platform was used to conduct a comprehensive literature search of the MEDLINE, EMBASE and CINHAL databases up to September 2018. Their search strategy consisted of the words 'Episcissors-60' or 'episcissors 60'. The advanced search strategy was adapted to suit the databases being searched. The search was restricted to 'humans'. No language or age group restrictions were applied. Cole (2019) performed a literature search of the PubMed, Embase and Cochrane databases using the key terms episiotomy, Episcissors-60, episiotomy scissors and Obstetric Anal Sphincter Injuries (OASIS) from inception to May 2018. The reference lists of any identified studies were also reviewed for studies that potentially met the inclusion criteria. No language filters were applied to the search. Both Systematic reviews followed the PRISMA guidelines. Cole (2019) also registered their review with PROSPERO database.

6.1.3 In addition, published non-human studies are separately presented.

All published data relevant to the decision problem must be included.

Unpublished studies

6.1.4 Describe the strategies used to retrieve relevant clinical data from unpublished sources.

Response One unpublished study was obtained directly from the authors Koh et al. We do not have details of this paper. The abstract is presented above.

The submission of unpublished evidence relevant to the decision problem is encouraged.

6.2 Study selection

Published studies

6.2.1 Complete table B1 to describe the inclusion and exclusion criteria used to select studies from the published literature. Suggested headings are listed in the table below. Other headings should be used if necessary.

Table B1 Selection criteria used for published studies

Since the two systematic reviews have published their methodologies, we reproduce them in full

DIVAKOVA (2019)

Used the National Heart Lung and Blood Institute's tool for assessing the quality of before-after studies (https://www.nhlbi.nih.gov/health-topics/study-qualityassessment-tools).

Inclusion criteria	
Population	Pregnant women who had undergone mediolateral or lateral episiotomy
Interventions	Mediolateral or lateral episiotomy with Episcissors-60™.
Outcomes	The primary outcome was rate of obstetric anal sphincter injury (OASI).
Study design	Systematic review and meta-analysis
Language restrictions	None
Search dates	From beginning to September 2018
Exclusion criteria	
Population	Non-human studies
Interventions	
Outcomes	
Study design	Case reports; commentaries and general reviews; overlapping publications from the same center; studies on midline episiotomy and case series studies which reported data on episiotomy using Episcissors-60™ without comparison with episiotomies with other scissors.
Language restrictions	None
Search dates	From beginning to September 2018

COLE (2019)

Quality assessment of studies done by using the Newcastle- Ottawa scale for non-randomised studies (AHRQ standards) and the Jadad scale for randomised studies.

Inclusion criteria	
Population	All peer-reviewed studies evaluating the use of Episcissors-60 in clinical practice
Interventions	Episiotomy
Outcomes	The primary outcome measure was the rate of OASIS
Study design	Systematic review and evidence synthesis
Language restrictions	none
Search dates	From beginning till May 2018
Exclusion criteria -non human studies	
Population	
Interventions	
Outcomes	
Study design	Birth model studies
Language restrictions	None
Search dates	

6.2.2 Report the numbers of published studies included and excluded at each stage in an appropriate format.

Response Since there are two systematic reviews about the EPISCISSORS-60 recently published in peer-reviewed journals (Cole 2019, Divakova 2019), we have cited them. They have already followed the PRISMA guidelines for conducting systematic reviews. Cole (2019) included 5 studies in their qualitative synthesis. Divakova (2019) included 4 studies in their meta-analysis. Both excluded 3 published studies, which were case series with no comparators and non-human studies. The PRISMA flow diagram for both reviews are available in the publication pdfs.

It is recommended that the number of published studies included and excluded at each stage is reported using the PRISMA statement flow diagram (available from *www.prisma-statement.org/statement.htm*)

Unpublished studies

6.2.3 Complete table B2 to describe the inclusion and exclusion criteria used to select studies from the unpublished literature. Suggested

headings are listed in the table below. Other headings should be used if necessary.

Table B2 Selection criteria used for unpublished studies

Inclusion criteria	
Population	Pregnant women requiring episiotomy
Interventions	EPISCISSORS-60 compared with historical controls
Outcomes	OASIS
Study design	Time Series analysis
Language restrictions	None
Search dates	Beginning till 20th May 2019
Exclusion criteria	
Population	Multiparous women
Interventions	
Outcomes	
Study design	
Language restrictions	
Search dates	

6.2.4 Report the numbers of unpublished studies included and excluded at each stage in an appropriate format.

Response None that we are aware of.

It is recommended that the number of unpublished studies included and excluded at each stage is reported using the PRISMA statement flow diagram (available from *www.prisma-statement.org/statement.htm*)

6.3 Complete list of relevant studies

The sponsor should provide a PDF copy of all studies included in the submission if the sponsor is either the copyright owner or has adequate copyright clearance to permit the intended use by NICE. If the sponsor does not have sufficient copyright clearance, they are asked to submit references or links only, or details of contacts for unpublished studies. For unpublished studies for which a manuscript is not available, provide a structured abstract

about future journal publication. If a structured abstract is not available, the sponsor must provide a statement from the authors to verify the data provided.

6.3.1 Provide details of all published and unpublished studies identified using the selection criteria described in tables B1 and B2.

6.3.2 Freeman (2014), Patel (2014), Sawant (2015), van Roon (2015), Lou (2016) are available as free downloads from journals. Mohiudin (2018), Divakova (2019) and Cole (2019) have been provided to us by the authors in accordance with their journals' policies of allowing certain number of copies for free distribution. Van Roon 2016 is a non-human study measuring episiotomy angles with EPISCISSORS-60 and normal scissors. It was provided by the authors.

6.3.3

The details of all published and unpublished studies that compare the technology with other treatments for the relevant group of patients should be presented using tables B3 and B4 respectively. The studies that ***compare the intervention directly with the appropriate comparator(s)*** *referred to in the decision problem should be clearly highlighted. If there are none, please state this. All types of studies should be considered, including observational studies such as cohort, case series and case-control studies, and single case reports and qualitative studies when relevant to the scope.*

The list of relevant studies must be complete and will be validated by independent searches conducted by the External Assessment Centre.

Published studies should be referenced by first author name and year of publication. Unpublished studies should be referenced by first author and date of report. Full details of each reference should be provided in the reference list after section 9. In addition, list any trial short names if useful.

Table B3 List of relevant published studies

Primary study reference	Study name (acronym)	Population	Intervention	Comparator
Freeman 2014		17 patients undergoing instrumental delivery	EPISCISSO RS-60	None; case series
Patel 2014		25 spontaneous vaginal deliveries	EPISCISSO RS-60	None; case series
Sawant 2015	RCT/Braun stadler	63 patients	Episcissors-60 (n=31)	Braun Stadler scissors (n=32)
Van Roon 2015	Poole/Hinchingbrooke study	838 nulliparous deliveries	EPISCISSO RS-60	Regular episiotomy scissors; historic controls
Lou 2016	Croydon study	79 deliveries	EPISCISSO RS-60	None; case series
Van Roon 2016	Simulation Model study	110 doctors and midwives	EPISCISSO RS-60	Regular episiotomy scissors
Mohiudin 2018	Royal Free Study	2566 births	EPISCISSO RS-60	Regular episiotomy scissors; historic controls
Divakova 2019	Meta-analysis	1919 deliveries	EPISCISSO RS-60 (n=797)	Regular episiotomy scissors.
Cole 2019	Systematic review	3509 women	EPISCISSO RS-60	Regular episiotomy scissors.

Table B4 List of relevant unpublished studies

Data source	Study name (acronym)	Population	Intervention	Comparator
Personal Communication	Koh 2019	6840 deliveries	EPISCISSO RS-60	Regular episiotomy scissors.(historical controls)

6.3.4 State the rationale behind excluding any of the published studies listed in tables B3 and B4.

6.3.5 The systematic reviews, in accordance with PRISMA standards excluded case series, non-human studies and duplicated publications.

The rationale for study exclusion must be provided by the sponsor for transparency. For example, if studies have been identified but there is no access to the level of study data needed, this should be indicated.

6.4 Summary of methodology of relevant studies

It is expected that all key aspects of the methodology will be in the public domain. If a sponsor wishes to submit aspects of the methodology in confidence, section 11.2 describes how to highlight confidential information.

6.4.1 Describe the study design and methodology for each of the published and unpublished studies using tables B5 and B6 as appropriate. A separate table should be completed for each study.

Table B5 Summary of methodology for randomised controlled trials

Study name	**Sawant et al (2015)**
Objectives	Compare post-suture episiotomy angles with the EPISCISSORS-60 and Braun-Stadler scissors
Location	Navi Mumbai, India
Design	Block/Cluster randomisation
Duration of study	9 months
Sample size	63
Inclusion criteria	Nulliparous women
Exclusion criteria	Multiparous women
Method of randomisation	Prospective cluster randomisation
Method of blinding	None; each arm of the study was conducted by a different team so concealment was unnecessary and the Hawthorne effect prevented. Lack of allocation concealment has no importance in studies with objective outcomes (Wood, BMJ 2008) Blinding also not possible as scissors have different designs.
Intervention(s) (n =) and comparator(s) (n =)	Intervention (n=31); comparator (n=32)

Baseline differences	None
Duration of follow-up, lost to follow-up information	Immediate post-partum.
Statistical tests	Two-tailed T tests
Primary outcomes (including scoring methods and timings of assessments)	Post-suture episiotomy angles. Measured immediately after suturing with a protractor transparency.
Secondary outcomes (including scoring methods and timings of assessments)	OASIS (as detected during birth). Objective assessment is the clinical standard. Caudal distance between episiotomy and anus.
BIAS/Quality	Low bias, good quality

Table B6 Summary of methodology for observational studies

Study name	**Freeman 2014**
Objective	Efficacy in achieving sutured episiotomy angles of 40-60 degrees (safe zone)
Location	UK
Design	Observational study
Duration of study	4 months
Patient population	Women undergoing episiotomy during childbirth
Sample size	17
Inclusion criteria	Operative vaginal deliveries (OVD)
Exclusion criteria	Non-OVD
Intervention(s) (n =) and comparator(s) (n =)	N=17, no comparator
Baseline differences	none
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	No follow up required
Statistical tests	Not described
Primary outcomes (including scoring methods and timings of assessments)	Sutured episiotomy angles; immediate with a protractor transparency
Secondary outcomes (including scoring methods and timings of assessments)	OASIS, immediate

Bias	Moderate

Study name	**Patel 2014**
Objective	Sutured episiotomy angle
Location	Thane, India
Design	Observational study
Duration of study	Not stated
Patient population	Women undergoing episiotomy
Sample size	25
Inclusion criteria	Spontaneous Vaginal Delivery (SVD)
Exclusion criteria	OVD
Intervention(s) (n =) and comparator(s) (n =)	25, no comparators
Baseline differences	n/a
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	No follow up
Statistical tests	Not described
Primary outcomes (including scoring methods and timings of assessments)	Sutured Episiotomy angle measured with protractor transparencies; immediate
Secondary outcomes (including scoring methods and timings of assessments)	OASIS; immediate
Bias	Low

Study name	**Van Roon 2015**
Objective	Compare OASIS rates before and after adoption of the EPISCISSORS-60
Location	2 hospitals in UK (Poole and Hinchingbrooke)
Design	Observational study

Duration of study	5 months of intervention compared to 1 year previous data
Patient population	Nulliparous women undergoing episiotomy
Sample size	3076 nulliparous vaginal births
Inclusion criteria	Nulliparous women undergoing clinically indicated episiotomy
Exclusion criteria	Multiparous women
Intervention(s) (n =) and comparator(s) (n =)	EPISCISSORS-60 period (838), Comparator=2238
Baseline differences	None
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	None
Statistical tests	Fisher exact test
Primary outcomes (including scoring methods and timings of assessments)	OASIS rates
Secondary outcomes (including scoring methods and timings of assessments)	With and without episiotomy, in SVD and OVD, OASIS with EPISCISSORS-60 and regular scissors in historical controls; episiotomy angles, perineal length, distance from episiotomy to anus
Bias	Moderate, but good quality

Study name	**Lou 2016**
Objective	Efficacy in achieving sutured episiotomy angles of 40-60 degrees (safe zone); user friendliness and OASIS rate
Location	UK
Design	Observational study
Duration of study	5 months
Patient population	Women undergoing episiotomy during childbirth
Sample size	79
Inclusion criteria	Women undergoing episiotomy during childbirth
Exclusion criteria	No episiotomy
Intervention(s) (n =) and comparator(s) (n =)	N=79, no comparator
Baseline differences	none

How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	No follow up required
Statistical tests	Not described
Primary outcomes (including scoring methods and timings of assessments)	Sutured episiotomy angles; immediate with a protractor transparency; Likert scale 1-5 for user preference over regular episiotomy scissors, OASIS rate
Secondary outcomes (including scoring methods and timings of assessments)	OASIS, immediate
Bias	Moderate

Study name	**Van Roon 2016**
Objective	Efficacy in achieving sutured episiotomy angles with EPISCISSORS-60 versus regular episiotomy scissors (Mayo)
Location	UK
Design	Observational study
Duration of study	5 months
Patient population	Doctors and midwives attending the SUPPORT course at 2 UK hospitals
Sample size	110
Inclusion criteria	As above
Exclusion criteria	None
Intervention(s) (n =) and comparator(s) (n =)	N=110, EPISCISSORS-60 and regular episiotomy scissors.
Baseline differences	none
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	No follow up required
Statistical tests	Paired sample T tests
Primary outcomes (including scoring	Episiotomy angles;

methods and timings of assessments)	
Secondary outcomes (including scoring methods and timings of assessments)	
Bias	n/a

Study name	**Mohiudin 2018**
Objective	OASIS rates before and after full adoption of the EPISCISSORS-60
Location	UK (2 north London hospitals, Barnet and Royal Free)
Design	Observational study
Duration of study	6 months of full adoption of the EPISCISSORS-60
Patient population	Nulliparous vaginal births
Sample size	2566
Inclusion criteria	Nulliparous women undergoing episiotomy
Exclusion criteria	None stated
Intervention(s) (n =) and comparator(s) (n =)	Nulliparous vaginal births during EPISCISSORS-60 implementation=1122 (905 Barnet+ 217 RFL); comparator (Nulliparous vaginal births during 2014-15)= 1172(725 Barnet +447 RFL)
Baseline differences	none
How were participants followed-up (for example, through pro-active follow-up or passively). Duration of follow-up, participants lost to follow-up	Not applicable
Statistical tests	Chi Square with Yates' correction; Fisher Exact tests
Primary outcomes (including scoring methods and timings of assessments)	OASIS rates overall, by episiotomy and without, by type of birth (SVD, NVD)
Secondary outcomes (including scoring methods and timings of assessments)	Nil mentioned

6.4.2 Provide details on data from any single study that have been drawn from more than one source (for example a poster and unpublished report) and/or when trials are linked this should be made clear (for example, an open-label extension to randomised controlled trial).

Response duplicate publications were omitted.

6.4.3 Highlight any differences between patient populations and methodology in all included studies.

Response Sawant et al (2015) is the only RCT, but only powered to detect sutured episiotomy angle differences. All other studies are either Case Series or Observational studies with historical controls as comparators. All studies examined OASIS, while some additionally reported the post-suture episiotomy angles with the EPISCISSORS-60. It may be noted that sutured episiotomy angles were never measured previously in routine practice before the EPISCISSORS-60 were introduced. There is one study about the EPISCISSORS-60 in birth model; efficacy and preference of the EPISCISSORS-60 during the SUPPORT programme (van Roon 2016).

Differences between study groups to consider include, but are not limited to, baseline patient characteristics, delivery of intervention and care setting.

6.4.4 Provide details of any subgroup analyses that were undertaken in the studies included in section 7.4.1. Specify the rationale and state whether these analyses were pre-planned or post-hoc.

Response UK studies reported OASIS as outcomes in nulliparous deliveries. Some studies reported outcomes in Spontaneous (SVD) and Operative vaginal deliveries (OVD) separately as OASIS is much higher in OVDs. Subgroups as defined by NICE were not studied as no information was available on ethnicity etc.

6.4.5 If applicable, provide details of the numbers of patients who were eligible to enter the study(s), randomised, and allocated to each treatment in an appropriate format.

Response Only nulliparous deliveries were reported in the UK studies. There were no randomised UK studies. The overall number of overall nulliparous births and the episiotomy details were described. In the Indian studies (Patel 2014, Sawant 2015) multiparae were also included. However, Sawant 2015 was not powered to detect the differences in OASIS rates, only to detect differences in sutured episiotomy angles. This was 12 degrees and statistically significant.

Van Roon 2016 found a mean 15 degrees difference between episiotomies cut with EPISCISSORS-60 (60 degrees) versus regular episiotomy scissors (45 degrees) in a distended perineum model simulating actual childbirth.

It is recommended that details of the numbers of patients that were eligible to enter the study(s), randomised and allocated to each treatment are presented as CONSORT flow charts if possible (see www.consort-statement.org/consort-statement/).

6.4.6 If applicable provide details of and the rationale for, patients that were lost to follow-up or withdrew from the studies.

Response no patients were lost to follow up or reported as having withdrawn.

6.5 Critical appraisal of relevant studies

The validity of the results of an individual study will depend on the robustness of its overall design and execution, and its relevance to the scope. Each study that meets the criteria for inclusion should therefore be critically appraised. Whenever possible, the criteria for assessing published studies should also be used to assess the validity of unpublished and part-published studies.

For the quality assessments use an appropriate and validated quality assessment instrument. Key aspects of quality to be considered can be found in 'Systematic reviews: CRD's guidance for undertaking reviews in health care' (www.york.ac.uk/inst/crd).

The critical appraisal will be validated by the External Assessment Centre.

6.5.1 Complete a separate quality assessment table for each study. A suggested format for the quality assessment results is shown in tables B7 and B8.

Table B7 Critical appraisal of randomised control trials

Study name	**Sawant 2015**	
Study question	**Response (yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was randomisation carried out appropriately?	Yes	Block/cluster randomisation. It actually prevents the Hawthorne effect.
Was the concealment of treatment allocation adequate?	Yes	Allocation concealment does not affect results where outcomes are objective. Scissors design also precludes blinding.
Were the groups similar at the outset of the study in terms of prognostic factors, for example, severity of disease?	Yes	Two separate units conducting alternate 24 hour management of the SAME labour ward in the SAME hospital.
Were the care providers, participants and outcome assessors blind to treatment allocation? If any of	No	No bias is introduced in cluster randomisation as allocation does not affect objective outcomes (Wood BMJ 2008). Moreover, it actually prevented bias as the Hawthorne effect was avoided (Cole 2019).

these people were not blinded, what might be the likely impact on the risk of bias (for each outcome)?		
Were there any unexpected imbalances in drop-outs between groups? If so, were they explained or adjusted for?	n/a	
Is there any evidence to suggest that the authors measured more outcomes than they reported?	No	
Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing data?	n/a	They measured sutured episiotomy angles and diagnosed OASIS. There was no missing data.
Adapted from Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

Table B8 Critical appraisal of observational studies

Study name Freeman 2014		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Opportunistic, consecutive recruitment of women undergoing OVD
Was the exposure accurately measured to minimise bias?	Not clear	This is standard practice in early case series where proof of efficacy is being generated
Was the outcome accurately measured to minimise bias?	Yes	Objective measurement of episiotomy angles and OASIS
Have the authors identified all	Not clear	

important confounding factors?		
Have the authors taken account of the confounding factors in the design and/or analysis?	Not clear	
Was the follow-up of patients complete?	Yes	Limited to episiotomy angles and OASIS
How precise (for example, in terms of confidence interval and p values) are the results?	Fairly good	Mean sutured episiotomy angle is 42.4 (+/- 7 SD). Median=43 degrees (95% CI 38.8-46). The distribution seems symmetric as mean and median are identical.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Study name	**Patel 2014**	
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Opportunistic, consecutive recruitment of women undergoing OVD
Was the exposure accurately measured to minimise bias?	Not clear	This is standard practice in early case series where proof of efficacy is being generated.
Was the outcome accurately measured to minimise bias?	Yes	Objective measurement of episiotomy angles and OASIS.
Have the authors identified all important confounding factors?	Not clear	
Have the authors taken account of the confounding factors in the design and/or analysis?	Not clear	

Was the follow-up of patients complete?	Yes	Limited to measurement of episiotomy angles and OASIS
How precise (for example, in terms of confidence interval and p values) are the results?	Fairly good	Authors report median 50 degrees angle (SD=3.5, IQR=48-54))
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Study name van Roon 2015		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Extracted from maternity database.
Was the exposure accurately measured to minimise bias?	Yes	No cherry picking, straight from hospital database
Was the outcome accurately measured to minimise bias?	Yes	Measurement of perineal body, episiotomy angles are geometric with tools and OASIS detection was clinical
Have the authors identified all important confounding factors?	Not clear	
Have the authors taken account of the confounding factors in the design and/or analysis?	No	It was a straight correlation between type of birth and OASIS with the impact of episiotomies performed with EPISCISSORS-60 and regular scissors
Was the follow-up of patients complete?	Yes	Limited to episiotomy angles and OASIS
How precise (for example, in terms of confidence interval and p values) are the results?	Yes	Tests used are cited; raw data is provided to verify calculations.

Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study

Study name Lou 2016		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Opportunistic, consecutive recruitment of women undergoing episiotomy
Was the exposure accurately measured to minimise bias?	Not clear	This is standard practice in early case series where proof of efficacy is being generated.
Was the outcome accurately measured to minimise bias?	Yes	Objective measurement of episiotomy angles and OASIS.
Have the authors identified all important confounding factors?	Not clear	
Have the authors taken account of the confounding factors in the design and/or analysis?	Not clear	
Was the follow-up of patients complete?	Yes	Limited to measurement of episiotomy angles and OASIS; user preference scoring
How precise (for example, in terms of confidence interval and p values) are the results?	Fairly good	Authors report median 51 degrees angle. OASIS reduction by 43%; and 91% users preferred the EPISCISSORS-60 over regular episiotomy scissors.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Study name Van Roon 2016		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**

Was the cohort recruited in an acceptable way?	Yes	All doctors and midwives attending the SUPPORT programme
Was the exposure accurately measured to minimise bias?	Yes	
Was the outcome accurately measured to minimise bias?	Yes	Objective measurement of cut episiotomy angles by protractor transparency
Have the authors identified all important confounding factors?	Not clear	
Have the authors taken account of the confounding factors in the design and/or analysis?	Not clear	
Was the follow-up of patients complete?	N/A	
How precise (for example, in terms of confidence interval and p values) are the results?	Yes	Statistical tests cited; raw data provided to verify computations. 95% Confidence intervals do not overlap.
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

Study name Mohiudin 2018		
Study question	**Response yes/no/not clear/N/A)**	**How is the question addressed in the study?**
Was the cohort recruited in an acceptable way?	Yes	Extracted from hospital maternity database and verified via dashboard.

Was the exposure accurately measured to minimise bias?	Yes	
Was the outcome accurately measured to minimise bias?	Yes	No cherry picking; straight from hospital database
Have the authors identified all important confounding factors?	Not clear	
Have the authors taken account of the confounding factors in the design and/or analysis?		It was a straight correlation between type of birth and OASIS with the impact of episiotomies performed with EPISCISSORS-60 and regular scissors
Was the follow-up of patients complete?	Yes	Limited to OASIS detection clinically.
How precise (for example, in terms of confidence interval and p values) are the results?	Yes	Statistical tests cited; raw data provided to verify computations
Adapted from Critical Appraisal Skills Programme (CASP): Making sense of evidence 12 questions to help you make sense of a cohort study		

6.6 Results of the relevant studies

All outcomes pertinent to the scope and the measures used to assess those outcomes should be presented.

6.6.1 Complete a results table for **each** study with all relevant outcome measures pertinent to the decision problem. A suggested format is given in table B9.

A separate table for each study must be completed. State N/A or unknown if appropriate. Any outcomes not tested statistically can be included in the comments section.

For each outcome for each included study, provide the following information:

- *The primary hypothesis under consideration and the statistical analysis used for testing hypotheses. Provide details of the power of the study and a description of sample size calculation, including rationale and assumptions.*
- *The outcome name and unit of measurement. Indicate the outcomes that were specified in the study protocol as primary or secondary, and whether they are relevant with reference to the decision problem.*
- *The size of the effect. For dichotomous outcomes, the results ideally should be expressed as both relative risks (or odds ratios) and risk (or rate) differences. For time-to-event analysis, the hazard ratio is an equivalent statistic. Both absolute and relative measures should be presented.*
- *A 95% confidence interval.*
- *The number of participants in each group included in each analysis and whether the analysis was by 'intention to treat'. State the results in absolute numbers if feasible.*
- *Details of how the analysis took account of patients who withdrew and if patients were excluded from the analysis, give the rationale for this.*
- *Data from pre-specified outcomes rather than post-hoc analysis. If appropriate, provide evidence of reliability or validity, and current status of the measure (such as use in current clinical practice).*
- *Clear statements of when interim study data are quoted, along with the point at which data were taken and the time remaining until completion of that study. Analytical adjustments should be described to cater for the interim nature of the data.*

- *Other relevant data that may assist in interpretation of the results, such as adherence to medication and/or study protocol.*
- *Discussion and justification of definitions of any clinically important differences.*
- *Reports of any other analyses performed, including subgroup analysis and adjusted analyses, indicating whether they are pre-specified or exploratory.*
- *Graphs or figures to supplement text and tabulated data if available.*

Table B9 Outcomes from published and unpublished studies

Study name		**Freeman 2014**
Size of study groups	**Treatment**	17
	Control	0
Study duration	**Time unit**	5 months
Type of analysis	**Intention-to-treat/per protocol**	All recruited delivered patients per protocol
Outcome	**Name**	Sutured episiotomy angles
	Unit	Degrees
		OASIS; present or absent clinically
Effect size	**Value**	Mean angle=42.4 degrees, median 43 degrees
	95% CI	38.8-46
Statistical test	**Type**	Not mentioned
	p value	
Other outcome	**Name**	Ease of use
	Unit	Likert scale 1-5
Effect size	**Value**	88% agreed or strongly agreed they were easy to use
	95% CI	
Statistical test	**Type**	
	p value	
Comments		See Divakova 2019 and Cole 2019 for further details

Study name		Patel 2014
Size of study groups	Treatment	25
	Control	Nil (case series)
Study duration	Time unit	5 months
Type of analysis	Intention-to-treat/per protocol	Per protocol
Outcome	Name	Episiotomy angles and OASIS
	Unit	Degrees, clinical detection
Effect size	Value	50 degrees, no OASIS
	95% CI	IQR 48-54, range 45-55 degrees
Statistical test	Type	Not described
	p value	n/a
Other outcome	Name	
	Unit	
Effect size	Value	
	95% CI	
Statistical test	Type	
	p value	
Comments		See Divakova 2019 and Cole 2019 for further details

Study name		Sawant 2015
Size of study groups	Treatment	31
	Control	32
Study duration	Time unit	8 months
Type of analysis	Intention-to-treat/per protocol	Per protocol
Outcome	Name	Episiotomy angle; OASIS
	Unit	Degrees; OASIS
Effect size	Value	40.6 degrees v 28.6 degrees
	95% CI	+/- 2
Statistical test	Type	Not mentioned
	p value	P<0.0001
Other outcome	Name	Post-delivery linear distance between the caudal end of the episiotomy and the anus
	Unit	mm
Effect size	Value	35 mm v 19.5 mm (comparator)
	95% CI	35mm (+/- 2.2) v 19.5mm (+/- 1.3)
Statistical test	Type	Not mentioned
	p value	P<0.0001
Comments		No OASIS with EPISCISSORS-60; 1 with Braun Stadler scissors. See Divakova 2019 and Cole 2019 for further details

Study name		Van Roon 2015
Size of study groups	Treatment	838
	Control	2238
Study duration	Time unit	5 months of full adoption of EPISCISSORS-60 versus 12 months of historical data
Type of analysis	Intention-to-treat/per protocol	Per protocol
Outcome	Name	OASIS
	Unit	Clinical detection
Effect size	Value	84% OASIS reduction in SVD given episiotomy; 1% with EPISCISSORS-60 versus 6.25% with regular scissors; 5.25% risk difference; RR=7 if no episiotomy is given versus if EPISCISSORS-60 were used.
	95% CI	
Statistical test	Type	Fisher exact 2 tailed test
	p value	P=0.04
Other outcome	Name	Episiotomy angle
	Unit	degrees
Effect size	Value	100% achieved angles between 40-60 degrees
	95% CI	Mean=53; 50.7-55.8 in SVD; Mean=52; 49-54 in OVD
Statistical test	Type	Fisher exact 2 tailed
	p value	
Comments		See Divakova 2019 and Cole 2019 for further details

Study name		Van Roon 2016
Size of study groups	Treatment	110
	Control	110
Study duration	Time unit	Duration of SUPPORT training programme
Type of analysis	Intention-to-treat/per protocol	Per protocol
Outcome	Name	Episiotomy angle
	Unit	Degrees
Effect size	Value	60 degrees with EPISCISSORS-60; 45 degrees with regular episiotomy scissors
	95% CI	59.3-60.7; 43.3-46.7
Statistical test	Type	Paired t test
	p value	P=0.05
Other outcome	Name	
	Unit	
Effect size	Value	
	95% CI	
Statistical test	Type	
	p value	
Comments		

Study name		**Lou 2016**
Size of study groups	**Treatment**	79
	Control	0
Study duration	**Time unit**	5 months
Type of analysis	**Intention-to-treat/per protocol**	All recruited delivered patients per protocol
Outcome	**Name**	Sutured episiotomy angles
	Unit	Degrees
		OASIS; present or absent clinically
		User preferences over regular episiotomy scissors
Effect size	**Value**	Mean angle=51degrees
	95% CI	+/- 3.4 SD
Statistical test	**Type**	Not mentioned
	p value	
Other outcome	**Name**	Ease of use
	Unit	Likert scale 1-5
Effect size	**Value**	91% agreed or strongly agreed they were easy to use and preferred them to regular episiotomy scissors 43% OASIS reduction
	95% CI	
Statistical test	**Type**	
	p value	
Comments		See Divakova 2019 and Cole 2019 for further details
Study name		**Mohiudin 2018**
Size of study groups	**Treatment**	1122
	Control	1172
Study duration	**Time unit**	6 months of EPISCISSORS-60 adoption versus 6 month of prior historical controls
Type of analysis	**Intention-to-treat/per protocol**	protocol
Outcome	**Name**	OASIS
	Unit	Clinical detection
Effect size	**Value**	0.63% (EPISCISSORS-60) v 6.3% without in OVD Barnet (p=0.01) 0% (EPISCISSORS-60) v 6.6% without in SVD Barnet (p=0.006)
	95% CI	Not stated

Statistical test	**Type**	Chi square with Yates' correction; Fisher exact
	p value	As above
Other outcome	**Name**	Royal Free; EPISCISSORS-60 v no episiotomy after adoption
	Unit	OASIS
Effect size	**Value**	OVD= 2.6% (EPISCISSORS-60) versus 42%; p=0.000 SVD=0% (EPISCISSORS-60) versus 4.7%; p=0.03
	95% CI	
Statistical test	**Type**	
	p value	As above
Comments		See Divakova 2019 and Cole 2019 for further details

6.6.2 Justify the inclusion of outcomes in table B9 from any analyses other than intention-to-treat.

6.7 Adverse events

In section 7.7 the sponsor is required to provide information on the adverse events experienced with the technology being evaluated in relation to the scope.

For example, post-marketing surveillance data may demonstrate that the technology shows a relative lack of adverse events commonly associated with the comparator.

6.7.1 Using the previous instructions in sections 7.1 to 7.6, provide details of the identification of studies on adverse events, study selection, study methodologies, critical apprasial and results.

For studies that have already been identified as relevant and appraised in sections 7.1 to 7.6 of the submission that were designed primarily to assess safety outcomes (for example, they are powered to detect significant differences between treatments with respect to the incidence of an adverse

event), should be presented as a list of studies with the relevant study reference used in the submission.

Examples of search strategies for specific adverse effects and/or generic adverse-effect terms and key aspects of quality criteria for adverse-effects data can found in 'Systematic reviews: CRD's guidance for undertaking reviews in health care' (available from www.york.ac.uk/inst/crd).

Exact details of the search strategy used should be provided in section 10 appendix 2.

The sponsor's search strategy will be replicated by the External Assessment Centre.

6.7.2 Provide details of all important adverse events reported for each study. A suggested format is shown in table B10.

When providing details of important adverse events reported for each study, for each group, give the number of people with the adverse event, the total number of people in the group and the percentage with the event. Present the relative risk and risk difference and associated 95% confidence intervals for each adverse event.

Table B10 Adverse events across patient groups

	Time period 1			***Time period 2 etc.***		
	***Intervention* % of patients (n = *x*)**	***Comparator* % of patients (n = *x*)**	**Relative risk (95% CI)**	***Intervention* % of patients (n = *x*)**	***Comparator* % of patients (n = *x*)**	**Relative risk (95% CI)**
Class 1 (for example, nervous system disorders)						
Adverse event 1						
Adverse event 2						
Class 2 (for example, vascular disorders)						
Adverse event 3						
Adverse event 4						

CI, confidence interval
Adapted from European Public Assessment Reports published by the European Medicines Agency

6.7.3 Describe all adverse events and outcomes associated with the technology in national regulatory databases such as those maintained by the MHRA and FDA (Maude).

Response No adverse events have been brought to our notice nor in the MHRA (search words episcissors60, EPISCISSORS-60, episiotomy). FDA is not applicable.

The primary outcome for all clinical studies was OASIS *which in itself can be regarded an adverse event.* None of the studies had 'a priori' power calculations to detect a difference between the EPISCISSORS-60 and the comparator group. The UK studies were observational in nature, and simply reported a case series with the EPISCISSORS-60 (Freeman 2014, Lou 2016) or extracts from the Maternity database over time periods when the EPISCISSORS-60 were not in use and after they were FULLY ADOPTED by the reporting hospitals, ie the underlying assumption was that ALL episiotomies would have been performed with the EPISCISSORS-60 in that period, to fulfil the safety recommendations of the RCOG. OASIS was reported as an overall incidence and also by type of birth (SVD v OVD). OASIS was also analysed by whether episiotomy was given.

6.7.4 Provide a brief overview of the safety of the technology in relation to the scope.

Response The EPISCISSORS-60 is essentially a patient safety device. The RCOG recommends a 60 degree episiotomy cutting angle at crowning. By taking away the human error inherent in estimating episiotomy angles of 60 degrees at the time of crowning of the fetus. It prevents avoidable harm which is one of the key aims of the maternity pathway. It is a fixed angle device, which is patented. It has a unique flexible guide-limb that when properly aligned to the anal midline in the posterior perineum, will ensure a 60 degree episiotomy cut, irrespective of the degree of perineal distension (which is dependent on many factors like the baby's weight, malpresentation, malposition, whether vacuum or forceps used). The post-delivery sutured episiotomy angles reported by multiple studies is between 40-60 degrees as

reported in a published meta-analysis (Cole 2019), which is regarded as the SAFE ZONE for episiotomies (Eogan 2006, Andrews 2006, Kalis 2008, Kalis 2011).

6.8 Evidence synthesis and meta-analysis

When more than one study is available and the methodology is comparable, a meta-analysis should be considered.

Section 7.8 should be read in conjunction with the 'Medical Technologies Evaluation Programme Methods Guide', available from www.nice.org.uk/mt

When direct comparative evidence about two key treatments is not available, indirect treatment comparison methods can be used to derive comparative estimates of the effectiveness of these two treatments. For example, if there is evidence comparing A with B, and B with C, indirect treatment comparison techniques could be used to help compare A with C. This option should be considered even though it may be less suitable for the evaluation of many new medical technologies, either because of lack of multiple comparators in the evidence base, or limitations in the evidence base/study designs.

6.8.1 Describe the technique used for evidence synthesis and/or meta-analysis. Include a rationale for the studies selected, details of the methodology used and the results of the analysis.

Response 1] Divakova 2019- Meta-analysis and systematic review.

This meta-analysis was performed in accordance with the PRISMA guidelines.

Search strategy

The Healthcare Databases Advanced Search platform was used to conduct a comprehensive literature search of the MEDLINE, EMBASE and CINHAL databases up to September 2018. The search strategy consisted of the words Episcissors-60' or 'episcissors 60'. The advanced search strategy was

adapted to suit the databases being searched. The search was restricted to 'humans'. No language or age group restrictions were applied.

Study selection and data extraction procedures

The following process was used to identify eligible studies: the titles and abstracts of the citations identified by the electronic searches were screened and full text papers of potentially eligible abstracts were retrieved. Hand searching of reference lists of the articles was also performed to retrieve other articles that might have been missed by our search strategy. The manufacturing company of Episcissors-60™(Medinvent Ltd) was also contacted.

Methodological quality assessment and data synthesis

The quality of all the papers fulfilling the inclusion criteria was assessed using a quality assessment tool based on National Heart, Lung and Blood Institute's tool for assessing the quality of before-after studies (https://www.nhlbi.nih.gov/health-topics/study-qualityassessment-tools),

Size: Studies which included ≥ 630 subjects, around 315 in each arm at a 1:1 ratio, were awarded a score of 1; others were awarded a score of 0. This number was based on the ability of the study to detect a 50% reduction in OASI from 5% to 2.5% with 90% power.

Generalizability: Studies which were readily generalizable as they did not super-select their population were awarded a score of 1, whilst other studies which selected especially high risk group were awarded a score of 0.

Comparator: Studies with a contemporaneous comparator group were awarded a score of 1, whilst studies with a historic comparator group were awarded a score of 0.

A random effect model was used to allow for the effect of other potential factors—such as previous OASI—on the risk of OASI. Heterogeneity was evaluated statistically using the I2 test. An I2 value of < 25% was considered indicative of low heterogeneity, 25–75% was considered indicative of moderate heterogeneity and > 75% was considered indicative of high heterogeneity. Statistical analysis was performed using Review Manager 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration 2011).

Twenty-one studies were initially identified. After exclusion of duplicates and irrelevant studies, four citations were included in the systematic review and had enough information to be included in our meta-analysis.

For the outcome of OASIs in deliveries with episiotomies, when three studies were pooled together [14, 16, 18], there was a significant reduction in risk of OASIs when Episcissors- 60™ were used (15/797 = 1.88%) compared with when other scissors were used (70/1122 = 6.23%).The risk difference (RD) in favour of Episcissors-60™ (RD = −0.04; 95% CI = −0.07 to −0.01; p = 0.005, I2 = 41%).

For the outcome of OASIs in the total number of vaginal deliveries, when three studies were pooled together, there was a significant reduction in risk of OASIs in units where Episcissors-60™ were used (125/3483 = 3.58%) compared with units where other scissors were used (295/4668 =6.31%).The risk difference in favour of Episcissors-60™ (RD -0.02; 95% CI = −0.04 to −0.01; p =0.002, I2 = 59%).

None of the studies scored 3 out of 3 on quality score; therefore, no subgroup meta-analysis was undertaken.

Details should include the selection and quality assessment of the studies, the methodology used for combining the outcomes from the studies, including any tests for heterogeneity, and the results of the analysis including an assessment of the uncertainty associated with these results.

6.8.2 If evidence synthesis is not considered appropriate, give a rationale and provide a qualitative review. The review should summarise the overall results of the individual studies with reference to their critical appraisal.

Response Cole 2019: Systematic review and evidence synthesis.

All studies identified were independently reviewed in full by two researchers in accordance with the PRISMA statement to confirm eligibility for inclusion, any disagreements were resolved through discussion and involvement of a third reviewer where necessary. Studies that only used Episcissors-60 in a birth simulation model were excluded, as the primary outcome of this review is to examine the rate of OASI. Two reviewers, using the Cochrane risk of bias

tool, independently assessed the risk of bias in each study. The quality of the studies was assessed using the Newcastle-Ottawa Scale, expressed as Agency for Healthcare Research and Quality (AHRQ) standards, (for non-randomised studies) and Jadad Scale (for randomised studies). As OASI is an acute outcome that occurs during childbirth the Newcastle-Ottawa Scale categories for length of follow-up were not relevant to this review.

Rate of OASIS with Episcissors-60

Three of the included studies compared the incidence of OASIS between women who had an episiotomy performed using Episcissors-60 with a control group. Two studies compared rates of OASIS in nulliparous women during both operative and spontaneous deliveries following the introduction of Episcissors-60 along with other measures including antenatal perineal massage and perineal support at delivery as part of the SUPPORT training programme across four UK hospitals (Table 1). Mohiudin et al (2018) demonstrated a 73% overall decrease in OASIS in the larger of the maternity units studied following the introduction of the SUPPORT training programme and Epicissors-60, resulting in a 2% OASI incidence rate ($p = 0.001$). However, these figures include OASIS in women who delivered without an episiotomy. A comparison of OASI rate in women who delivered with an episiotomy before and after introduction of Episcissors- 60 provides a more accurate reflection of the impact of this intervention. Among women who had an operative vaginal delivery with an episiotomy, Mohiudin et al (2018) reported a 33% and 83% reduction in OASIS in the two maternity units studies ($p = 0.4$ and $p = 0.01$), which resulted in an OASI rate of 2.6% and 0.6% respectively. The number of OASIS sustained during spontaneous vaginal deliveries with an episiotomy halved across both units studied ($p = 0.03$ and $p = 0.24$). The study by Van Roon et al (2015) also assessed the impact of the introduction of the SUPPORT programme and use of Episcissors-60 on the incidence of OASIS. The authors reported an 18% overall reduction among all nulliparous vaginal deliveries, with the incidence rate falling from 7.1% to 5.8% ($p = 0.22$). Among women who had an operative vaginal delivery with an episiotomy, the authors report a 14% reduction in OASIS ($p = 0.7$) following

the introduction of Episcissors-60. A statistically significant 84% reduction in OASIS was demonstrated in women who delivered by spontaneous vaginal delivery with an episiotomy (p = 0.04). A smaller study by Sawant et al (2015) cluster randomised nulliparous women into two groups; with one group using the Episcissors-60 and another using standard episiotomy scissors to allow comparison of OASI rates [14]. Again, low rates of OASIS were reported with only 1 OASI in the control group (n = 1/32) and none in the Episcissors-60 group [14]. However, this study was not sufficiently powered to detect significant differences in OASI rates. The two other studies included in this review reported the rate of OASI in a cohort of women who had episiotomies performed using Episcissors-60 without a control group for comparison. Patel et al (2014) had no OASIS during the study period (n = 0/25), while Freeman et al (2014) reported one OASI (n = 1/17).

User satisfaction

Operator satisfaction with Episcissors-60 was assessed using a 5-point Likert scale in two studies. Overall, feedback was very positive, with 84% rating the Episcissors-60 as ‘good’ or ‘very good.’ Furthermore, 88% ‘agreed’ or ‘strongly agreed’ that the scissors are easy to use.

6.9 Interpretation of clinical evidence

Provide a statement of principal findings from the clinical evidence highlighting the clinical benefit and any risks relating to adverse events from the technology.

Response There is clear evidence from published studies that EPISCISSORS-60 achieve the desired post-sutured episiotomy angles in the safe zone. Consequently they have been shown to reduce OASIS in time-series analyses and systematic reviews. No risks have been mentioned in any published literature.

6.9.1 Provide a summary of the strengths and limitations of the clinical-evidence base of the technology.

Response Having two independent systematic reviews in prestigious peer-reviewed journals published endorsing their use is a strong testament to their efficacy. While purists would argue for an RCT, we strongly feel that it would not be ethically approved by a UK Ethics committee, as the comparator is ‘eyeballing’ which has not been shown to work, and is responsible for the current high OASIS rate. There is ample published evidence that ‘eyeballing does not provide the requisite episiotomy angles either in-vivo or in-vitro (Tincello 2003, Andrews 2006, Silf 2014, Naidu, 2015, Wong 2014, Van Roon 2016) and no published evidence that a 60 degree episiotomy can be performed consistently by better training in visual estimation of episiotomy angles.

6.9.2 Provide a brief statement on the relevance of the evidence base to the scope. This should focus on the claimed patient- and system-benefits described in the scope.

Response The evidence proves the claims in the scope document. Patients benefit by reduced OASIS, safer childbirth. The NHS benefits from lower OASIS repair costs (circa £25 million per year), reduced bed stays- £6.9 million per year (Orlovic 2018), reduced wound breakdown and infections, lower elective CS costs circa £5 million per year (Edozien 2014), and reduced anal incontinence disease management costs,

6.9.3 Identify any factors that may influence the external validity of study results to patients in routine clinical practice.

Response All the 4 studies from the UK are self-conducted by NHS trusts and reflect routine clinical practice. They are not company sponsored. Therefore they have very strong applicability to routine clinical practice.

6.9.4 Based on external validity factors identified in 7.9.4 describe any criteria that would be used in clinical practice to select patients for whom the technology would be suitable.

Response EPISCISSORS-60 should be used in all patients who require episiotomy.

Section C – Economic evidence

Section C requires sponsors to present economic evidence for their technology.

All statements should be evidence-based and directly relevant to the decision problem.

The approach to the de novo cost analysis expected to be appropriate for most technologies is cost-consequence analysis. Sponsors should read section 7 of the Medical Technologies Evaluation Programme Methods guide on cost-consequences analysis, available from www.nice.org.uk/mt

Sponsors are requested to submit section C with the full submission. For details on timelines, see the NICE document 'Guide to the Medical Technologies Evaluation Programme process', available from www.nice.org.uk/mt

7 Existing economic evaluations

7.1 Identification of studies

The review of the economic evidence should be systematic and transparent and a suitable instrument for reporting such as the PRISMA statement (www.prisma-statement.org/statement.htm).

A PDF copy of all included studies should be provided by the sponsor.

7.1.1 Describe the strategies used to retrieve relevant health economics studies from the published literature and to identify all unpublished

data. The search strategy used should be provided as in section 10, appendix 3.

Response Medline and other database searches. Free text words third, fourth degree tears, health economics. Five studies were returned, only Orlovic (2018) was relevant.

Health economics studies should include all types of economic evaluation and cost studies, including cost analyses and cost-effectiveness and budget-impact analyses. The methods used should be justified with reference to the decision problem.

Sufficient detail should be provided to enable the methods to be reproduced (the External Assessment Centre must be able to reproduce the search), and the rationale for any inclusion and exclusion criteria regarding search terms should be used.

7.1.2 Describe the inclusion and exclusion criteria used to select studies from the published and unpublished literature. Suggested headings

are listed in the table below. Other headings should be used if necessary.

Table C1 Selection criteria used for health economic studies

Inclusion criteria	
Population	All studies
Interventions	All
Outcomes	Third, fourth degree tears, OASIS
Study design	All
Language restrictions	None
Search dates	Until April 2019
Exclusion criteria	
Population	None
Interventions	None
Outcomes	None
Study design	None
Language restrictions	None
Search dates	None

7.1.3 Report the numbers of published studies included and excluded at each stage in an appropriate format.

Response 1; 4

It is recommended that the number of published studies included and excluded at each stage is reported using the PRISMA statement flow diagram (available from *www.prisma-statement.org/statement.htm*)

7.2 Description of identified studies

7.2.1 Provide a brief review of each study, stating the methods, results and relevance to the scope. A suggested format is provided in table C2.

Outcome measures should be included if applicable. Patient outcomes could include gains in life expectancy, improved quality of life, longer time to recurrence, and comparative costs.

Table C2 Summary list of all evaluations involving costs

Study name (year)	**Location of study**	**Summary of model and comparators**	**Patient population *(key characteristics, average age)***	**Costs *(intervention and comparator)***	***Patient outcomes (clinical outcomes, utilities, life expectancy, time to recurrence for intervention and comparator)***	***Results (annual cost savings, annual savings per patient, incremental cost per QALY)***
Orlovic (2017	NHS	Propensity Score matching (PSM) using third/fourth degree tears as Patient Safety Indicators (PSI)	All deliveries on HES database from 2010-14.	Additional Length of Stay	Additional inpatient bed stays due to patient safety events as an approximate estimation.	PSI additional bed stay costs were £10.5 million in 2010-11, and $14.5 million in 2013-14. Additional Length of Stay (LOS)=0.46-0.51 days
YHEC (2017)	NHS	Economic Impact Case Study on EPISCISSORS-60		OASIS repair	Avoided OASIS; avoided complications; Avoided elective CS in subsequent births	Net saving is £1669 per OASIS case avoided. ROI (year one)= 3056%.

7.2.2 Provide a complete quality assessment for each health economic study identified. A suggested format is shown in table C3.

Table C3 Quality assessment of health economic studies

Study name YHEC Economic Impact Evaluation Case Study of the EPISCISSORS-60.		
Study design		
Study question	**Response (yes/no/not clear/N/A)**	**Comments**
1. Was the research question stated?	Yes	Potential ROI on replacing all episiotomy scissors with the EPISCISSORS-60.
2. Was the economic importance of the research question stated?	Yes	"Significant costs associated with OASIS". "Fourth largest cause for litigation in obstetrics."
3. Was/were the viewpoint(s) of the analysis clearly stated and justified?	Yes	Return on Investment
4. Was a rationale reported for the choice of the alternative programmes or interventions compared?	Yes	Comparison with traditional scissors without integral guide to cutting angle.
5. Were the alternatives being compared clearly described?	Yes	Traditional scissors without integral guide to cutting angle
6. Was the form of economic evaluation stated?	Yes	Economic Impact Evaluation Case Study
7. Was the choice of form of economic evaluation justified in relation to the questions addressed?	Yes	
8. Was/were the source(s) of effectiveness estimates used stated?	Yes	Lou 2016, Van Roon 2015
9. Were details of the design and results of the effectiveness study given (if based on a single study)?	n/a	
10. Were details of the methods of synthesis or meta-analysis of estimates given (if based on an overview of a number of effectiveness studies)?	n/a	

11. Were the primary outcome measure(s) for the economic evaluation clearly stated?	Yes	Potential ROI on replacing all episiotomy scissors with the EPISCISSORS-60.
12. Were the methods used to value health states and other benefits stated?	Yes	NHS Payment by Results Tariff 2017/18
13. Were the details of the subjects from whom valuations were obtained given?	Yes	Referenced
14. Were productivity changes (if included) reported separately?	No	Not applicable.
15. Was the relevance of productivity changes to the study question discussed?	n/a	
16. Were quantities of resources reported separately from their unit cost?	Yes	
17. Were the methods for the estimation of quantities and unit costs described?	Yes	
18. Were currency and price data recorded?	Yes	Pounds sterling
19. Were details of price adjustments for inflation or currency conversion given?	No	Not applicable
20. Were details of any model used given?	Yes	Economic Impact Evaluation Model
21. Was there a justification for the choice of model used and the key parameters on which it was based?	Yes	
22. Was the time horizon of cost and benefits stated?	Yes	1 year
23. Was the discount rate stated?	No	Not applicable
24. Was the choice of rate justified?	n/a	
25. Was an explanation given if cost or benefits were not discounted?	n/a	
26. Were the details of statistical test(s) and confidence intervals given for stochastic data?	n/a	

27. Was the approach to sensitivity analysis described?	Yes	No of uses per pair of EPISCISSORS 60. Effectiveness of EPISCISSORS 60 at reducing OASIS incidence.
28. Was the choice of variables for sensitivity analysis justified?	Yes	
29. Were the ranges over which the parameters were varied stated?	Yes	
30. Were relevant alternatives compared? (That is, were appropriate comparisons made when conducting the incremental analysis?)	Yes	
31. Was an incremental analysis reported?	No	
32. Were major outcomes presented in a disaggregated as well as aggregated form?	Yes	
33. Was the answer to the study question given?	Yes	Potential ROI on replacing all episiotomy scissors with the EPISCISSORS-60 was 3,056%
34. Did conclusions follow from the data reported?	Yes	Cost effectiveness was relatively insensitive to changes in the impacts or costs
35. Were conclusions accompanied by the appropriate caveats?	Yes	Savings dependent on EPISCISSORS-60 being used in all births requiring episiotomy.
36. Were generalisability issues addressed?	Yes	
Adapted from Drummond MF, Jefferson TO (1996) Guidelines for authors and peer reviewers of economic submissions to the BMJ. The BMJ Economic Evaluation Working Party. British Medical Journal 313 (7052): 275–83. Cited in Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in health care. York: Centre for Reviews and Dissemination		

8 De novo cost analysis

Section 9 requires the sponsor to provide information on the de novo cost analysis.

The de novo cost analysis developed should be relevant to the scope.

All costs resulting from or associated with the use of the technology should be estimated using processes relevant to the NHS and personal social services.

Note that NICE cites the price of the product used in the model in the Medical Technology guidance.

8.1 Description of the de novo cost analysis

8.1.1 Provide the rationale for undertaking further cost analysis in relation to the scope.

Response The economic evaluation carried out by Orlovic (2017) focussed solely on the additional healthcare costs resulting from the increased length of hospital stay experienced by patients suffering third and fourth degree tears. This study did not consider the costs of the surgical repair of the Obstetric Anal Sphincter injury. The economic evaluation carried out by the York Health Economics Consortium (2017) focussed solely on the additional costs of the initial OASIS repair. Both studies acknowledged that the total costs related to OASIS were greater than identified in these focussed studies.

The *De Novo* cost analysis submitted compares the cost of EPISCISSORS-60 and comparator episiotomy scissors, and the incidence of OASIS in both groups. The analysis considers both the costs of initial OASIS repair and the costs associated with the increased average length of stay identified by Orlovic (2017). This is considered to provide a more comprehensive view of the differential costs associated with the use of EPISCISSORS-60.

Patients

8.1.2 What patient group(s) is (are) included in the cost analysis?

Response NHS patients undergoing episiotomies as clinically indicated.

The patient group(s) included in the cost analysis must reflect the licensed indication/CE mark/marketing authorisation and be relevant to the scope.

The sponsor should not deviate from the scope.

Technology and comparator

8.1.3 Provide a justification if the comparator used in the cost analysis is different from the scope.

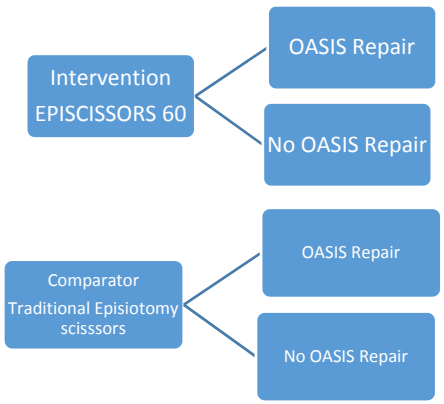
Response Not applicable

If the choice of comparator used in the cost analysis is different from the scope an explanation must be provided.

Model structure

8.1.4 Provide a diagram of the model structure you have chosen.

Response The model chosen is the YHEC Cost Consequence Analysis Template for use in MTG Submissions (NUTH, YHEC (2016). The model has one level, two branches and a single comparator. The time horizon is set at one year to model the initial differential consequences of OASIS. No subgroups of the patient population are modelled separately. The perspective selected is NHS only.



We have used the unit costs of the EPISCISSORS-60 and comparator scissors per use. Please note that NHS Supply Chain have refused to provide this data as it is commercially sensitive. We have assumed EPISCISSORS-60 per use cost as £16, and comparator per use cost as £2. We have calculated the OASIS costs based on the 2019-20 reference costs for OASIS at £1538 (National average reference cost for NZ27Z). The latest published (2017/18) National average reference cost for NZ27Z excess bed days is £665.20 per day excl MFF. We have used the OASIS incidences reported in the published scientific literature of 2.85% of all births (Thiagamoorthy 2014). We have taken a worst case of 4% and best case of 2%. For the EPISCISSORS-60 we have used the OASIS reduction quoted in the YHEC financial impact analysis. Base reduction=43%; worst case=20%; best case=50%. Please note that Cole et al 2019 found OASIS reduction of 50% with the EPISCISSORS-60 in a systematic review, while Divakova 2019 reported 4% absolute OASIS reduction in their systematic review. So our assumptions are modest in comparison to these studies.

The model structure must be supplied to NICE in a legible format when printed on A4 paper.

8.1.5 Justify the chosen structure in line with the clinical pathway of care identified in response to question 3.3.

Response The model sets out a simple comparison of the initial costs to the National Health Service of OASIS repair between the intervention and the comparator. The model does not attempt to quantify the longer-term economic costs of OASIS, therefore the single level and one-year time horizon are considered appropriate. The model aims to distinguish between EPISCISSORS 60 and all previous episiotomy scissors, which do not embody a guide to cutting at the correct angle to minimise the risk of OASIS, therefore only a single comparator is required. The branches considered are those patients requiring OASIS repair and those not requiring repair based on the different probabilities of requiring repair between the intervention and the comparator. The NHS only perspective was selected, as additional cost are not likely to be incurred in the Personal Social Services sector within the one-year timescale selected.

The model assumes the following progression:

Obstetric Delivery requiring episiotomy with use of either EPISCISSORS 60 or traditional episiotomy scissors. The outcome of the use of scissors is either an OASIS with costs associated with the immediate repair or no significant injury, which does not incur additional costs.

Consider how the model structure captures the main aspects of the condition for patients and the NHS. What was the underlying disease progression implemented in the model? Or what treatment was assumed to reflect underlying disease progression? Cross-reference to section 3.3.

8.1.6 Provide a list of all assumptions in the cost model and a justification for each assumption.

Response The model uses the unit costs of the EPISCISSORS-60 and comparator scissors per use. EPISCISSORS-60 costs are based on standard NHS average cost per use of £16. Please note that NHS Supply Chain has refused to provide price data for comparator scissors, as this is considered commercially sensitive. A comparator cost per use of £2.00 has been used.

The costs of OASIS have been based on the 2019-20 reference costs for OASIS at £1,538 (National Non-Mandatory Tariff for OASIS repair; average reference cost for NZ27Z excl MFF). The costs of the extended inpatient stay have been based on the latest published (2017/18) National average reference cost for NZ27Z excess bed days at £665.20 per day excl MFF. The incidence of OASIS has been assumed to be that reported in the published scientific literature of 2.85% of all births, with a range from 4%(worst case) to 2% (Best case) (Thiagamoorthy 2014).. For the EPISCISSORS-60 the OASIS reduction quoted in the YHEC financial impact analysis has been used. Base reduction=43%; worst case=20%; best case=50%. This again is considered conservative. Cole et al 2019 found OASIS reduction of 50% with the EPISCISSORS-60 in a systematic review, while Divakova 2019 reported a 4% absolute OASIS reduction in their systematic review. The assumptions used are therefore considered modest in comparison to these studies.

8.1.7 Define what the model's health states are intended to capture.

Response The model aims to capture the level of prevention of OASIS with EPISCISSORS-60 compared to ordinary episiotomy scissors, which are taken to be responsible for the current OASIS incidence and costs.

8.1.8 Describe any key features of the cost model not previously reported. A suggested format is presented below.

Table C4 Key features of model not previously reported

Factor	Chosen values	Justification	Reference
Time horizon of model	< 1 year	OASIS is an acute event. OAIS repair costs are only studied/reported.	
Discount of 3.5% for costs	N/A	OASIS is an acute event. OASIS repair costs in year 1 are only studied/reported.	
Perspective (NHS/PSS)	NHS only	PSS costs are unlikely to be incurred in year 1. No data available to quantify long term costs of anal incontinence.	
Cycle length	N/A	Not applicable to this Cost Consequence Analysis	
NHS, National Health Service; PSS, Personal Social Services			

8.2 Clinical parameters and variables

When relevant, answers to the following questions should be derived from, and be consistent with, the clinical evidence section of the submission (section 7). Cross-references should be provided. If alternative sources of evidence have been used, the method of identification, selection and synthesis should be provided as well as a justification for the approach.

8.2.1 Describe how the data from the clinical evidence were used in the cost analysis.

Response We have used a national OASIS rate of 2.85% as reported by Thiagamoorthy et al 2014. This equates to 17,846 cases (HES 2017-18 626203 English NHS Births). Orlovic 2018 reported Patient Safety Indicator data from HES records. For 2013-14, the total number of OASIS was 21,064 cases in England. Therefore our cost analysis may underestimate the OASIS

rate and consequent cost savings. It may be noted that ONS data includes both England and Wales Birth statistics.

The OASIS reduction rates with EPISCISSORS-60 are reported from the published literature and quoted by the YHEC study. We have assumed a 43% base OASIS reduction, a worst case reduction of 20%, and a best case reduction of 50%. Please note that Cole et al 2019 found OASIS reduction of 50% with the EPISCISSORS-60 in a systematic review, while Divakova 2019 reported 4% absolute OASIS reduction in their systematic review. So our assumptions are modest in comparison to these studies.

We have not used the Orlovic 2018 assumption of excess bed day cost of £1279 (2013-14) and have instead used a much lower cost of £665 excl MFF. This is the latest published (2017/18) National average reference cost for NZ27Z excess bed days

In addition, if transition probabilities have been used in the model, explain how they were calculated from the clinical data. If appropriate, provide the transition matrix, details of the transformation of clinical outcomes or other details here. If the (transition) probabilities vary over time for the condition or disease, state how this has this been included in the evaluation and if it has not been included, provide an explanation of why it has been excluded. If transition probabilities have not been used, explain how the results of the clinical evidence were incorporated into the model.

8.2.2 Are costs and clinical outcomes extrapolated beyond the study follow-up period(s)? If so, what are the assumptions that underpin this extrapolation and how are they justified?

Response No. However, the published literature acknowledges the significant long-term impact of OASIS on patients. This includes infection, anal incontinence, postpartum urinary retention, pain, depression and the likely requirement for caesarean section in subsequent births.(YHEC 2017). All of these are likely to result in costs to primary and secondary care NHS services and may affect Personal Social Services. Other long term consequences may include the requirement for further corrective surgery like further anal sphincter

repair or neuromodulation (e..g sacral nerve stimulation) for anal incontinence with significant costs to the Health Service. Insufficient published economic analysis is available for these significant costs to be included in the submitted cost model. However, the benefits of the increased level of protection from the initial OASIS provided by EPISCISSORS 60 will be carried through to reductions in these long-term costs.

In particular, consider what assumption was used regarding the longer term difference in effectiveness between the technology and its comparator.

Were any assumptions and/or techniques used for the extrapolation of longer term differences in clinical outcomes between the technology and its comparator?

8.2.3 Were intermediate outcome measures linked to final outcomes (for example, was a change in a surrogate outcome linked to a final clinical outcome)? If so, how was this relationship estimated, what sources of evidence were used and what other evidence is there to support it?

Response No

8.2.4 Were adverse events such as those described in section 7.7 included in the cost analysis? If appropriate, provide a rationale for the calculation of the risk of each adverse event.

Response OASIS itself is an adverse event. OASIS costs were calculated with/without the EPISCISSORS-60.

8.2.5 Provide details of the process used when the sponsor's clinical advisers assessed the applicability of available or estimated clinical model parameter and inputs used in the analysis.

Response Being a practising obstetrician and gynaecologist, I used the published data available. Financial metrics were discussed with Brian Jones, Associate Finance Director, University Hospitals Plymouth NHS Trust. No other clinical experts were approached by us.

This is a critical step and the names and professional titles of the clinical advisers should be included along with the following[1]:

- *the criteria for selecting the experts*
- *the number of experts approached*
- *the number of experts who participated*
- *declaration of potential conflict(s) of interest from each expert or medical speciality whose opinion was sought*
- *the background information provided and its consistency with the totality of the evidence provided in the submission*
- *the method(s) used to collect and collate the opinions*
- *the medium used to collect opinions (for example, was information gathered by direct interview, telephone interview or self-administered questionnaire?)*
- *the questions asked*
- *whether iteration was used in the collation of opinions and if so, how it was used*
- *the uncertainly around these values should be addressed in the sensitivity analysis.*

8.2.6 Summarise all the variables included in the cost analysis. Provide cross-references to other parts of the submission. A suggested format is provided in table C5 below.

All parameters used to estimate cost should be presented clearly and include details of data sources. For continuous variables, mean values should be presented and used in the analyses. For all variables, measures of precision should be detailed.

Details should also include the values used, range (and distribution) and source.

[1] Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee.

OASIS incidence prior to EPISCISSORS-60 introduction=2.85% of all births (Thiagamoorthy 2014); Range taken at 2-4% for best and worst case computations.

Total number of births as per 2017-18 HES English NHS Births=626,203

Total OASIS cases at 2.85% of above population= 17,846

EPISCISSORS-60 OASIS reduction base case=43% (YHEC and published data)

Range of EPISCISSORS-60 OASIS reduction=20% worst case, 50% best case (derived from Systematic reviews and published studies cited in the Scientific evidence submission).

OASIS repair unit cost= £1,538 excl. MFF; National average reference cost for NZ27Z.

NZ27Z excess bed days = £665.20 excl MFF. (2017/18) National average reference cost for NZ27Z.

EPISCISSORS-60 unit cost=£16; NHS England Innovation and Technology Tariff/Payment 2017-20.

Comparator ordinary episiotomy scissors unit cost= £2. This is information sourced from 1 NHS trust which was willing to provide this information confidentially, as such data is commercially sensitive. It may be noted that NHS Supply Chain refused to divulge such costs as such data is considered commercially sensitive.

Episiotomy numbers=94,000 per year in England. (15% of all births, HES 2017-18).

Unit Cost per intervention= £16 X 94,000/ 626,203= £2.4 per birth

Unit Cost of comparator= £2 X 94,000/626,203= £0.30 per birth

Table C5 Summary of variables applied in the cost model- not applicable

Variable	Value	Range or 95% CI (distribution)	Source
Age	*All child-bearing ages*	*N/A*	
Overall survival	*N/A*	*N/A*	
Cost of EPISCISSORS-60	£16 per pair	*N/A*	NHS E ITT 2017-20
***[*Cost of ordinary episiotomy scissors**	*£2 per pair*		*1 NHS trust*
OASIS incidence prior to introduction of EPISCISSORS-60	*2.85% of all births*	*2-4%*	*Thiagamoorthy 2014*
Total number of births in English NHS	*626,203*		*2017-18 HES data for English NHS*
EPISCISSORS-60 OASIS reduction	*43%*	*20-50%*	*YHEC 2017; Systematic reviews, published studies cited in the Scientific Evidence Submission*
OASIS repair unit cost	*£1538 excl MFF*	*N/A*	*2019-20 National Non Mandatory Tariff for NZ27Z*
Episiotomy numbers	*94,000*	*N/A*	*2017-18 HES data for English NHS*
Unit Cost per intervention	*£16 X94,000/626,203= £2.40 per birth*	*N/A*	NHS England Innovation and Technology Tariff/Payment 2017-20. Manufacturer's data.
Unit Cost of comparator.	*£2 X 94,000/626,203 = £0.30 per birth*		*1NHS trust*
CI, confidence interval			

8.3 Resource identification, measurement and valuation

NHS costs

8.3.1 Describe how the clinical management of the condition is currently costed in the NHS in terms of reference costs and the payment by results (PbR) tariff.

Response OASIS repair costs= £1,538+MFF for 2019-20. OPCS procedure Codes R322 and R325). HRG NZ27 Post-Natal Therapeutic Procedures

Payment By Results costs of Caesarean section and vaginal delivery.

Provide Healthcare Resource Groups (HRG) and PbR codes and justify their selection.

8.3.2 State the Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures (OPCS) codes for the operations, procedures and interventions relevant to the use of the technology for the clinical management of the condition.

Response

R322	Repair of obstetric laceration of perineum and sphincter of anus	NZ27
R325	Repair of obstetric laceration of perineum and sphincter and mucosa of anus	NZ27

R322 and R325 are the relevant OPCS codes for the repair of Third - and Fourth - degree obstetric lacerations as advised by the Clinical Coding Department, University Hospitals Plymouth NHs Trust.

As per the 2019/20 NHS Code to Group Tables OPCS, (https://digital.nhs.uk/services/national-casemix-office/downloads-groupers-and-tools/local-payment-grouper-2019-2020), Codes R322 and R325 group to HRG NZ27Z Post-Natal Therapeutic Procedures.

PBR costs of Caesarean section and vaginal delivery.

Resource identification, measurement and valuation studies

8.3.3 Provide a systematic search of relevant resource data for the NHS in England. Include a search strategy and inclusion criteria, and consider published and unpublished studies.

Response N/A. Only clearly stated NHS National reference costs and Non-Mandatory Tariffs were cited.

8.3.4 Provide details of the process used when clinical advisers assessed the applicability of the resources used in the model[2].

Response Not applicable. No clinical advisers were employed. Only NHS reference cost and tariff data was obtained from the Finance Directorate of a large NHS teaching hospital trust.

The details of the process should include:

- *the criteria for selecting the experts*
- *the number of experts approached*
- *the number of experts who participated*
- *declaration of potential conflict(s) of interest from each expert or medical speciality whose opinion was sought*
- *the background information provided and its consistency with the totality of the evidence provided in the submission*
- *the method(s) used to collect and collate the opinions*
- *the medium used to collect opinions (for example, was information gathered by direct interview, telephone interview or self-administered questionnaire?)*
- *the questions asked*
- *whether iteration was used in the collation of opinions and if so, how it was used*

[2] Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee.

- *the uncertainty around these values should be addressed in the sensitivity analysis.*

Technology and comparators' costs

8.3.5 Provide the list price for the technology.

Response The price of EPISCISSORS 60 to the National Health Service is £16 per use, as per the Innovation and Technology Payment Tariff 2017-20. This will also be the cost of the single use EPISCISSORS-60 that will be the ONLY version available for sale when the NICE MTG 457 is published.

We are not privy to the costs of regular episiotomy scissors as these are not publicly available due to commercial confidentiality. We have informed NICE about this. We have based our calculation of ordinary episiotomy scissors as £2 per unit. This is received confidentially from 1 NHS trust, as they cannot otherwise divulge the price data due to suppliers' commercial confidentiality rights. NHS Supply Chain refused to provide such data on grounds of commercial confidentiality.

8.3.6 If the list price is not used in the de novo cost model, provide the alternative price and a justification.

8.3.7 The list price of EPISCISSORS 60 is used in the *De Novo* model.

8.3.8 A rationale must be provided for the choice of values used in the cost model. All prices should be referenced. Any uncertainty around prices should be addressed by sensitivity analysis. All costs must be cross-referenced to other sections of the submission if possible.

8.3.9 Summarise the annual costs associated with the technology and the comparator technology (if applicable) applied in the cost model. A suggested format is provided in tables C6 and C7. Table C7

should only be completed when the most relevant UK comparator for the cost analysis refers to another technology.

When completing tables C6 and C7 the price of the technology should refer to the list price stated in 9.3.4 unless a justification for using an alternative price has been provided in 9.3.5. If a technology is not for single use and consumables are needed to provide a treatment, these must be itemised and a breakdown of prices presented.

For all costs presented a source of the data must be stated.

Table C6 Costs per treatment/patient associated with the technology in the cost model

Items	Value (£)	Source
Price of the technology per treatment/patient	2.40	£16 X 94,000 episiotomies/total 626,203 births
Consumables (if applicable)	16	NHS England ITT per use cost
Maintenance cost	Nil	
Training cost	Nil	
Other costs	Nil	
Total cost per treatment/patient	2.40	

Table C7 Costs per treatment/patient associated with the comparator technology in the cost model

Items	Value (£)	Source
Cost of the comparator per treatment/patient	0.30 per English NHS Birth	£2.00 X 94,000 episiotomies/total 626,203 births
Consumables (if applicable)	2	Confidentially obtained from a NHS trust
Maintenance cost	Nil	
Training cost	Nil	
Other costs	Nil	
Total cost per treatment/patient	0.30	

Health-state costs

8.3.10 If the cost model presents health states, the costs related to each health state should be presented in table C8. The health states

should refer to the states in section 9.1.7. Provide a rationale for the choice of values used in the cost model.

Table C8 List of health states and associated costs in the economic model

Health states	Items	Value	Reference
Health state 1 OASIS Repair	**Technology cost**		
	Staff		
	Hospital costs – OASIS repair	£1,538+MFF	NZ27Z national reference cost; Non Mandatory Tariff
	Hospital costs – extended length of stay	£665.20 excl. MFF	NZ27Z excess bed days national reference cost 2019-20
	Total	2,203.20 excl MFF	
Health state 2 – No OASIS Repair	Nil additional costs		
Health state [X]			

Adverse-event costs

8.3.11 Complete table C9 with details of the costs associated with each adverse event referred to in 9.2.4 included in the cost model. Include all adverse events and complication costs, both during and after longer-term use of the technology. .

8.3.12

Table C9 List of adverse events and summary of costs included in the

cost model

Adverse events	Items	Value [£]	Reference
Adverse event 1	**Technology**		
	Staff		
	Hospital costs – OASIS repair	£1,538+MFF	NZ27Z national non-mandatory Tariff 2019-20
	Hospital costs – extended length of stay	£665.20 excl. MFF	NZ27Z excess bed days national reference cost 2017-18
	Total	£2,203.20 excl MFF	
Adverse event 2	**Technology**		
	Staff		
Adverse event [X]			

Miscellaneous costs

8.3.13 Describe any additional costs and cost savings that have not been covered anywhere else (for example, PSS costs, and patient and carer costs). If none, please state.

Response None

8.3.14 Are there any other opportunities for resource savings or redirection of resources that it has not been possible to quantify?

Response YHEC 2017 identifies treatment costs for complications e.g. infection, pain, incontinence, mental health problems as difficult to quantify as there is no information available. Similarly, 25% of women with OASIS opt for an elective caesarean section (CS) delivery in their next pregnancy (Edozien 2014). These are significant cost savings of £704 per avoided CS, this is the incremental cost over vaginal birth. YHEC states avoided time off work for treatment (surgery and physiotherapy). Average salary is £28,200 pa but the size of effect not available. Therefore, it is not possible to quantify.

Include a justification as to why it has not possible to quantify the resource use and/or costs.

8.4 Approach to sensitivity analysis

Section 9.4 requires the sponsor to carry out sensitivity analyses to explore uncertainty around the structural assumptions and parameters used in the analysis. All inputs used in the analysis will be estimated with a degree of imprecision. For technologies whose final price/acquisition cost has not been confirmed, sensitivity analysis should be conducted over a plausible range of prices.

Analysis of a representative range of plausible scenarios should be presented and each alternative analysis should present separate results.

8.4.1 Has the uncertainty around structural assumptions been investigated? State the types of sensitivity analysis that have been carried out in the cost analysis.

Response The sensitivity analysis was conducted by the programmed excel work sheet provided by NICE for the de novo Cost model. The analysis reports on incremental cost per patient and incremental cost per use. It shows 'high value' for the EPISCISSORS-60 compared to ordinary episiotomy scissors.

8.4.2 Was a deterministic and/or probabilistic sensitivity analysis undertaken? If not, why not? How were variables varied and what was the rationale for this? If relevant, the distributions and their sources should be clearly stated.

Response All deterministic sensitivity analyses are done as per the NICE provided excel work sheet.

All scenarios and/or ranges of variables must be justified.

8.4.3 Complete table C10.1, C10.2 and/or C10.3 as appropriate to summarise the variables used in the sensitivity analysis.

Table C10.1 Variables used in one-way scenario-based deterministic

sensitivity analysis

Variable	Base-case value	Range of values
Rate of OASIS repair using EPISCISSORS-60	1.6%	1.4-2.3%
Rate of OASIS repair using comparator scissors.	2.85 %	2-4%

Table C10.2 Variables used in multi-way scenario-based sensitivity analysis

Variable	***Parameter 1***	***Parameter 2***	***Parameter 3***
Base case			
Scenario 1			
Scenario 2			

Table C10.3 Variable values used in probabilistic sensitivity analysis

Variable	Base-case value	Distribution

8.4.4 If any parameters or variables listed in section 9.2.6 were omitted from the sensitivity analysis, provide the rationale.

Response N/A

It is acknowledged that some model parameters may be excluded from sensitivity analysis considerations, for example, because they can be considered 'constant' or because evidence exists about unbiased and accurate measurement.

8.5 Results of de novo cost analysis

Section 9.5 requires the sponsor to report the de novo cost analysis results. These should include the following:

- costs
- disaggregated results such as costs associated with treatment, costs associated with adverse events, and costs associated with follow-up/subsequent treatment
- a tabulation of the mean cost results
- results of the sensitivity analysis.

Base-case analysis

8.5.1 Report the total costs associated with use of the technology and the comparator(s) in the base-case analysis. A suggested format is presented in table C11.

Table C11 Base-case results

	Total per patient cost (£)
Technology	2.40 or 32.80
Comparator 1	0.30 or 53.46
...incremental savings	20.67

8.5.2 Report the total difference in costs between the technology and comparator(s).

Response

The total difference in costs between the technology and comparator per patient is £20.67 in favour of the EPISCISSORS-60. This equates to a total saving of £12942274 (£12.94 million) incremental cost with comparator versus the EPISCISSORS-60 from the universal use of EPISCISSORS-60 nationally per annum.

	Intervention	tional episitomy scis	Incremental
Net capital cost	£0.00	£0.00	£0.00
Consumables	£1,504,000	£88,000	£1,416,000
Maintenance cost	£0.00	£0.00	£0.00
Training cost	£0.00	£0.00	£0.00
Other device and staffing costs	£0.00	£0.00	£0.00
Operating theatre sessions	£0.00	£0.00	£0.00
Inpatient bed days			
- ward 1	£0.00	£0.00	£0.00
- ward 2	£0.00	£0.00	£0.00
- ward 3	£0.00	£0.00	£0.00
Day cases	£0.00	£0.00	£0.00
Outpatient attendances	£0.00	£0.00	£0.00
GP appointments	£0.00	£0.00	£0.00
Community nurse visits	£0.00	£0.00	£0.00
Laboratory tests:			
- Microbiology	£0.00	£0.00	£0.00
- Pathology	£0.00	£0.00	£0.00
- Haematology	£0.00	£0.00	£0.00
OASIS Repair	£15,645,563	£27,448,356	-£11,802,793
Excess LOS	£3,387,498	£5,942,980	-£2,555,481
Total NHS cost - Year 1	**£20,537,061**	**£33,479,336**	**-£12,942,274**
Total PSS cost - Year 1	**£0**	**£0**	**£0**
Total long term NHS costs	**£0**	**£0**	**£0**
Total long term PSS costs	**£0**	**£0**	**£0**
Total cost per patient	**£32.80**	**£53.46**	**-£20.67**
Total cost per use	**£32.80**	**£53.46**	**-£20.67**

8.5.3 Provide details of the costs for the technology and its comparator by category of cost. A suggested format is presented in table C12.

Table C12 Summary of costs by category of cost per patient

Item	Cost *intervention (X)*	Cost *comparator (Y)*	Increment	Absolute increment	% absolute increment
Technology cost	*2.40*	*0.30*	*2.10*	*1416000*	*10.9*
Mean total treatment cost	*30.40*	*53.16*	*22.77*	*14358274*	*110.9*
Administration cost					
Monitoring cost					
Tests					
[Additional items]					
Total	*32.80*	*53.46*	*20.67*	*12942274*	*100%*
Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee					

8.5.4 If appropriate, provide details of the costs for the technology and its comparator by health state. A suggested format is presented in table C13.

Table C13 Summary of costs by health state per patient NOT APPLICABLE

Health state	Cost *intervention (X)*	Cost *comparator (Y)*	Increment	Absolute increment	% absolute increment
Health state 1	*XHS1*	*YHS1*	*XHS1 – YHS1*	*|XHS1 – YHS1|*	*|XHS1 – YHS1|/ (Total absolute increment)*
Health state 2	*XHS2*	*YHS2*	*XHS2 – YHS2*	*|XHS2 – YHS2|*	*|XHS2 – YHS2|/ (Total absolute increment)*
Health state X					
Total	*XTotal*	*YTotal*	*XTotal – YTotal*	*Total absolute increment*	*100%*
Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee					

8.5.5 If appropriate, provide details of the costs for the technology and its comparator by adverse event. A suggested format is provided in table C14.

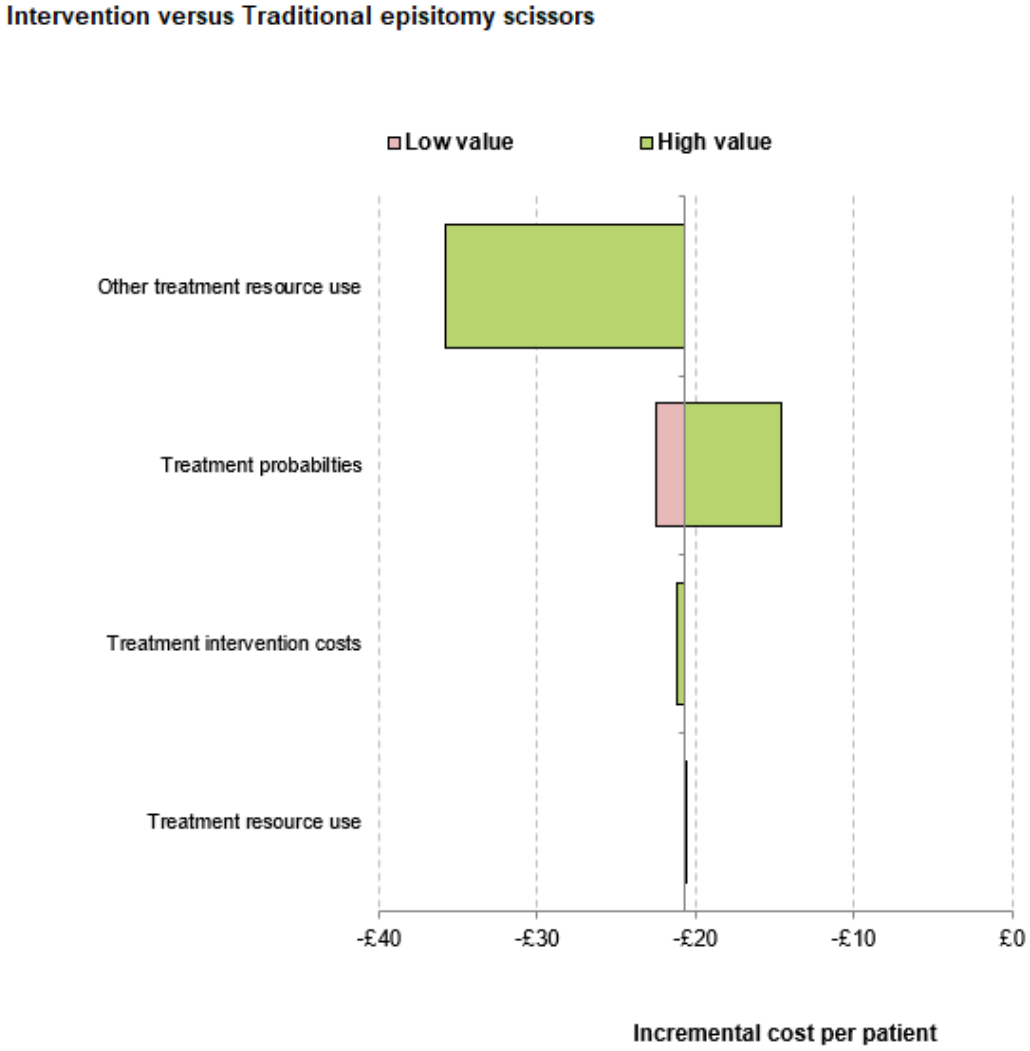
Table C14 Summary of costs by adverse events per patient NOT APPLICABLE

Adverse event	Cost *intervention (X)*	Cost *comparator (Y)*	Increment	Absolute increment	% absolute increment
Adverse event 1	*XAE1*	*YAE1*	*XAE1 – YAE1*	*|XAE1 – YAE1|*	*|XAE1 – YAE1|/ (Total absolute increment)*
Adverse event 2	*XAE2*	*YAE2*	*XAE2 – YAE2*	*|XAE2 – YAE2|*	*|XAE2 – YAE2|/ (Total absolute increment)*
Total	*XTotal*	*YTotal*	*XTotal – YTotal*	*Total absolute increment*	*100%*
Adapted from Pharmaceutical Benefits Advisory Committee (2008) Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (Version 4.3). Canberra: Pharmaceutical Benefits Advisory Committee					

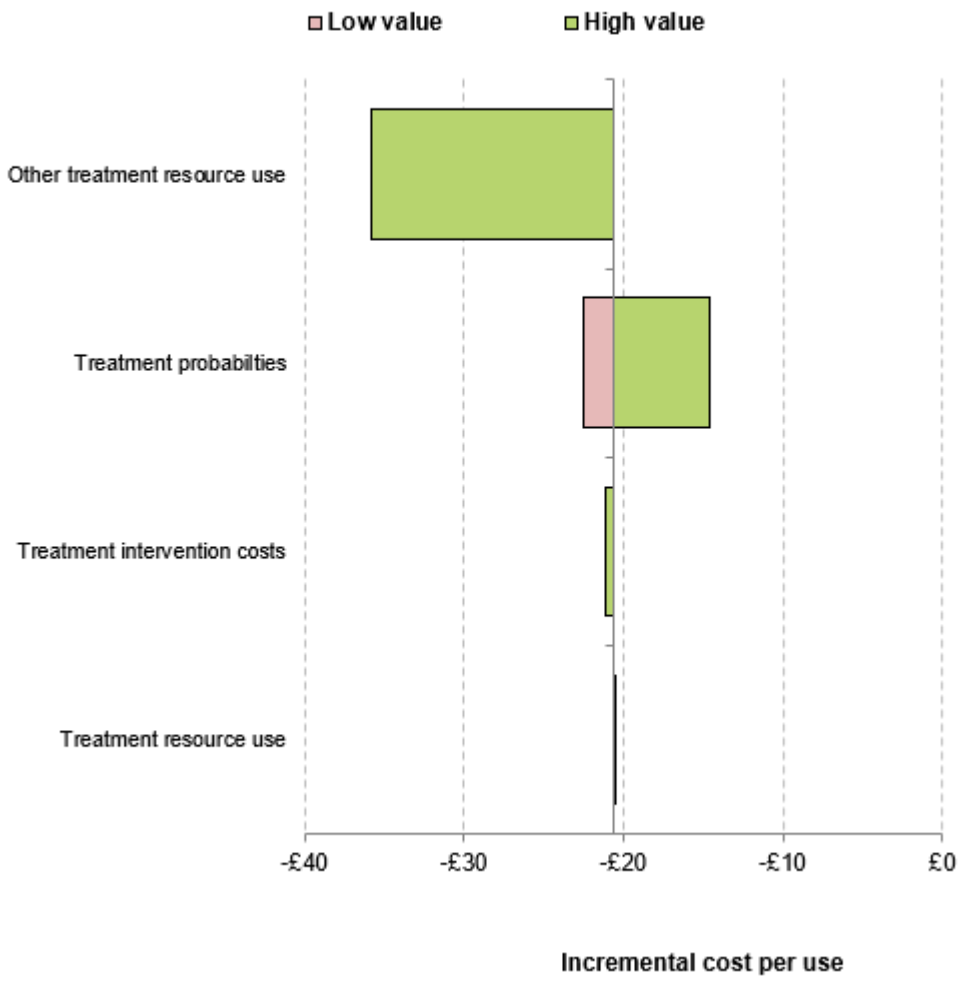
Sensitivity analysis results

8.5.6 Present results of deterministic one-way sensitivity analysis of the variables described in table C10.1.

Response High value for the EPISCISSORS-60 with both incremental cost per patient and per use.



Intervention vs traditional ordinary episiotomy scissors



8.5.7 Present results of deterministic multi-way scenario sensitivity analysis described in table C10.2.

Response N/A

8.5.8 Present results of the probabilistic sensitivity analysis described in table C10.3.

Response In the submitted excel sheet

8.5.9 What were the main findings of each of the sensitivity analyses?

Response High value for the EPISCISSORS-60 with both incremental cost per patient and per use. The overall result that EPISCISSORS-60 delivers significant savings compared with the use of traditional episiotomy scissors was not over-turned in any of the sensitivity scenarios identified.

8.5.10 What are the key drivers of the cost results?

8.5.11 Reduced OASIS and reduced bed days. The key drivers of the cost results were the savings in OASIS repair costs and reduced bed days at different levels of incidence of OASIS. In the worst-case sensitivity, the increased protective effect of EPISCISSORS 60 increased the overall incremental savings against the comparator

to £18.7 million per annum. In the best- case scenario, these overall savings were reduced to £5.3 million p.a.

Worst case

	Intervention	tional episitomy scis	Incremental
Net capital cost	£0.00	£0.00	£0.00
Consumables	£1,504,000	£88,000	£1,416,000
Maintenance cost	£0.00	£0.00	£0.00
Training cost	£0.00	£0.00	£0.00
Other device and staffing costs	£0.00	£0.00	£0.00
Operating theatre sessions	£0.00	£0.00	£0.00
Inpatient bed days			
- ward 1	£0.00	£0.00	£0.00
- ward 2	£0.00	£0.00	£0.00
- ward 3	£0.00	£0.00	£0.00
Day cases	£0.00	£0.00	£0.00
Outpatient attendances	£0.00	£0.00	£0.00
GP appointments	£0.00	£0.00	£0.00
Community nurse visits	£0.00	£0.00	£0.00
Laboratory tests:			
- Microbiology	£0.00	£0.00	£0.00
- Pathology	£0.00	£0.00	£0.00
- Haematology	£0.00	£0.00	£0.00
OASIS Repair	£21,958,685	£38,524,009	-£16,565,324
Excess LOS	£4,754,384	£8,341,024	-£3,586,640
Total NHS cost - Year 1	**£28,217,069**	**£46,953,033**	**-£18,735,964**
Total PSS cost - Year 1	**£0**	**£0**	**£0**
Total long term NHS costs	**£0**	**£0**	**£0**
Total long term PSS costs	**£0**	**£0**	**£0**
Total cost per patient	**£45.06**	**£74.98**	**-£29.92**
Total cost per use	**£45.06**	**£74.98**	**-£29.92**

8.5.12

Best case

	Intervention	tional episitomy scis	Incremental
Net capital cost	£0.00	£0.00	£0.00
Consumables	£1,504,000	£88,000	£1,416,000
Maintenance cost	£0.00	£0.00	£0.00
Training cost	£0.00	£0.00	£0.00
Other device and staffing costs	£0.00	£0.00	£0.00
Operating theatre sessions	£0.00	£0.00	£0.00
Inpatient bed days			
- ward 1	£0.00	£0.00	£0.00
- ward 2	£0.00	£0.00	£0.00
- ward 3	£0.00	£0.00	£0.00
Day cases	£0.00	£0.00	£0.00
Outpatient attendances	£0.00	£0.00	£0.00
GP appointments	£0.00	£0.00	£0.00
Community nurse visits	£0.00	£0.00	£0.00
Laboratory tests:			
- Microbiology	£0.00	£0.00	£0.00
- Pathology	£0.00	£0.00	£0.00
- Haematology	£0.00	£0.00	£0.00
OASIS Repair	£13,724,178	£19,262,004	-£5,537,826
Excess LOS	£2,971,490	£4,170,512	-£1,199,022
Total NHS cost - Year 1	**£18,199,668**	**£23,520,516**	**-£5,320,848**
Total PSS cost - Year 1	**£0**	**£0**	**£0.00**
Total long term NHS costs	**£0**	**£0**	**£0.00**
Total long term PSS costs	**£0**	**£0**	**£0.00**
Total cost per patient	**£29.06**	**£37.56**	**-£8.50**
Total cost per use	**£29.06**	**£37.56**	**-£8.50**

8.6

Miscellaneous results

8.6.1 Describe any additional results that have not been specifically requested in this template. If none, please state.

Response None

8.7 Subgroup analysis

For many technologies, the capacity to benefit from treatment will differ for patients with differing characteristics. Sponsors are required to complete section 9.6 in accordance with the subgroups identified in the scope and for any additional subgroups considered relevant.

Types of subgroups that are not considered relevant are those based solely on the following factors.

- Subgroups based solely on differential treatment costs for individuals according to their social characteristics.
- Subgroups specified in relation to the costs of providing treatment in different geographical locations within the UK (for example, if the costs of facilities available for providing the technology vary according to location).

8.7.1 Specify whether analysis of subgroups was undertaken and how these subgroups were identified. Cross-reference the response to the decision problem in table A1 and sections 3.2 and 7.4.4.

Response No subgroup analysis was undertaken as there is insufficient evidence in the published data to support such analysis.

Consider if these subgroups were identified on the basis of a hypothesised expectation of differential clinical benefit or cost because of known, biologically plausible, mechanisms, social characteristics or other clearly justified factors.

8.7.2 Define the characteristics of patients in the subgroup(s).

Response n/a

8.7.3 Describe how the subgroups were included in the cost analysis.

Response n/a

8.7.4 What were the results of the subgroup analysis/analyses, if conducted? The results should be presented in a table similar to that in section 9.5.1 (base-case analysis).

Response n/a

8.7.5 Were any subgroups not included in the submission? If so, which ones, and why were they not considered?

Response Some evidence suggests that Ethnicity is a differential risk factor in the overall incidence of OASIS following episiotomy. However, no comparative studies have been carried out to determine the relative protective effect of EPISCISSORS-60 between ethnic groups. There is therefore no reliable evidence on which to base a sub-group analysis. It would be scientifically plausible to assume that ALL ethnic groups will benefit from OASIS reduction due to an accurately angled 60 degree episiotomy.

8.8 Validation

8.8.1 Describe the methods used to validate and cross-validate (for example with external evidence sources) and quality-assure the model. Provide references to the results produced and cross-reference to evidence identified in the clinical and resources sections.

Response validated as per fixed NHS reference costs and unit prices.

8.9 Interpretation of economic evidence

8.9.1 Are the results from this cost analysis consistent with the published economic literature? If not, why do the results from this evaluation

differ, and why should the results in the submission be given more credence than those in the published literature?

Response Yes. The results of the De Novo cost analysis are entirely consistent with the published economic literature (Orlovic 2017, YHEC 2017)

8.9.2 Is the cost analysis relevant to all groups of patients and NHS settings in England that could potentially use the technology as identified in the scope?

Response Yes

8.9.3 What are the main strengths and weaknesses of the analysis? How might these affect the interpretation of the results?

Response The main strengths of the analysis are the consistency of the model with the published evidence base and the significant level of savings identified, which is highly resilient to sensitivity analysis.

The main weakness of the analysis is the inability to include the long-term cost implications of OASIS, including subsequent surgical repair and neuromodulation. The analysis does not include the wider costs to the individual and health and national economies of infection, anal incontinence, postpartum urinary retention, pain, depression, the likely requirement for caesarean section in subsequent births and the requirement for long term use of anal incontinence pads. If sufficient data were available to include these costs, the savings delivered by EPISCISSORS-60 would be far higher than presented here. Despite this, the analysis shows that EPISCISSORS-60 present value for money and high value for the NHS in full adoption for use with each episiotomy.

8.9.4 What further analyses could be undertaken to enhance the robustness/completeness of the results?

Response Further analysis of the long term costs of OASIS avoided by the use of EPISCISSORS-60.

References

Please use a recognised referencing style, such as Harvard or Vancouver.

Response

1] Royal College of Obstetricians and Gynaecologists. Third- and fourth-degree perineal tears, management (Green-top Guideline No. 29), London: RCOG; 2015.

2] Eogan M, Daly L, O'Connell PR and O'Herlihy C. Does the angle of episiotomy affect the incidence of anal sphincter injury? BJOG 2006; 113: 190-4.

3] Andrews V, Thakar R, Sultan AH and Jones PW. Are mediolateral episiotomies actually mediolateral? BJOG 2005; 112: 1156-8.

4] Stedenfeldt M, Pirhonen J, Blix E, Wilsqaard T, Vonen B, Qian P. Episiotomy characteristics and risks for obstetric anal sphincter injury: a case-control study. BJOG 2012; 119:724-30

5] Kalis V, Karbanova J, Horak M, Lobovsky L, Kralickova M and Rokyta Z. The incision angle of mediolateral episiotomy before delivery and after repair. Int J Gynecol Obstet. 2008; 103: 5-8.

6] Kalis V, Landsmanova J, Bednarova B, Karbanova J, Laine K and Rokyta Z. Evaluation of the incision angle of mediolateral episiotomy at 60 degrees. Int J Gynecol Obstet 2011; 112: 220-4

7] El-Din AS, Kamal MM, Amin MA. Comparison between two incision angles of mediolateral episiotomy in primiparous women: a randomised controlled trial. J Obstet Gynaecol Res 2014;40:1877-82.

8] Gurol-Urganci I, Cromwell D, Edozien L, Mahmood T, Adams E, Richmond D, Templeton A, van der Meulen J. Third- and fourth-degree perineal tears among primiparous women in England between 2000 and 2012: time trends and risk factors. BJOG Nov 2013

9] Thiagamoorthy G, Johnson A, Thakar R, Sultan AH. National survey of perineal trauma and its subsequent management in the United Kingdom. Int Urogynecol J 2014.

11] Silf K, Woodhead N, Kelly J, Fryer A, Kettle C, Ismail KMK. Evaluation of accuracy of mediolateral episiotomy incisions using a training model. Midwifery 2014;

12] Fodstad K, Laine K, Staff AC. Different episiotomy techniques, postpartum perineal pain, and blood loss: an observational study. Int Urogynecol J 2013; 24:865-72

13] Naidu M, Kapoor DS, Evans S, Vinayakarao L, Thakar R, Sultan AH. Cutting an episiotomy at 60 degrees: how good are we? Int Urogynecol J 2015.

14] Divakova O, Kunda A, Ballard PA. Episcissors-60™ and obstetrics anal sphincter injury: a systematic review and meta-analysis. Int Urogynecol J. 2019 Mar 2. doi: 10.1007/s00192-019-03901-4. [Epub ahead of print]

15] Cole J, Lacey L, Bulchandani S. The use of Episcissors-60 to reduce the rate of Obstetric Anal Sphincter Injuries: A systematic review. Eur J Obstet Gynecol Reprod Biol. 2019 Apr 6;237:23-27. doi: 10.1016/j.ejogrb.2019.04.004. [Epub ahead of print]

16] Freeman RM, Hollands HJ, Barron LF, Kapoor DS. Cutting a mediolateral episiotomy at the correct angle: evaluation of a new device, the Episcissors-60™. Medical Devices: Evidence and Research. 2014;7:23–8.

17] Patel RP, Ubale SM. Evaluation of the angled Episcissors-60TM episiotomy scissors in spontaneous vaginal deliveries. Medical Devices: Evidence and Research. 2014;7(1):253–6.

18] Sawant G, Kumar D. Randomized trial comparing episiotomies with Braun-Stadler episiotomy scissors and Episcissors-60™®. Medical Devices: Evidence and Research. 2015;8:251–4.

19] van Roon Y, Kirwin C, Rahman N, Vinayakarao L, Melson L, Kester N, et al. Comparison of obstetric anal sphincter injuries in nulliparous women before and after introduction of the EPISCISSORS-60™® at two hospitals in the United Kingdom. Int J Women's Health. 2015;7:949–55.

20] Lou YY, Thakar R, Sultan AH, Ajay B. Does Episcissors-60™ reduce the incidence of obstetric anal sphincter injuries (OASIS)? BJOG. 2016;123:51.

21] Mohiudin H, Ali S, Pisal PN, Villar R. Implementation of the RCOG guidelines for prevention of obstetric anal sphincter injuries (OASIS) at two London hospitals: a time series analysis. Eur J Obstet Gynecol Reprod Biol. 2018;224:89–92.

22] Wood L, Egger M, Gluud LL, Schulz KF, Jüni P, Altman DG, Gluud C, Martin RM, Wood AJ, Sterne JA. Empirical evidence of bias in treatment effect estimates in controlled trials with different interventions and outcomes: meta-epidemiological study. BMJ. 2008 Mar 15;336(7644):601-5. doi: 10.1136/bmj.39465.451748.AD. Epub 2008 Mar 3.

23] Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JPA, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. Ann Intern Med. 2009;151(4):W65–94.

DUPLICATE AND NON-HUMAN STUDIES

Rahman N, Vinayakarao L, Pathak S, Minden D, Melson L, Vitue E, et al. Evaluation of training programme uptake in an attempt to reduce obstetric anal sphincter injuries: the SUPPORT programme. Int Urogynecol J. 2017a;28:403–7.

Rahman N, Pradhan A, Van Roon Y, Kirwin C, Vinayakarao L, Melson L, et al. Introduction of Episcissors-60TM in response to rising OASIS: combined results from two district general hospitals in England. Int Urogynecol J Pelvic Floor Dysfunct. 2016a;27(7): 1109–10.

Rahman N, Pradhan A, van Roon Y, Kirwin C, Vinayakarao L, Melson L, Kester N, Pathak S. Combined results from two district general hospitals in England. Selected Abstracts from the Annual Research Meeting of the British Society of Urogynaecology 2015. Int Urogynecol J Pelvic Floor Dysfunct. 2016b;27(7.

van Roon Y, Kirwin C, Rahman N, Vinayakarao L, Melson L, Kester N, et al. Comparison of Obstetric anal sphincter injuries (OASIS) in nulliparous women before and after introduction of the EPISCISSORS-60TM® at two Hospitals in the United Kingdom. Kongress Deutsche Gesellschaft fur Pranatal- und Geburtsmedizin. Geburtshilfe und Frauenheilkunde. 2016;76(5).

Rahman N, Pradhan A, Vinayakarao L, Minden D, Melson L, Pathak S, et al. Evaluation of training programme uptake in an attempt to reduce obstetric anal sphincter injuries: the SUPPORT programme. Int Urogynecol J. 2017b;28(3):403–7.

van Roon Y, Percival R, Pathak S, Pradhan A, Vinayakarao L, Melson L. Comparative study of episiotomy angles achieved by cutting with straight Mayo scissors and the EPISCISSORS-60™ in a birth simulation model. Int Urogynecol J. 2017;28(7):1063–6.

Patel RP, Ubale SM. Prospective series of 53 episiotomies performed with the angled EPISCISSORS-60™©. BJOG. 2015;122: 204.

Kumar D, Sawant G. Prospective comparative study comparing episiotomy suture angles with Braun-Stadtler episiotomy scissors and EPISCISSORS-60™. BJOG. 2015;122:214–5.

9 Appendices

9.1 Appendix 1: Search strategy for clinical evidence (section 7.1.1)

The following information should be provided:

9.1.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- The Cochrane Library.

Response Medline Embase, Cinahl Cochrane

9.1.2 The date on which the search was conducted.

Response 20th May 2019

9.1.3 The date span of the search.

Response beginning to 20-5-19

9.1.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

Response Episcissors 60, EPISCISSORS-60, episiotomy

9.1.5 Details of any additional searches, such as searches of company or professional organisation databases (include a description of each database).

Response n/a

9.1.6 The inclusion and exclusion criteria.

ResponseNo exclusions based on search words.

9.1.7 The data abstraction strategy.

Response As per PRISMA

9.2 Appendix 2: Search strategy for adverse events (section 7.7.1)

The following information should be provided.

9.2.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- The Cochrane Library.

Response Medline, Embase, Cochrane

9.2.2 The date on which the search was conducted.

Response 20th May 2019

9.2.3 The date span of the search.

Response beginning to 20-5-19

9.2.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean).

Response episcissors 60, EPISCISSORS-60, episiotomy

9.2.5 Details of any additional searches (for example, searches of company databases [include a description of each database]).

Response N/A

9.2.6 The inclusion and exclusion criteria.

Response Inclusion- Only studies with EPISCISSORS-60 used.

9.2.7 The data abstraction strategy.

Response N/A

9.3 Appendix 3: Search strategy for economic evidence (section 8.1.1)

The following information should be provided.

9.3.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- EconLIT
- NHS EED.

Response Medline, NHS EED, Embase, EconLIT

9.3.2 The date on which the search was conducted.

Response 22 April 2019

9.3.3 The date span of the search.

Response beginning to 22-4-19

9.3.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example,

MeSH) and the relationship between the search terms (for example, Boolean).

Response episcissors 60, EPISCISSORS-60, episiotomy

9.3.5 Details of any additional searches (for example, searches of company databases [include a description of each database]).

Response none

9.4 Appendix 4: Resource identification, measurement and valuation (section 9.3.2)

The following information should be provided.

9.4.1 The specific databases searched and the service provider used (for example, Dialog, DataStar, OVID, Silver Platter), including at least:

- Medline
- Embase
- Medline (R) In-Process
- NHS EED
- EconLIT.

Response All above

9.4.2 The date on which the search was conducted.

Response 20-5-2019

9.4.3 The date span of the search.

Response beginning to 20-5-2019

9.4.4 The complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example,

MeSH) and the relationship between the search terms (for example, Boolean).

Response episcissors 60, EPISCISSORS-60, episiotomy

9.4.5 Details of any additional searches (for example, searches of company databases [include a description of each database]).

Response none

9.4.6 The inclusion and exclusion criteria.

Responseno exlcusions

9.4.7 The data abstraction strategy.

Responsen/a

10 Related procedures for evidence submission

10.1 Cost models

An electronic executable version of the cost model should be submitted to NICE with the full submission.

NICE accepts executable cost models using standard software – that is, Excel, TreeAge Pro, R or WinBUGs. If you plan to submit a model in a non-standard package, NICE should be informed in advance. NICE, in association with the External Assessment Centre, will investigate whether the requested software is acceptable, and establish if you need to provide NICE and the External Assessment Centre with temporary licences for the non-standard software for the duration of the assessment. NICE reserves the right to reject cost models in non-standard software. A fully executable electronic copy of the model must be submitted to NICE with full access to the programming code. Care should be taken to ensure that the submitted versions of the model programme and the written content of the evidence submission match.

NICE may distribute the executable version of the cost model to a consultee if they request it. If a request is received, NICE will release the model as long as it does not contain information that was designated confidential by the model owner, or the confidential material can be redacted by the model owner without producing severe limitations on the functionality of the model. The consultee will be advised that the model is protected by intellectual property rights, and can be used only for the purposes of commenting on the model's reliability and informing comments on the medical technology consultation document.

Sponsors must ensure that all relevant material pertinent to the decision problem has been disclosed to NICE at the time of submission. NICE may request additional information not submitted in the original submission of evidence. Any other information will be accepted at NICE's discretion.

When making a full submission, sponsors should check that:

- an electronic copy of the submission has been given to NICE with all confidential information highlighted and underlined
- a copy of the instructions for use, regulatory documentation and quality systems certificate have been submitted
- an executable electronic copy of the cost model has been submitted
- the checklist of confidential information provided by NICE has been completed and submitted.

- A PDF version of all studies (or other appropriate format for unpublished data, for example, a structured abstract) included in the submission have been submitted

10.2 Disclosure of information

To ensure that the assessment process is as transparent as possible, NICE considers it highly desirable that evidence pivotal to the Medical Technologies Advisory Committee's decisions should be publicly available at the point of issuing the medical technology consultation document and medical technology guidance.

Under exceptional circumstances, unpublished evidence is accepted under agreement of confidentiality. Such evidence includes 'commercial in confidence' information and data that are awaiting publication ('academic in confidence').

When data are 'commercial in confidence' or 'academic in confidence', it is the sponsor's responsibility to highlight such data clearly, and to provide reasons why they are confidential and the timescale within which they will remain confidential. The checklist of confidential information should be completed: if it is not provided, NICE will assume that there is no confidential information in the submission. It is the responsibility of the manufacturer or sponsor to ensure that the confidential information checklist is kept up to date.

It is the responsibility of the sponsor to ensure that any confidential information in their evidence submission is clearly underlined and highlighted

correctly. NICE is assured that information marked ‘academic in confidence’ can be presented and discussed during the public part of the Medical Technologies Advisory Committee meeting. **NICE is confident that such public presentation does not affect the subsequent publication of the information, which is the prerequisite allowing for the marking of information as ‘academic in confidence’.**

Please therefore underline all confidential information, and highlight information that is submitted under ‘commercial in confidence’ in blue and information submitted under ‘academic in confidence’ in yellow.

NICE will ask sponsors to reconsider restrictions on the release of data if there appears to be no obvious reason for the restrictions, or if such restrictions would make it difficult or impossible for NICE to show the evidential basis for its guidance. Information that has been put into the public domain, anywhere in the world, cannot be marked as confidential.

Confidential information submitted will be made available for review by the External Assessment Centre and the Medical Technologies Advisory Committee. NICE will at all times seek to protect the confidentiality of the information submitted, but nothing will restrict the disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

The Freedom of Information Act 2000, which came into force on 1 January 2005, enables any person to obtain information from public authorities such as NICE. The Act obliges NICE to respond to requests about the recorded information it holds, and it gives people a right of access to that information. This obligation extends to submissions made to NICE. Information that is designated as ‘commercial in confidence’ may be exempt under the Act. On receipt of a request for information, the NICE secretariat will make every effort to contact the designated company representative to confirm the status of any information previously deemed ‘commercial in confidence’ before making any decision on disclosure.

10.3 Equality

NICE is committed to promoting equality and eliminating unlawful discrimination, including paying particular attention to groups protected by equalities legislation. The scoping process is designed to identify groups who are relevant to the evaluation of the technology, and to reflect the diversity of the population. NICE consults on whether there are any issues relevant to equalities within the scope of the evaluation, or if there is information that could be included in the evidence presented to the Medical Technologies Advisory Committee to enable them to take account of equalities issues when developing guidance.

Evidence submitters are asked to consider whether the chosen decision problem could be impacted by NICE's responsibility in this respect, including when considering subgroups and access to recommendations that use a clinical or biological criterion.

For further information, please see the NICE website (www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp).

NICE National Institute for Health and Care Excellence

Medical technologies guidance

Collated expert questionnaires

Technology name & indication: Episcissors-60 for guided mediolateral episiotomy

Experts & declarations of interest (DOI)

Expert #1	Ashish Pradhan, Consultant Urogynaecologist, Addenbrookes Hospital, Cambridge University Hospitals NHS Foundation Trust
	DOI: none
Expert #2	Abdul H. Sultan, Consultant Obstetrician and Gynaecologist, Croydon University Hospital
	DOI: NONE
Expert #3	Ranee Thakar, Consultant Urogynaecologist, Croydon University Hospital
	DOI: NONE
Expert #4	Kylie Watson, Senor Midwife, Manchester University Hospitals Foundation Trust
	DOI: NONE
Expert #5	Bini Ajay, Consultant Obstetrician and Gynaecologist, Croydon University Hospital
	DOI: NONE
Expert #6	Latha Vinayakarao, Consultant Obstetrician, Poole Hospital NHS Foundation Trust
	DOI: NONE
Expert #7	Kerry Barker -Williams, Research Midwife, Countess of Chester NHS Foundation Trust
	DOI: Yes, Consultancy fee received from the company, professional development towards portfolio
Expert #8	Allison Farnworth, Senior Research Midwife, Newcastle University

	DOI: Yes, Co-authored paper: “Obstetric anal sphincter injuries (OASIs) before and after the introduction of the Episcissors-60: A multi-centre time series analysis”. Time funded by Academic Health Science Network North East and North Cumbria to complete a project exploring implementation of Episcissors-60 in the region (0.2WTE for 12 months)
Expert #9	Dr Paul Ayuk, Consultant Obstetrician, Newcastle-upon-Tyne Hospitals NHS Trust
	DOI: Yes, Lead author of the paper: ‘Obstetric anal sphincter injuries (OASIs) before and after the introduction of the Episcissors-60: A multi-centre time series analysis.’ Revised version submitted for publication. At early stages of a proposal for a randomised controlled trial to evaluate the Episcissors-60
Expert #10	Dr Patricia Seddon, Locum Consultant Obstetrician, Manchester Foundation Trust
	DOI: None

How NICE uses this information: the advice and views given in these questionnaires are used by the NICE medical technologies advisory committee (MTAC) to assist them in making their draft guidance recommendations on a technology. It may be passed to third parties associated with NICE work in accordance with the Data Protection Act 2018 and data sharing guidance issued by the Information Commissioner’s Office. Expert advice and views represent an individual’s opinion and not that of their employer, professional society or a consensus view (unless indicated). Consent has been sought from each expert to publish their views on the NICE website.

For more information about how NICE processes data please see our privacy notice.

1. **Please describe your level of experience with the technology, for example: Are you familiar with the technology? Have you used it? Are you currently using it? Have you been involved in any research or development on this technology? Do you know how widely used this technology is in the NHS?**

Expert #1	Yes I am familiar with the EPISCISSCORS-60. I have conducted a prospective time series analysis of this product and published the results in a peer reviewed medical journal. We are currently using it in our department. My time series analysis was the first large prospective cohort study published about this product and further studies have been publishes since then. I am not aware of how widely it is used in the NHS currently.
Expert #2	I am familiar with the technology and have used the Episcissors 60 and it is currently being used in our delivery suite. We have evaluated it and published the results. I am aware that the Episcissors 60 is used in many NHS hospitals in the UK but I do not know the current percentage.
Expert #3	I am familiar with the technology and have used the Episcissors -60 on labour ward. It is currently being utilised on our labour ward in Croydon. We have produced an abstract based on this technology. It is widely being used in the United Kingdom in response to the NHS Innovation and Technology Tariff (ITT).
Expert #4	I am familiar with the Episcissors and we currently use them at the Trust I am based at. We have 67 pairs in circulation and they are used by midwives, obstetricians and junior doctors the majority of the time an episiotomy is needed. I am not involved in any research or development on the technology.
Expert #5	No answer given.
Expert #6	Yes. We use it in labour ward everyday.
Expert #7	I am aware of the technology but I have never used it. I have not been involved in the research or the development of the technology. To my knowledge it is not widely used in the NHS.
Expert #8	I am familiar with the technology. I have not personally used it and was not involved in the research or development of it. I was funded by the Academic Health Science Network (AHSN) in North East and North Cumbria (NENC) region to conduct a project exploring adoption and implementation of the technology in the nine maternity units in NENC. This involved speaking with senior

	midwives and consultants leading implementation. I know how widely it was implemented in the NENC region last year and what staff reported about adoption and implementation (or non-adoption/implementation) of the technology.
Expert #9	Very familiar with the Episcissors-60. Led a project funded by AHSN North-East and North Cumbria to introduce the technology in 4 NHS Trusts and evaluate its safety and efficacy. Project report submitted to the AHSN and manuscript being currently revised for publication. Also used the technology personally and supervised junior doctors using it. As part of the AHSN-funded project, we also undertook a qualitative study to examine barriers and facilitators to the uptake of the technology. I also have experience with the adoption of technologies that appear self-evidently cost-effective. When I took over as lead for intra-partum care at my Trust in 2008, the unit was set to deploy cell salvage for all women having an emergency caesarean section (~1000 / year). A business case had been accepted and £25,000 had been spent on equipment. NICE had issues a technology assessment on cell salvage in obstetrics. Despite this, I revised local guidelines to restrict adoption because of the lack of high-quality evidence. I then worked with colleagues across the country to undertake an RCT (SALVO, HTA-funded). This showed that cell salvage in obstetrics is not cost-effective. Cell salvage is now rarely used in our unit and without this trial we will be spending £30 more per emergency CS on cell salvage consumables. I am currently working with a team of other clinicians to develop further high-quality research on the Episcissors and we have undertaken a survey on the use of this technology across the NHS.
Expert #10	I have used Episcissors as a clinician for the last 3 years and am currently using it within MFT as part of the OASI bundle, I have not been involved in the development of the technology.

2. Has the technology been superseded or replaced?

Expert #1	No it has not been superseded or replaced
Expert #2	Yes, it as been superceded in centres that have the Episcissors-60
Expert #3	Yes, Most units now use these scissors as opposed to straight scissors
Expert #4	Not to my knowledge.
Expert #5	No

Expert #6	No
Expert #7	No
Expert #8	Not as far as I am aware.
Expert #9	No
Expert #10	No

Current management

3. How innovative is this technology, compared to the current standard of care? Is it a minor variation or a novel concept/design?

Expert #1	Novel design based on scientific data
Expert #2	Although the design is novel in that it ensures that the correctly placed scissors virtually guarantees a 60 degree angle of incision, ordinary scissors have been used previously to perform the same procedure. Unfortunately, our research has shown that with ordinary scissors very few midwives and doctors were performing a 60 degree angle resulting in an increase in obstetric anal sphincter injuries (OASIS) a collective term used for third and fourth degree tears
Expert #3	This is a novel innovation as it ensures a 60 degree angle of episiotomy which is associated with a lower rate of 3rd and 4th degree anal sphincter tears which occur at the time of vaginal delivery.
Expert #4	This is technology with a novel (albeit minor) variation that assists the practitioner in performing an episiotomy at a 60 degree angle on an extended and stretched perineum.
Expert #5	Blank
Expert #6	Minor variation
Expert #7	It is a novel design. A variation of the usual scissors used for episiotomies. It is also innovative.

Expert #8	A minor variation, i.e. the innovative aspect of this technology is that they have angled the scissors in a specific way and added a guide wire – a well-trained clinician *should* be able to get the same effect with a regular pair of Mayo scissors but Episcissors-60 promote consistency and reduce potential for user error (and there is evidence that user error is an issue with regular scissors).
Expert #9	It is a novel application of an established concept.
Expert #10	

4. Are you aware of any other competing or alternative technologies available to the NHS which have a similar function/mode of action to the notified technology? If so, how do these products differ from the technology described in the briefing?

Expert #1	There are other scissors for cutting an episiotomy but none have the angled design which allows EPISCISSORS-60 to cut at an accurate angle of 60 degrees
Expert #2	No
Expert #3	No
Expert #4	No.
Expert #5	NO
Expert #6	No
Expert #7	No I am not aware of any competing designs.
Expert #8	No. I am aware of other ways of reducing incidence of OASI but not a specific technology like episcissors-60 – the alternative would be standard scissors.
Expert #9	Standard episiotomy scissors. They rely on the surgeon estimating the angle of episiotomy and its length. The key question is whether scissors that enable cutting at a pre-specified angle and length are better at reducing obstetric anal sphincter injuries than those that rely on human judgement. The available evidence (recently published systematic review and meta-analysis plus our paper) would indicate uncertainty remains and better quality studies are needed.

Expert #10	No

Potential patient benefits

5. What do you consider to be the potential benefits to patients from using this technology?

Expert #1	Reduced risk of obstetric anal sphincter injury and reduced risk of anal incontinence.
Expert #2	As recommended by the RCOG, an incision of 60 degrees should be made when an episiotomy is planned during perineal distension by the head. Episcissors-60 is the only instrument that would ensure the correct angle of incision would be made and thereby reduce the risk of OASIS. Secondly these scissors are sharp and tend to maintain their sharpness if used correctly, ensuring an adequate incision. I am aware of litigation resulting in the development of OASIS due to the use of blunt scissors.
Expert #3	Reduction in 3rd and 4th degree anal sphincter tears, which have short and long term consequences on a woman's quality of life, reduction in litigation and economical benefits to the NHS.
Expert #4	The benefits to patients using this technology may be many. Episiotomies performed with post-delivery angles of <30 degrees or >60 degrees increase the likelihood of obstetric anal sphincter injuries (OASIS). This technology assists in the episiotomy being performed at the correct angle thereby potentially reducing OASIS. The short and long-term effects of OASIS can have a devastating effect on women including pain, dyspareunia and anal incontinence and increase cost to the NHS long term.
Expert #5	Prevention of OASIS
Expert #6	To avoid perineal tears
Expert #7	The technology could have a very positive effect on patient's physical and psychological outcomes following childbirth. The epi-scissors could reduce obstetric anal sphincter injuries which can lead to further complications for women both physically and psychologically.
Expert #8	If Episcissors-60 reduce incidence of OASI then this is of benefit to the women who will avoid an OASI and all the associated morbidity. To my knowledge nobody has looked at women's views of this technology – I think it would be safe to say that no woman

	would have an issue with avoiding OASI though! That said, the majority of women who have an episiotomy would not have an OASI regardless so these women will not benefit, neither will women who have an OASI without an episiotomy.
Expert #9	Reducing the risk of obstetric anal sphincter injury. However, there are potential risks – bigger episiotomies and possibly more blood loss at delivery. Whether the totality of benefits outweighs risks / disadvantages is unknown.
Expert #10	Reduction in 3rd degree tears

6. Are there any groups of people who would particularly benefit from this technology?

Expert #1	All women having a vaginal delivery
Expert #2	All women having a vaginal delivery in whom an episiotomy is indicated
Expert #3	Midwives and Obstetricians
Expert #4	Women with an increased risk of OASIS may benefit from this technology and this will include women undergoing instrumental (by forcep or ventouse) births.
Expert #5	Every pregnant women planning to have a vaginal delivery
Expert #6	Primi
Expert #7	Any woman who requires an episiotomy for any reason during childbirth.
Expert #8	Any woman having a vaginal delivery may benefit; nulliparous women and women who are having an assisted vaginal delivery are most likely to experience OASI and would therefore benefit most from a technology that reduces this risk.
Expert #9	First time mothers having a vaginal birth
Expert #10	No

7. Does this technology have the potential to change the current pathway or clinical outcomes? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Expert #1	Yes it has potential to improve clinical outcomes by reducing patient follow up appointments and reducing the cost of managing women with anal incontinence following childbirth.
Expert #2	Yes. By reducing the OASIS rate, it would reduce the risk of the woman developing anal incontinence. Depending on the local protocol there would be reduced follow-up visits in the perineal clinic, investigations with anal ultrasound and anal manometry and repeating these investigations in subsequent pregnancies. In women who sustain OASIS, it would also reduce the risk of requiring caesarean sections in subsequent pregnancies
Expert #3	Yes. Reduction in rates of 3rd and 4th degree tears, less hospital appointments, less need for invasive investigations, reduction in caesarean sections and psychological effects, less litigation
Expert #4	The technology has the potential to reduce OASIS (although a stronger evidence base is needed). If OASIS rates are reduced then this could lead to reduced postnatal care and outpatient visits including with obstetricians, midwives and physiotherapists. Quality of life would be improved for women and other indirect benefits to consider may also be parental attachment and breastfeeding.
Expert #5	Yes it will become mandatory
Expert #6	Yes
Expert #7	Yes it could lead to less anal sphincter injuries during childbirth. These injuries need surgery to repair them and can lead to complications such as infection, anal incontinence and pain. These complications would require longer stays in hospital or more hospital appointments. The psychological benefits also need consideration, anal sphincter injuries can cause anxiety and depression in women who suffer complications which requires treatment and support.
Expert #8	If Episcissors-60 reduce incidence of OASI then this should lead to reduced care needs in women who would previously have had OASI (i.e. less complicated repair, less follow up appointments, less treatment for associated morbidities)
Expert #9	Yes, but this needs to be demonstrated
Expert #10	May lead to reduced 3rd degree tear rates with reduction in morbidity to patients. Also reduction in follow up visits and invasive FU anorectal investigations. Reduction in morbidity in future pregnancies

Potential system impact

8. What do you consider to be the potential benefits to the health or care system from using this technology?

Expert #1	Reduce incidence of anal sphincter injury during childbirth and reduce costs of managing women with after effects of anal sphincter injury.
Expert #2	In prospective studies and a systematic review the use Episcissors-60 has shown as significant reduction in OASIS. Therefore implementation of this practice throughout every hospital will reduce the morbidity associated with vaginal delivery.
Expert #3	A recent systematic review the use Episcissors-60 has shown as significant reduction in OASIS with no increase in episiotomy rates There is increasing evidence of the benefits. .
Expert #4	A decrease in OASIS leading to reduced morbidity from childbirth. We have seen a reduction in our OASIS rate but the Episcissors and the OASIS care bundle were introduced at a similar time and so difficult to determine robust reasons for the drop in OASIS rate.
Expert #5	Prevention of OASIS, less medicolegal cases, money saved by NHS, quality of life better
Expert #6	Less incidence of Perineal tears • Improvement in life quality • reduce the incidence of C/S due to previous third degree tear
Expert #7	Improved outcomes in patients which means less injuries for medical staff to repair or treat. Shorter stays in hospital, fewer hospital visits, possible reduction in legal claims. All of these can lead to cost saving.
Expert #8	Reduced resource use associated with repair and follow up of OASI and the morbidities associated with it
Expert #9	Fewer obstetric anal sphincter injuries and therefore fewer women with long-term complications such as perineal pain, incontinence or caesarean section in future pregnancies
Expert #10	Reduction in theatre time with reduction in 3rd degree tear rate . Reduction in follow up investigations and appointments

9. Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the technology likely to cost more or less than current standard care, or about the same?

Expert #1	It is likely to cost equivalent to current technology and in the long term save costs with the savings on managing women with long term effects of anal sphincter injury.
Expert #2	Compared to standard scissors, Episcissors-60 is more expensive to purchase but business cases have shown it to be cost effective. The. York Health Economic Consortium's report suggests a return on investment of more than 3000% within one year.
Expert #3	More due to the cost of the device
Expert #4	This is impossible to answer without a strong evidence base that includes a comprehensive health economic evaluation.
Expert #5	It is one time investment to buy episcissors as it can be reused it can be cost effective
Expert #6	Cost more (instrument cost)
Expert #7	Likely to cost less.
Expert #8	I don't know, it is complicated. Some models suggest a cost saving associated with use of the device assuming a reduction in the incidence of OASI and the costs associated with that. However some studies have observed an increase in the episiotomy rate or an increased maternal blood loss - the implications of this and the associated potential costs have not been incorporated into these models as far as I am aware.
Expert #9	This is unknown. Any potential benefits from a reduction in obstetric anal sphincter injuries may be negated by the consequences of bigger episiotomies (more blood loss, more pain). The number of episiotomies needed to prevent one anal sphincter injury is about 30. So in effect 30 women may need bigger episiotomies so 1 woman does not sustain a sphincter injury. Whether this benefits the population of women having a vaginal birth is uncertain.
Expert #10	Less

10. What do you consider to be the resource impact from adopting this technology? Could it, for example, change the number or type of staff needed, the need for other equipment, or effect a shift in the care setting such as from inpatient to outpatient, or secondary to primary care?

Expert #1	The impact will not be on reduction in staff needed nor will any other equipment will be needed. It is a replacement for current type of scisssors but with the added benefit of reducing anal sphincter injury, and as a result reducing the burden of managing patients with the effects of anal sphincter injury.
Expert #2	I foresee no impact on the resources indicated
Expert #3	No, but should be accompanied with a good training package
Expert #4	There is the potential for reduced resource impact from using this technology but again, robust research is needed. There may be a reduction in women attending for follow-up care in the secondary setting for an OASIS and potential reduced length of stay.
Expert #5	No extra staff required
Expert #6	No
Expert #7	It has the potential to lighten the workload of obstetric doctors as the epi-scissors could lead to less injuries for them to repair and reduce the amount of complications these injuries can cause. I do not think it would change the number of staff needed, but they have the potential to reduce the amount of equipment needed in that if anal sphincter injuries are avoided women will not need surgery to repair those injuries.
Expert #8	There is a small resource impact from initial purchase and specific containers are sometimes required to sterilise Episcissors-60 in a way that protects the guide wire – these are small costs. Otherwise it should have little resource impact, it is just a matter of medics and midwives using these scissors instead of regular scissors.
Expert #9	In the 4 maternity units that we studied, there was no reduction in the rates of anal sphincter injuries although other centres have reported a benefit. If there is a reduction in sphincter injuries then there should be a resource benefit in terms of savings from the initial surgical repair and future complications / cost of litigation. I will not expect a change in care pathways as risk is reduced but not eliminated.
Expert #10	Reduction in theatre time with reduction in 3rd degree tear rate . Reduction in follow up investigations and appointments

11. Are any changes to facilities or infrastructure, or any specific training needed in order to use the technology?

Expert #1	No change to facilities or infrastructure needed but staff need training in the use of this device.
Expert #2	No, except initially when introduced to new doctors and midwives and this can be taught using models
Expert #3	No
Expert #4	A simple training package is needed to familiarise staff with the technology and ensure correct adoption of its use. We have a training perineum that can be used with the Episcissors for staff training and the use of the Episcissors is included in our perineal training workshop for midwives.
Expert #5	Initial training of doctors and midwives
Expert #6	Needs training for the staff
Expert #7	There would need to be a brief explanation to midwives and doctors on how to use the epi-scissors.
Expert #8	Respondents in our study suggested that little training is required in order to use this technology and all managed training in-house without difficulty
Expert #9	The expected training in the use of any surgical instrument.
Expert #10	Basic training requiring just one or two training opportunities before able to use

12. Are you aware of any safety concerns or regulatory issues surrounding this technology?

Expert #1	None
Expert #2	No
Expert #3	No

Expert #4	The Episcissors can become blunt and if this occurs then the risk of damage increases. We have had suggestions that there is an increase in blood loss and the episiotomy has to be repaired promptly. There is anecdotal evidence that there may be heavier blood loss with the episcissors but we would need to collect this data
Expert #5	None
Expert #6	I am not aware
Expert #7	No
Expert #8	I am aware that a study in the NENC region observed a small increase in maternal blood loss of around 50ml (blood loss as estimated by clinicians).
Expert #9	We have highlighted the risk that episiotomies with these scissors are longer (published reports) and this may contribute to greater delivery blood loss. We also need to evaluate the implications of bigger episiotomies on women (potentially more pain or they could be beneficial and reduce the risk of more complex tears). We do not fully understand whether the benefits outweigh these risks given the number of episiotomies needed to prevent one sphincter injury.
Expert #10	No

General advice

13. Please add any further comments on your particular experiences or knowledge of the technology, or experiences within your organisation.

Expert #1	This device has significant advantages and cost saving to patients and wider NHS.
Expert #2	In an audit conducted in our hospital, 91% of doctors and midwives preferred EPISCISSORS-60 to normal scissors (RCOG World Congress 2016).
Expert #3	The scissors are of excellent quality.
Expert #4	We have purchased 67 pairs of the Episcissors for circulation within our maternity unit. Unfortunately this is not enough to ensure that a pair is available for every delivery pack and so sometimes they need to be sought out prior to birth. We have also had some issues with the Episcissors becoming blunt. This has been resolved and once a pair has been used 20 times then it gets sharpened.

	We have been unable to collect any data on how frequently the Episcissors are used or clinical outcome data as we do not have the IT capability within our labour recording system (K2). This should be resolved shortly and we hope to collect data within the next 6 months.
Expert #5	Have been using since 2015
Expert #6	It is a useful guide to perform episiotomy at correct angle. I felt that Midwives are confident in giving episiotomy using episcissors
Expert #7	I have had conversations with obstetric staff who have used the epi-scissors in other units and they speak very positively about the epi-scissors.
Expert #8	A number of the clinicians involved in our study noted that their old stock of episiotomy scissors (mayos) were blunt – they described having to 'hack' through the perineum several times to achieve an episiotomy. Their most consistent observation about episcissors was that they are very sharp and this was seen as the key advantage of episcissors. Some observed that they would have liked to see a comparison of sharp mayos versus episcissors. In the post implementation period some noted that episcissors were starting to blunt also.
Expert #9	No answer given.
Expert #10	There are some general concerns about the efficacy of the episcissors in relation to their use. Most noticeably that the product can often be blunt leading to repositioning of the scissors and ultimately a changed in direction of episiotomy hindering its intended benefit. Midwifery staff have concerns about the size of episiotomy often being larger then they intended.

Other considerations

14. Approximately how many people each year would be eligible for intervention with this technology, either as an estimated number, or a proportion of the target population?

Expert #1	All women having vaginal birth in the NHS
Expert #2	Approximately 100 000 episiotomies are performed in the UK annually
Expert #3	The average episiotomy rates in the United Kingdom is 20%. Likely to be huge.
Expert #4	Approximately 2000 (22% of all births) women per year undergo an episiotomy at our Trust.

Expert #5	75% of pregnant women having vaginal delivery
Expert #6	Can't provide exact numbers
Expert #7	Approx 15% of births in the UK require an episiotomy and would be eligible for the epis-scissors.
Expert #8	I am aware of research by the NPMA reporting episiotomy rates of 21.7% of all women having a singleton cephalic baby at term and an OASI rate of 3.6% (England, 2015-16). I am aware of research by Gurol-Urganci et al (2013) that quotes an episiotomy rate of 36% and an OASI rate of 5.9% for primparous women with a singleton term cephalic baby having a vaginal delivery in 2012 in the NHS. Both of these represent subsets of the total birthing population. I am not sure there is data about the total number of women having a vaginal birth with an episiotomy AND sustaining an OASI which are the population you would be trying to prevent OASI in.
Expert #9	About 20% of women who have a vaginal birth have an episiotomy and will be eligible – about 91,000 women / year in England.
Expert #10	1400 per year (instrumental delivery rate) plus a proportion of normal deliveries

15. Would this technology replace or be an addition to the current standard of care?

Expert #1	Replace current scissors
Expert #2	It would replace the standard scissors being used to cut an episiotomy
Expert #3	Replace
Expert #4	If the evidence base existed and we had the funds then all scissors for episiotomies would be replaced by Episcissors.
Expert #5	It should be replaced by the current scissors we use
Expert #6	No
Expert #7	It would replace usual episiotomy scissors.
Expert #8	It would replace the scissors usually used for episiotomies

Expert #9	Replace
Expert #10	Addition

16. Are there any issues with the usability or practical aspects of the technology?

Expert #1	Needs appropriate training prior to use.
Expert #2	No
Expert #3	Should be accompanied with training
Expert #4	No
Expert #5	None
Expert #6	I am not aware of any issues.
Expert #7	No
Expert #8	It is not designed for left handed clinicians and I have heard left handers being told to deal with this in different ways. I have also heard senior clinicians say that sometimes they feel the angle of cut is not correct or will cut too far into the buttock, and I have also spoken to senior clinicians who admit to altering the angle of cut where they feel this required (i.e. not angling the guide wire towards the anus as intended) – if this becomes widespread it may naturally impact on the effectiveness of the technology
Expert #9	No
Expert #10	See above – general advise

17. Are you aware of any issues which would prevent (or have prevented) this technology being adopted in your organisation or across the wider NHS?

Expert #1	Initial costs of purchasing the device
Expert #2	A financial business case was not possible as the hospital was losing PBR-tariff income for repair of OASIS.
Expert #3	No
Expert #4	Further funding to purchase.
Expert #5	None
Expert #6	No
Expert #7	No
Expert #8	I completed a study explicitly exploring barriers and facilitators to adoption and sustainable implementation. Key barriers were: • Bureaucratic systems that make it difficult for clinicians to procure the technology • Lack of leadership in relation to organising adoption/implementation • Units where OASI rates are already low • Units where other clinical or organisational issues are a major priority • Failure to acknowledge the different training, support and leadership needs of medical staff and midwives • Limitations of the evidence base leaving clinicians unconvinced that episcissors make any difference/are a worthwhile expenditure • Price differential between traditional scissors (mayo) and episcissors • Concerns about observed unexpected increase in blood loss • Feelings that there are better ways to reduce incidence of OASI
Expert #9	We approached 9 NHS Trusts in our network to introduce the technology and 5 agreed to adopt it. We have undertaken a qualitative study including interviews with key staff in adopting and non-adopting centres. I am also aware of a survey by our AHSN with adopting and non-adopting Trusts. The key barrier to adoption is that clinicians are concerned about the low level of evidence on efficacy.

Expert #10	No answer given.

18. Are you aware of any further evidence for the technology that is not included in this briefing?

Expert #1	none
Expert #2	No
Expert #3	No
Expert #4	No.
Expert #5	No
Expert #6	No
Expert #7	No
Expert #8	A large scale before and after study has been conducted in the north east and north cumbria, led by Dr Paul Ayuk.(before (n = 11,192) and after (n = 8,064)) – I was part of this study team. This study did not find a reduction in episiotomy or OASI rates but did observe a significant increase in maternal blood loss (increase ~ 50mls). The study has been submitted for publication but is not yet published - the AHSN-NENC, who funded the study, have a report detailing the outcomes.
Expert #9	Recently published systematic review & meta-analysis plus our study which has been peer-reviewed and currently being revised for publication.
Expert #10	No

19. Are you aware of any further ongoing research or locally collected data (e.g. audit) on this technology? Please indicate if you would be able/willing to share this data with NICE. Any information you provide will be considered in confidence within the NICE process and will not be shared or published.

Expert #1	We have submitted longer term data about outcomes following use of this device and awaiting response from the scientific journal. Yes I would be willing to share this data
Expert #2	No
Expert #3	No
Expert #4	As above, we hope to collect data within the next 6 months.
Expert #5	Every hospital is collecting there data
Expert #6	No
Expert #7	No
Expert #8	I am not
Expert #9	As above and our study will hopefully be published soon. I will also ask co-authors who published recent systematic review to update it.
Expert #10	Regular audit on occurrence of 3rd degree tears.

20. Is there any research that you feel would be needed to address uncertainties in the evidence base?

Expert #1	no
Expert #2	I do not believe that a randomised controlled trial is feasible because of learning bias in the non epscissors-60 arm. Therefore, I believe that currently there is adequate research in the literature for its introduction into all hospitals

Expert #3	A randomised study may be beneficial but would need a lot of resources.
Expert #4	Yes, a large multi-centre RCT with health economic analysis is needed to determine true benefit.
Expert #5	No
Expert #6	No
Expert #7	No, but ongoing audit of units using the epi-scissors should take place to be able to assess their impact on obstetric anal sphincter injuries.
Expert #8	The research completed so far is limited is mostly observational and before/after research methods which has clear limitations. Published research from the UK is somewhat compromised by the introduction of the RCOG care bundle around the same making it difficult to tease out which interventions have impacted on OASI rates and to what extent episcissors has contributed to that. The results of the large study completed in the North East (which excluded maternity units introducing the OASI care bundle) have not confirmed a reduction in OASI rate though this study has its own limitations. One would expect a gold standard RCT to address the shortcomings in the existing evidence base however how achievable this is when Episcissors-60 have been promoted so heavily in the NHS already is questionable.
Expert #9	A high-quality study (RCT) is now essential otherwise some maternity units may not adopt a useful technology because of concerns about the evidence base or the NHS could incentivise a technology for several years only to find out that it is ineffective or harmful. My experience with cell salvage in obstetrics suggests that we should be very cautious about wide-spread adoption of surgical interventions without high-quality evidence. Even in the presence of such evidence, recent experience with mesh surgery in gynaecology will indicate that post-adoption surveillance is essential and this should become standard practice.
Expert #10	No

National Institute for Health and Care Excellence
Patient Organisation Submissions for Medical Technologies - Submission Template

NICE Medical Technologies Advisory Committee

Episcissors-60

Please read the guide to completing a submission fully before completing this template.

Information about your organisation	
Organisation name	Birth Trauma Association (Reg Charity1120531)
Contact person's name	[redacted]
Role or job title	[redacted]
Email	[redacted]
Telephone	[redacted]
Organisation type	Patient/carer organisation (e.g. a registered charity) ☐X Informal self-help group ☐ Unincorporated organisation ☐ Other, please state:
Organisation purpose (tick all that apply)	Advocacy ☐X Education ☐X Campaigning ☐X Service provider ☐ Research ☐X Other, please specify:
What is the membership of your organisation (number and type of members, region that your organisation represents, demographics, etc)? FB MEMBERS 7,500 (mainly women who have experienced traumatic birth but also partners and fathers) about 15 committee and trustees National, all demographics	

Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.

National Institute for Health and Care Excellence
Patient Organisation Submissions for Medical Technologies - Submission Template

If you haven't already, please register as a stakeholder by completing the stakeholder registration form and returning it to medtech@nice.org.uk

Further information about registering as a stakeholder is available on the NICE website.

Did you know NICE meetings are held in public? You can register on the NICE website to attend a meeting up to 20 working days before it takes place. Registration will usually close 10 days before the meeting takes place. Up to 20 places will be available, depending on the size of the venue. Where meetings are oversubscribed NICE may need to limit the number of places we can offer.

Sources of information

What is the source of the information about patients' and carers' experiences and needs that are presented in this submission?

I personally have over 14 years' experience working on the support line dealing directly with OASI cases, the BTA is involved in various projects to reduce maternal injury and our Chair worked on the RCOG OASI project as lay collaborator. OASI, episiotomy and its impact are regularly discussed on our FB group of over 7500 members.

National Institute for Health and Care Excellence
Patient Organisation Submissions for Medical Technologies - Submission Template

Impact of the symptoms, condition or disease

1. How do symptoms and/or the condition or disease affect people's lives or experiences?

Depends on severity but we hear of many life changing cases. There is frequent under diagnosis of OASI and when it is recognised, it is often when scar tissue has formed and repair is difficult or impossible. This can leave some women needing to pump out their lower bowel before leaving the house, thus wrecking their career and often relationships. It can have a catastrophic effect on self-image, self-esteem and mental health. In other cases, complications of surgery can occur and women are left with colostomy.

Unfortunately, these cases are not being tracked by NPEU because it is currently impossible for UKOSS to identify them from existing data.

Even in less severe cases, pain, incontinence, dyspareunia, fear of subsequent pregnancy can severely affect quality of life. Many women complain of constant perineal pain and difficult defecating

2. How do symptoms and/or the condition or disease affect carers and family?

Relationship breakdown as a result of loss of self-esteem, financial impact resulting from work related difficulties, problems leaving the house etc. Associated mental health issues as a consequence of OASI and its life impact are common. Overall, OASI can be devastating and life changing. Anything that can improve or reduce the incidence of the injury is to be welcomed.

3. Are there groups of people that have particular issues in managing their condition?

Single parents who are severely impacted by OASI are unable to work and this leads to enormous financial and emotional stress.

Experiences with currently available technologies

4. How well do currently available technologies work?

This is where we will have problems commenting. There are clearly problems with current episiotomy practice but women who talk to us do not know the details. All we can say is that women would benefit enormously from anything that would reduce the impact and incidence of OASI. Moreover, it would also save NHS resources as OASI and perineal trauma are major sources of legal claims.

5. Are there groups of people that have particular issues using the currently available technologies?

Women of South East Asian ethnicity seem to have a particularly high incidence of OASI

National Institute for Health and Care Excellence
Patient Organisation Submissions for Medical Technologies - Submission Template

About the medical technology being assessed

6. For those with experience of this technology, what difference did it make to their lives?

N/A

7. For those without experience of the technology being assessed, what are the expectations of using it?

That it would reduce OASI

8. Which groups of people might benefit most from this technology?

Groups of women facing delivery problems in the late stages of labour e.g. requiring instrumental delivery. Those at high risk of OASI (older mothers, SE Asian ethnicity, women expecting large babies or where the baby is malpositioned etc)

Additional information

9. Please include any additional information you believe would be helpful in assessing the value of the medical technology (for example ethical or social issues, and/or socio-economic considerations)

Women are having first children at ever later ages and this increases the risk of OASI – it is definitely getting more common.

Key messages

10. In up to five statements, please list the most important points of your submission.

- Reduction in incidence of OASI
- Improvement in techniques that would improve the impact of episiotomy for other women
- Less litigation and hopefully more resources for standard care

Thank you for your time. Please return your completed submission to medtech@nice.org.uk

Using your personal information: The personal data submitted on this form will be used by the National Institute for Health and Care Excellence for work on Medical Technologies (including reviews) and will be held on the Institute's databases for future reference in line with our privacy notice.

National Institute for Health and Care Excellence

External Assessment Centre correspondence table

MT457 Episcissors-60 for guided mediolateral episiotomy

The purpose of this table is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the sponsors' original submission. This is normally where the External Assessment Centre:

a) become aware of additional relevant evidence not submitted by the sponsor
b) need to check "real world" assumptions with NICE's expert advisers, or
c) need to ask the sponsor for additional information or data not included in the original submission, or
d) need to correspond with an organisation or individual outside of NICE

These events are recorded in the table to ensure that all information relevant to the assessment of the topic is made available to MTAC. The table is presented to MTAC in the Assessment Report Overview, and is made available at public consultation.

Submission section #	Question / Request	Response	Action / Impact / Other comments
Company Reps			
Teleconference with manufacturer	1. What is the cost of disposable Episcissors-60?	Cost is the same as the reusable scissors in that it is priced on a per use basis at £16 per use	
	2. Will disposable scissors replace the re-usable completely	Yes	
	3. Are they different in any way or just re-marketed that single use item?	They don't have the tungsten carbide inserts and the additional confidential steps taken to prolong cutting durability in the reusable version.	
	4. Will trusts having already purchased reusable continue with these until the end of their lifespan?	That depends on them. Trusts may choose to use disposable scissors for certain types of birth, and continue using reusable scissors for other types.	
	5. For clarification: what is the difference between nulliparous and primiparous? Do we need specific clarification about nulliparous including still birth, non-viable infant?	Some authors chose the term according to their preference but both mean first births.	
	6. Is there a reason the evidence should exclude multiparous women? I understand the potential risk for OASIS is higher in nulliparous women but this topic is about women who have an episiotomy. Scope doesn't state if only about NP but probably need to be sure what the patient population is in each paper and be able to disaggregate data	All the published studies chose to focus on the nulliparous women as this is a more homogenous group, with an untried, untested perineum. We had no control over this. The OASIS reduction should be the same in multiparous women.	
	7. What is the likelihood of a Caesarean birth in subsequent pregnancies for women with an OASIS?	Edozien et al reported 25% of women with OASIS opted for elective Caesarean birth in their next pregnancy. This is cited in the submission.	

	8. What is the possibility that the availability of Episcissors-60 will result in a behaviour change?	It is possible but there is no evidence other than anecdotal evidence based on midwives/consultants saying they feel more confident to perform episiotomy with episcissors-60.	
Follow-up Questions	Could you give me a little more information about the Koh et al abstract that has been included in the clinical submission. You state that it is currently submitted for peer review, would you have any idea of whether the paper has been accepted for publication and if so what the timeline for publication might be?	I am not privy to their publication status but it has not been accepted anywhere yet otherwise I would have known. So unlikely to be published in our time frame. No journal will accept the paper if the contained information is in the public domain (barring conference abstracts). So they won't share their paper with you.	
	I know that you got the cost for the standard episiotomy scissors in confidence but could I just clarify that the cost per unit you were given was for a disposable (single use) episcissors	Yes, that is correct. I would draw your attention to two important points in understanding the pricing of surgical scissors. SINGLE USE= These scissors are usually manufactured in a low-wage country, and shipped to the UK/EU. They are then cleaned in a MHRA certified clean room, packed with protective inserts, and then sterilised with gamma radiation or ETO. There is per unit cost of this process which involves the UK labour, equipment, regulatory compliance, and maintenance. This usually cannot go below £.150-1.70 for a UK facility. The cost of the scissors is separate to this. REUSABLE= These are sold anywhere between £25-£300 per scissor. The wide variation in price is due to the kind of alloys used in making the scissors, the kind of processing that the blades undergo, and the cost of tungsten-carbide welding to the scissor blades.	

	I have a query about the values that you have put into the economic model that I am hoping I can clarify with you if possible. The rate of OASIS reported in Thiagmoorthy is a median of 2.85% (0%-8%). In the economic submission you have put 2.85% (2-4%) and I was wondering whether I had missed something in the Thiagmoorthy publication as I cannot see the range 2-4% in the paper.		
	Could you give me more information about the Episcissor-60 specific tray and its cost?	We do not sell a specific tray	No cost to be included in the model
Teleconference with NHS England & NHS Improvement: Alan Blighe	A teleconference was arranged by NICE between NICE, the EAC and Alan Blighe from NHS Improvement to discuss what data are available relating to Episcissors-60	Link to the paper I mentioned: http://www.ahsn-nenc.org.uk/wp-content/uploads/2019/03/AHSN-Episcissors-Implementation-Evaluation-Final-Report.pdf Link to our technical guidance: https://www.england.nhs.uk/publication/nhs-england-innovation-and-technology-payment-2019-to-2020-technical-notes/ In terms of data, we can share the following by AHSN region and at the national level: •Number of mothers requiring surgical repair after obstetric anal sphincter injury for the previous quarter. This is only required for the first claim. •Number of guided mediolateral episiotomies undertaken using the Episcissors or other approved device during this period of reporting. Providers will be paid based on this number. •Number of mothers requiring additional surgical repair after undergoing guided mediolateral episiotomy during this period of reporting. •Average discharge time of mothers who have received a guided mediolateral episiotomy using the Episcissors or other approved device.	

Follow-up email	NICE/EAC responded to say that the data might prove useful	Alan Blighe to look into getting the data to the EAC	Alan Blighe stated that there is a possibility that the data would not be available before the submission date. The EAC raised this with NICE and proposed that in the event the data were not available, a final report would be submitted and on receipt of the data any amendments could be made and submitted provided it was in time for the MTAC meeting.
Questions to Clinical Experts (additional to the original questionnaire sent by NICE)			
Abdul Sultan	1. Do you use the reusable or disposable version of Episcissors-60 2. If using the reusable scissors, could you please give me a brief outline of the sterilisation process	Yes Autoclaved in the central sterilisation department	
	3. Do you have any issues with scissors going missing, needing to be replaced?	infrequently	
	4. Could you estimate an average number of scissors per year?	1-2	
	5. What is the average number of uses per Episcissors?	There is no tracking system for either type of scissors	
	6. If you were using an alternative reusable scissors, how does the number of uses per scissors compare?		

	7. There appear to be some potential problems with reusable scissors becoming blunt. a. Is this an issue for all reusable scissors or just Episcissors? b. What is the process for sharpening the scissors and how long does this mean they are unavailable for use? c. Is there a cost associated with this?	 Yes Scissors are returned for sharpening when considered to be blunt by users. Unavailable for 3 weeks Cost unknown to me	
	8. In your clinical opinion, has the introduction of Episcissors-60 resulted in a behaviour change? 9. Has there been a change in the number of episiotomies since the introduction of Episcissors-60?	Yes	
	10. Could you provide an estimate of the cost of standard episiotomy scissors	No	
Follow up questions	***Related to Lou et al (2016)*** Would you have any idea why this discrepancy exists? Is it possible that the authors of the review included unpublished patient data from Croydon?	Unknown cost to NHS	
	Almost all the published literature is reporting the rate of OASIS with Episcissors-60 using the total births (with and without episiotomy) as the denominator which would seem to be inappropriate to me as the availability of Episcissors-60 cannot impact the rates of OASIS in women who do not have/need and episiotomy.	You are absolutely correct that this may not be perceived as a pure effect per se but what we want to know is the effect of an intervention into overall obstetric practice. Episiotomy is performed when clinically indicated BUT this is an individual decision made when the head is crowning. The only way to establish the direct effect is to perform a RCT between Episcissors and conventional scissors. However this will not be possible in the UK because there will be a learning effect that will introduce bias in the conventional scissors group.	

	some studies report the difference in OASIS rates between episiotomy and no episiotomy patients but my understanding is that there will be clinical indications that a women needs an episiotomy therefore I am not clear why these outcomes are being reported or are useful?	Yes that is true and discussed above	
	Is there a difference risk of OASIS between episiotomy and no episiotomy births?	Yes in large observational studies with instrumental deliveries	
	Is there a reason why an episiotomy would not be given when clinically indicated or given when not clinically indicated?	Because it is the doctor or midwife who decides at the time of crowning. Some midwives especially the newly qualified ones have not been trained and others are apprehensive and let the woman tear. Although there are many randomised studies with restrictive and routine episiotomy, none of these studies have measured the angle of the episiotomy but there are many studies that have shown that the the closer the angle to the anal sphincter the OASI rate.	
	Would an episiotomy scissors be included as standard in a birth pack? Should it be considered a cost to a birth whether a women is given an episiotomy or not?	If it is not disposable and if it is put in the birth pack then the risk is that it will be discarded. It is best to pack it separately as less than 40 percent will require an episiotomy unless off course it is disposable and low cost	
	Could tell me if any of your clinical staff have reported any problems using Episcissors-60 due to being left-handed?	I have enquired from my left handed staff and they all say that they use the right had to cut a right mediolateral episiotomies. This is similar practice with conventional scissors	
Myles Taylor	1. Do you use the reusable or disposable version of Episcissors-60 2. If using the reusable scissors, could you please give me a brief outline of the sterilisation process	No n/a	

	3. Do you have any issues with scissors going missing, needing to be replaced?	n/a	
	4. Could you estimate an average number of scissors per year?	0	
	5. What is the average number of uses per Episcissors? 6. If you were using an alternative reusable scissors, how does the number of uses per scissors compare?	Not Sure N/A	
	7. There appear to be some potential problems with reusable scissors becoming blunt. a. Is this an issue for all reusable scissors or just Episcissors? b. What is the process for sharpening the scissors and how long does this mean they are unavailable for use? c. Is there a cost associated with this?	Not Sure	
	8. In your clinical opinion, has the introduction of Episcissors-60 resulted in a behaviour change? 9. Has there been a change in the number of episiotomies since the introduction of Episcissors-60?	We don't use them	
	10. Could you provide an estimate of the cost of standard episiotomy scissors	£15	
Follow up Question	Are there any plans to introduce Episcissors?	No plans	
Ranee Thaker	1. Do you use the reusable or disposable version of Episcissors-60 2. If using the reusable scissors, could you please give me a brief outline of the sterilisation process	Reuseable sent to sterilisation services in the hospital	
	3. Do you have any issues with scissors going missing, needing to be replaced?	not yet, we use a cage for them	
	4. Could you estimate an average number of scissors per year?	I am unable to do this	
	5. What is the average number of uses per Episcissors?	Don't know Don't know	

	6. If you were using an alternative reusable scissors, how does the number of uses per scissors compare?		
	7. There appear to be some potential problems with reusable scissors becoming blunt. a. Is this an issue for all reusable scissors or just Episcissors? b. What is the process for sharpening the scissors and how long does this mean they are unavailable for use? c. Is there a cost associated with this?	All scissors get blunt with time Don't know Don't know	
	8. In your clinical opinion, has the introduction of Episcissors-60 resulted in a behaviour change? 9. Has there been a change in the number of episiotomies since the introduction of Episcissors-60?	Unable to answer this question but has increased awareness of performing an apisiotomy at 60 degress I am not aware of this. Certainly not in our unit	
	Could you provide an estimate of the cost of standard episiotomy scissors	Don't know We pack them separately in a metal cage	
	could tell me if any of your clinical staff have reported any problems using Episcissors-60 due to being left-handed?		
Ashish Pradhan	Do you use the reusable or disposable version of Episcissors-60 If using the reusable scissors, could you please give me a brief outline of the sterilisation process	Reusable They are sent to CSSD as per any other instrument	
	Do you have any issues with scissors going missing, needing to be replaced?	No	
	Could you estimate an average number of scissors per year?	50	
	What is the average number of uses per Episcissors? If you were using an alternative reusable scissors, how does the number of uses per scissors compare?	60-70 Less for alternative reusable scissors	
	There appear to be some potential problems with reusable scissors becoming blunt. a. Is this an issue for all reusable scissors or just Episcissors?	All reusable scissors Goes to medical device for sharpening, couple of weeks for each scissor Not sure	

	b. What is the process for sharpening the scissors and how long does this mean they are unavailable for use? Is there a cost associated with this?		
	In your clinical opinion, has the introduction of Episcissors-60 resulted in a behaviour change? Has there been a change in the number of episiotomies since the introduction of Episcissors-60?	Yes Small increase in numbers but more awareness of need and appropriate technique	
	Could you provide an estimate of the cost of standard episiotomy scissors	Not Sure	
	Could tell me if any of your clinical staff have reported any problems using Episcissors-60 due to being left-handed?	As far as I am aware, none of our staff have reported any problems with being left handed	
Follow up Question relating to: "Comparison of obstetric anal sphincter injuries in nulliparous women before and after introduction of the EPISC ISS ORS -60® at two hospitals in the United Kingdom"	table 1 which breaks down all of the data that there are rows for all Nulliparous and for Nulliparous (SVD+OVD) and I was wondering whether you could possibly explain the difference between these two? For example the table reports a combined total episiotomies of 792 for 2014 and 321 for 2015 but with different denominators depending on whether it is all Nulliparous or whether it is Nulliparous (SVD+OVD).	All NP includes SVD + OVD + caesarean sections. NP (SVD+OVD) excludes the caesarean section deliveries.	
Kylie Watson	E-mail sent with the same questions as to other experts, response received to say she was trying to find the answers and would get back to us.		
YHEC Case Study	E-mail sent to ask who to contact about the case study	E-mail forwarded to Jo Hanlon	
Jo Hanlon	Could you give me a little bit of insight as to why the case study was based on total births and not just births that require an episiotomy?	When developing the case study we had access to data on the rate of OASIS in total births, the rate of episiotomy in total births, plus evidence on the reduction in OASIS when using Episcissors-60 versus usual episiotomy scissors, for those births requiring episiotomy. The analysis included a number of assumptions, which are stated in the case study.	

Follow-up Question:	wondering more about the decision to cost Episcissors using the whole birth cohort? Was this just because those were the data available? I have seen that the clinical literature reports the rate of OASIS before and after episcissors in the whole birth cohort and not just in people who had an episiotomy. I am trying to understand the rationale behind that decision as Episcissors realistically can only impact the rate of OASIS in women who have an episiotomy and not in women who don't and depending whether you look at the episiotomy population only or total births this has an impact on both the clinical and cost outcomes.		
Divakova et al (2019)			
Olga Divakova	Table 2 states that the Lou (2016) study has a sample size of 2509 however the reference listed refers to only 79 deliveries. I do note in the PRISMA flow diagram that the Lou study represents a more recent audit and I wondered if you could tell me what the original study was and whether it is published. Would it be possible to clarify where the numbers in your review for Lou et al have been obtained? I was also wondering whether the numbers are available for the rate of OASIS in patients with episiotomy with episcissors versus episiotomy with other scissors (rates in the episiotomy cohort rather than the whole birth cohort).	We have contacted Lou directly via email. We told him that their poster published in BJOG supplement showed a reduction in OASIS from 5.6% to 3.2%, but we were asking to provide actual values. The reply was from Miss Bini Ajay (I think, one of the co-authors). She provided us with the number of total deliveries, number of SVD and OVD, episiotomy of SVD, total OASIS before and after using of Episcissors. There were no numbers for the rate of OASIS in patients with episiotomy with episcissors versus episiotomy with other scissors, just total number of OASIS before and after Episcissors-60. That's why we had two tables in our publication on the rate of OASIS, as not all the studies compared OASIS rate in the groups with versus without episiotomy if it does make sense for you.	

NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence
Centre for Health Technology Evaluation

Pro-forma Response

External Assessment Centre Report factual check

Episcissors-60 for guided mediolateral episiotomy

Please find enclosed the assessment report prepared for this assessment by the External Assessment Centre (EAC).

You are asked to check the assessment report from Cedar to ensure there are no factual inaccuracies contained within it. If you do identify any factual inaccuracies you must inform NICE by 12pm, **02 August 2019** using the below proforma comments table. All your comments on factual inaccuracies will receive a response from the EAC and when appropriate, will be amended in the EAC report. This table, including EAC responses will be presented to the Medical Technologies Advisory Committee and will subsequently be published on the NICE website with the Assessment report.

30 July 2019

NICE National Institute for Health and Care Excellence

Issue 1

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Executive summary- page 6; "..so the company submitted a de novo cost model…."	Company submitted a de novo cost model as mandated by the NICE MTG process.	MEDINVENT complied with NICE MTG, so it is wrong to ascribe this choice to us.	Thank you for your comment. The summary accurately describes that the company submitted the cost model. The responsibility of the sponsor to submit a cost model is stated on the MTG methods guide and is available on the NICE website. No changes made.

Issue 2

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Background 2.1 Only Sawant et al are quoted as reference for eyeballing	Tincello 2003, Naidu 2015, Silf 2014, Fodstad 2014,Sawant 2015,	Statement ignores other published evidence	Thank you for your comment. The EAC accept that there may be other evidence relating to the accuracy of eyeballing however the searches for this report concentrate on studies which discuss Episcissors-60 specifically. The EAC consider that the Sawant paper is sufficient evidence for the background/context.

Issue 3

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
2.1.para 3 "in primiparous women, 1.6% sustained OASIS in spontaneous births"	5.4% sustained OASIS in primiparous spontaneous vaginal births	Wrong figures have been cited from the National Maternity Audit. 1.6% is the OASIS rate in multiparous spontaneous vaginal births.	Thank you for your comment. The EAC has corrected the figures to be 5.4% in primiparous women.

Issue 4

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
2.2 Critique of Company's definition of the decision problem	Critique of NICE's definition of the decision problem	NICE defined the decision problem, not MEDINVENT.	Thank you for your comment. The EAC acknowledge that the decision problem is defined by NICE however the EAC are required to offer a critique of the decision problem and identify where there may be differences.

Issue 5

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
3.3; para 2, page 12 "an Episcissors Implementation Report from the North of England (Ayuk et al, 2018) was identifed."	Please delete this statement and study from the entire report including meta-analysis	Ayuk 2018 is not a peer-reviewed study. It is not part of any medical databases as it is unpublished. Simply put up on a website, accessed by EAC via a search engine like Google. It should be excluded from the meta-analysis done by EAC. EAC admit that its quality cannot be assessed (Page 44). Neither has EAC critically analysed the data. Nor is EAC competent to peer-review an unpublished study as it does not have domain skills in obstetrics and gynaecology. No checks on ethical aspects of excluding other OASIS reduction measures despite being recommended by RCOG, no checks on methods, no checks on data, intention to treat, no checks on statistical methods used, no checks	Thank you for your comment. The EAC accept that the report could have been clearer in its description of the handling of the Ayuk (2018) study. The EAC disagree that they have blindly accepted the data on the authors word as the EAC have clearly highlighted throughout the report that Ayuk (2018) has not been through the peer review process. The EAC did attempt to contact the authors to investigate whether this report was likely to be published however contact details could not be found. Ayuk et al is in fact published in so far as it is available publically on line. The

		on why the conclusions are different from published peer reviewed data. No quality assessment tools like Newcastle-Ottawa, Cochrane, NHLI, Jada even reported, unlike in the published systematic reviews. EAC have just blindly accepted the data at the authors' word. This is in gross violation of NICE's own guidance. NICE PMG33 for the Medical Technology Evaluation Programme-MTEP states in Section 6.3.1 [Unpublished evidence]:"Unpublished data may be used to support a **narrative** review of the evidence, as well as to inform the design and conduct of new secondary research studies". https://www.nice.org.uk/process/pmg33/chapter/introduction PMG 33 does not say that unpublished data can be used by EAC for evidence synthesis or a meta-analysis. In contrast, explicit mention is made in section 6.3.4 [Section on expert advisers]: "Expert advice can also be used as part of evidence synthesis or modelling studies". Section 6.3.2 [Unpublished evidence sources] says: "the external assessment centre may identify other unpublished evidence, such as analysis of data from observational research sources, including professional or company-sponsored registers."	EAC included it under the heading for Unpublished studies as the NICE template suggests that peer reviewed studies should come under the heading of published while all other studies should come under unpublished. The EAC would not generally carry out a critical appraisal for a non-peer reviewed study as highlighting that a paper has not been through the peer review process provides clinical experts with enough information for discussion purposes. In the case of Ayuk et al (2018) the EAC have conducted a critical appraisal of the study in response to the criticisms of the company and added this to Appendix B. This critical appraisal suggests that the Ayuk report is on a par with the published studies in terms of quality. The EAC disagrees that the results from Ayuk et al dramatically skew the results of the published meta-analysis, rather they present a possible alternative scenario based on additional data. The EAC has clearly stated the results of the meta-analysis (Divakova) in their submission. Both Divakova and the EAC meta-analysis suggest that Episcissors reduces OASIS in the episiotomy population, the additional data in the EAC analysis suggests that this difference may not be statistically significant but makes no comment on the clinical significance. The EAC highlight in their report that Divakova does not report a 43%

		The Ayuk 2018 data has not been identified from professional or company sponsored registers. It has been identified in a Google like search. PMG 33 Section 8.1 [Main considerations in decision-makings] says: "The committee needs to be confident that the evidence is of sufficient quality, quantity and consistency to form the basis of robust recommendations." This is not possible if the committee is provided a meta-analysis by the EAC that includes evidence from non-peer reviewed unpublished studies which dramatically skew the results of published meta-analysis (43% OASIS reduction, Divakova 2019) and systematic review (50% OASIS reduction, Cole 2019). EAC's inclusion of the Ayuk study is in violation of the MTEP's own guidance, therefore, in violation of the remit they were asked to follow. We contacted NICE urgently to highlight that their own guidance on developing MTG's had not been followed by the EAC. We pointed out the relevant sections of PMG33 and asked them to clarify whether inclusion of non-peer reviewed studies and unpublished studies on a MTG meta-analysis commissioned by them was acceptable. Despite several emails and phone calls, **NICE declined to clarify.** If NICE allows inclusion of the EAC meta-analysis in the report, it raises serious concerns about NICE's	reduction in OASIS. This is a rate reduction. The Absolute reduction in OASIS is approximately 2%. In addition, this absolute reduction is based on a reduction in OASIS across the total birth population. The EAC have presented the possible impact of Episcissors-60 in the Episiotomy patients only which is the population identified in the scope. Again the EAC have clearly stated in their report (section 4.2 and section 5.2) that confining the evidence to the episiotomy only population may not in fact represent the clinically relevant scenario and acknowledge that the committee may wish to consider whether there are potential subgroups worth investigating or whether the change across practice is more clinically useful.

		commitment to evidence based medicine.	

Issue 6

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 1; Sawant et al 2015; "There were some discrepancies in the paper related to reporting between text and tables "	There were some discrepancies in the paper related to reporting between text and tables. However, these discrepancies do not affect the overall conclusions.	This statement does not lend itself to rigour. EAC did not report contacting the authors for clarifications.	Thank you for your comment. The EAC agree that the discrepancies do not affect the overall conclusions and this is why it was felt that it was not necessary to contact the authors for clarification. The EAC is required to point out these discrepancies for transparency and because it will allow the committee to differentiate between minor issues which do not affect outcomes and any potentially major concerns with published literature. No changes made

Issue 7

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 1; van Roon 2015 "The EAC noted some discrepancies in the reporting between text and tables. This leads to a question over the quality and accuracy of the data"	Please delete or substantiate this statement.	This statement does not lend itself to rigour. EAC did not report contacting the authors for clarifications.	Thank you for your comment. The EAC agree that the discrepancies do not affect the overall conclusions and this is why it was felt that it was not necessary to contact the authors for clarification. The EAC is required to point out these discrepancies as it will allow MTAC to differentiate between minor issues which do not affect outcomes and any potentially major concerns with published literature.

			The EAC did in fact contact the authors of this paper (see correspondence log) and has amended table 1 to reflect this.

Issue 8

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Section 3.3; Table 1; Mohiudin 2018 “ Note that this study introduced a number of measures to reduce OASIS at the time of introducing Episcissors-60 and the results will reflect the impact of these measures combined. “	Note that this study introduced a number of measures to reduce OASIS at the time of introducing Episcissors-60 and the results will reflect the impact of these measures combined; although there is no reason to believe that the impact of these other measures would not be equal in both the episiotomy and no episiotomy groups in spontaneous and instrumental vaginal births. The differential reduction in OASIS rates between the Episiotomy and no Episiotomy groups suggest that the majority of the reduction in OASIS was due to the introduction of Episcissors-60. After introduction of the EPISCISSORS-60, OASIS rate was 0.63% with episiotomies v 16% without episiotomies (p = 0.000) at Barnet in OVD. At RFL, OASIS rate was 2.6% with episiotomies, and 42% without episiotomy (p = 0.000) in OVD. In SVD’s after introduction of the EPISCISSORS-60, OASIS was 0% in women with episiotomies and 3% in those without episiotomies (p = 0.04). In SVD’s at RFL, OASIS was 0% in women given episiotomy v 4.7% without episiotomy (p = 0.03).	There is no quantitative data presented on other measures. The results clearly show that it is safer to deliver with an EPISCISSORS-60 episiotomy in both spontaneous and instrumental births. If the other measures were significantly contributory, then OASIS would have reduced to the same extent in the no-episiotomy groups as well compared to the previous time period. After introduction of the EPISCISSORS-60, OASIS rate was 0.63% with episiotomies v 16% without episiotomies (p = 0.000) at Barnet in OVD. At RFL, OASIS rate was 2.6% with episiotomies, and 42% without episiotomy (p = 0.000) in OVD. In SVD’s after introduction of the EPISCISSORS-60, OASIS was 0% in women with episiotomies and 3% in those without episiotomies (p = 0.04). In SVD’s at RFL, OASIS was 0% in women given episiotomy v 4.7% without episiotomy (p = 0.03).	Thank you for your comment. The EAC acknowledge that the study did not present data on the other measures introduced. It is not within the remit of the EAC to investigate or to comment on how those measures might have impacted the results. The EAC simply highlight that other measures have been introduced at the same time so that the Clinical Experts can discuss whether and to what extent they think this may impact outcomes. The EAC has made a change to the text to suggest that the results ‘may’ reflect the impact of combined measures rather than ‘will’ affect the outcomes. Additionally, a comment has been added to Section 7 (Key Considerations) to highlight this as a discussion point.

NICE National Institute for Health and Care Excellence

Issue 9

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 1; Ayuk 2018	Please delete this study	Ayuk 2018 is not a peer-reviewed study. It is not part of any medical databases as it is unpublished. Simply put up on a website, accessed by EAC via a search engine like Google. It should be excluded from the meta-analysis done by EAC. EAC admit that its quality cannot be assessed (Page 44). Neither has EAC critically analysed the data. Nor is EAC competent to peer-review an unpublished study as it does not have domain skills in obstetrics and gynaecology. No checks on ethical aspects of excluding other OASIS reduction measures despite being recommended by RCOG, no checks on methods, no checks on data, intention to treat, no checks on statistical methods used, no checks on why the conclusions are different from published peer reviewed data. No quality assessment tools like Newcastle-Ottawa, Cochrane, NHLI, Jada even reported, unlike in the published systematic reviews. EAC have just blindly accepted the data at the authors' word. This is in gross violation of NICE's own guidance. NICE PMG33 for the Medical Technology Evaluation Programme-MTEP states in Section 6.3.1 [Unpublished evidence]:"Unpublished data may be used to support a **narrative** review of the evidence, as well as to inform the design and conduct of new secondary research studies". https://www.nice.org.uk/process/pmg33/chapter/introduction PMG 33 does not say that unpublished data can be used by EAC for evidence synthesis or a meta-analysis. In contrast, explicit mention is made in section 6.3.4 [Section on expert advisers]: "Expert advice can also be used as part of evidence synthesis or modelling studies". Section 6.3.2 [Unpublished evidence sources] says: "the external assessment centre may identify other unpublished evidence, such as analysis of data from observational	Thank you for your comment. Please see previous comment regarding this study (Issue 5)

		research sources, including professional or company-sponsored registers." The Ayuk 2018 data has not been identified from professional or company sponsored registers. It has been identified in a Google like search. PMG 33 Section 8.1 [Main considerations in decision-makings] says: "The committee needs to be confident that the evidence is of sufficient quality, quantity and consistency to form the basis of robust recommendations." This is not possible if the committee is provided a meta-analysis by the EAC that includes evidence from non-peer reviewed unpublished studies which dramatically skew the results of published meta-analysis (43% OASIS reduction, Divakova 2019) and systematic review (50% OASIS reduction, Cole 2019). EAC's inclusion of the Ayuk study is in violation of the MTEP's own guidance, therefore, in violation of the remit they were asked to follow. We contacted NICE urgently to highlight that their own guidance on developing MTG's had not been followed by the EAC. We pointed out the relevant sections of PMG33 and asked them to clarify whether inclusion of non-peer reviewed studies and unpublished studies on a MTG meta-analysis commissioned by them was acceptable. Despite several emails and phone calls, **NICE declined to clarify.** If NICE allows inclusion of the EAC meta-analysis in the report, it raises serious concerns about NICE's commitment to evidence based medicine.	

Issue 10

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
3.4; Sawant 2015 "no formal method of randomization has been described." The same issue should be addressed in Table 1 page 18 where this criticism of Sawant is repeated	Block/Cluster randomisation is described.	Block/Cluster randomisation is a well-accepted scientific method, each arm of the study was conducted by a different team so concealment was unnecessary and the Hawthorne effect prevented. Lack of allocation concealment has no importance in studies with objective outcomes (Wood, BMJ 2008)	Thank you for your comment. The EAC note that the methods section of Sawant et al state: "our study design was similar to a prospective cluster randomized study design." The EAC has not made any changes.

Issue 11

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
3.5, page 32 "GRADE Assessment of the outcomes in each of the studies suggest that the quality of the evidence is very low (Appendix C). This is primarily due to the fact that there are no randomised trials"	GRADE Assessment of the outcomes in each of the studies suggest that the quality of the evidence is very low (Appendix C). This is primarily due to the fact that there are no randomised trials. However, EAC acknowledge that a randomised trial could be regarded as being unethical, given that there is no evidence supporting eyeballing as a reliable method of visually estimating episiotomy angles.	EAC acknowledge this fact about the unethical nature of RCT's in this setting throughout the report. So the reader should not be misguided into believing that an RCT is possible, and would lead to better quality evidence.	Thank you for your comment The EAC do not think that the report misleads the reader into thinking that better quality evidence would be available with an RCT. The EAC is clear that they are in agreement that an RCT would be unethical in this situation and in section 8 (Implications for research), do not indicate that an RCT should be conducted. GRADE and critical appraisal tools are instruments designed to give an impression of the quality of evidence.

			They are not definitive, can be subject to interpretation and in no way are meant to over-ride clinical judgement. For clarity, the EAC has added some detail to section 7, table 18.

Issue 12

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 2; page 41 Ayuk 2018	Delete this study	Ayuk 2018 is not a peer-reviewed study. It is not part of any medical databases as it is unpublished. Simply put up on a website, accessed by EAC via a search engine like Google. It should be excluded from the meta-analysis done by EAC. EAC admit that its quality cannot be assessed (Page 44). Neither has EAC critically analysed the data. Nor is EAC competent to peer-review an unpublished study as it does not have domain skills in obstetrics and gynaecology. No checks on ethical aspects of excluding other OASIS reduction measures despite being recommended by RCOG, no checks on methods, no checks on data, intention to treat, no checks on statistical methods used, no checks on why the conclusions are different from published peer reviewed data. No quality assessment tools like Newcastle-Ottawa, Cochrane, NHLI, Jada even reported, unlike in the published systematic reviews. EAC have just blindly accepted the data at the authors' word. This is in gross violation of NICE's own guidance. NICE PMG33 for the Medical Technology Evaluation Programme-MTEP states in Section 6.3.1 [Unpublished evidence]:"Unpublished data may be used to support a	Thank you for your comment. Please see previous comment regarding this study (Issue 5)

		narrative review of the evidence, as well as to inform the design and conduct of new secondary research studies". https://www.nice.org.uk/process/pmg33/chapter/introduction PMG 33 does not say that unpublished data can be used by EAC for evidence synthesis or a meta-analysis. In contrast, explicit mention is made in section 6.3.4 [Section on expert advisers]: "Expert advice can also be used as part of evidence synthesis or modelling studies". Section 6.3.2 [Unpublished evidence sources] says: "the external assessment centre may identify other unpublished evidence, such as analysis of data from observational research sources, including professional or company-sponsored registers." The Ayuk 2018 data has not been identified from professional or company sponsored registers. It has been identified in a Google like search. PMG 33 Section 8.1 [Main considerations in decision-makings] says: "The committee needs to be confident that the evidence is of sufficient quality, quantity and consistency to form the basis of robust recommendations." This is not possible if the committee is provided a meta-analysis by the EAC that includes evidence from non-peer reviewed unpublished studies which dramatically skew the results of published meta-analysis (43% OASIS reduction, Divakova 2019) and systematic review (50% OASIS reduction, Cole 2019). EAC's inclusion of the Ayuk study is in violation of the MTEP's own guidance, therefore, in violation of the remit they were asked to follow. We contacted NICE urgently to highlight that their own guidance on developing MTG's had not been followed by the EAC. We pointed out the relevant sections of PMG33 and asked them to clarify whether inclusion of non-peer reviewed studies and unpublished studies on a MTG meta-analysis commissioned by them was acceptable. Despite several emails and phone calls, **NICE declined to clarify.**	

		If NICE allows inclusion of the EAC meta-analysis in the report, it raises serious concerns about NICE's commitment to evidence based medicine.	

Issue 13

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 3; Ayuk 2018	Delete this study from all analyses	Ayuk 2018 is not a peer-reviewed study. It is not part of any medical databases as it is unpublished. Simply put up on a website, accessed by EAC via a search engine like Google. It should be excluded from the meta-analysis done by EAC. EAC admit that its quality cannot be assessed (Page 44). Neither has EAC critically analysed the data. Nor is EAC competent to peer-review an unpublished study as it does not have domain skills in obstetrics and gynaecology. No checks on ethical aspects of excluding other OASIS reduction measures despite being recommended by RCOG, no checks on methods, no checks on data, intention to treat, no checks on statistical methods used, no checks on why the conclusions are different from published peer reviewed data. No quality assessment tools like Newcastle-Ottawa, Cochrane, NHLI, Jada even reported, unlike in the published systematic reviews. EAC have just blindly accepted the data at the authors' word. This is in gross violation of NICE's own guidance. NICE PMG33 for the Medical Technology Evaluation Programme-MTEP states in Section 6.3.1 [Unpublished evidence]:"Unpublished data may be used to support a	Thank you for your comment. Please see previous comment regarding this study (Issue 5)

		narrative review of the evidence, as well as to inform the design and conduct of new secondary research studies". https://www.nice.org.uk/process/pmg33/chapter/introduction PMG 33 does not say that unpublished data can be used by EAC for evidence synthesis or a meta-analysis. In contrast, explicit mention is made in section 6.3.4 [Section on expert advisers]: "Expert advice can also be used as part of evidence synthesis or modelling studies". Section 6.3.2 [Unpublished evidence sources] says: "the external assessment centre may identify other unpublished evidence, such as analysis of data from observational research sources, including professional or company-sponsored registers." The Ayuk 2018 data has not been identified from professional or company sponsored registers. It has been identified in a Google like search. PMG 33 Section 8.1 [Main considerations in decision-makings] says: "The committee needs to be confident that the evidence is of sufficient quality, quantity and consistency to form the basis of robust recommendations." This is not possible if the committee is provided a meta-analysis by the EAC that includes evidence from non-peer reviewed unpublished studies which dramatically skew the results of published meta-analysis (43% OASIS reduction, Divakova 2019) and systematic review (50% OASIS reduction, Cole 2019). EAC's inclusion of the Ayuk study is in violation of the MTEP's own guidance, therefore, in violation of the remit they were asked to follow. We contacted NICE urgently to highlight that their own guidance on developing MTG's had not been followed by the EAC. We pointed out the relevant sections of PMG33 and asked them to clarify whether inclusion of non-peer reviewed studies and unpublished studies on a MTG meta-analysis commissioned by them was acceptable. Despite several emails and phone calls, **NICE declined to clarify.**	

		If NICE allows inclusion of the EAC meta-analysis in the report, it raises serious concerns about NICE's commitment to evidence based medicine.	

Issue 14

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Page 46 "Removing the two studies from the pooled analysis (Mohiudin et al, 2018 and van Roon et al, 2015) which introduced bundle measures to reduce OASIS (of which Episcissors-60 was a part), results in a risk difference of 0.0"	Delete this statement; or add: In the absence of any quantitative data about the implementations of other measures, it would be reasonable to assume they were equally practiced in both the episiotomy and no episiotomy groups in both types of vaginal births. The differential reduction in OASIS rates between the Episiotomy and no Episiotomy groups reported in the studies suggest that the majority of the reduction in OASIS was due to the introduction of Episcissors-60. The results clearly show that it is safer to deliver with an EPISCISSORS-60 episiotomy in both spontaneous and instrumental births. (Please refer Issue 8 above for detailed explanations).	There is no quantitative data presented on other measures. The results clearly show that it is safer to deliver with an EPISCISSORS-60 episiotomy in both spontaneous and instrumental births. If the other measures were significantly contributory, then OASIS would have reduced in the no-episiotomy groups as well compared to the previous time period. Please see detailed statistics in Issue 8 above.	Thank you for your comment. The EAC acknowledge that there are no quantitative data reported relating to the other measures however the EAC feel that it is also important to acknowledge that there is a potential impact of these other measures and have explored this in the meta-analysis. The EAC highlight that the I^2 score (heterogeneity between studies) is 80% when both Mohiudin and vanRoon are included and drops to 0% when they are excluded. For clarity the EAC has added detail to section 7 to highlight this as a discussion area.

Issue 15

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Figures 1-4; page 47	Recompute after omitting Ayuk 2018 from analysis	Ayuk 2018 is not a peer-reviewed study. It is not part of any medical databases as it is unpublished. Simply put up on a website, accessed by EAC via a search engine like Google. It should be excluded from the meta-analysis done by EAC. EAC admit that its quality cannot be assessed (Page 44). Neither has EAC critically analysed the data. Nor is EAC competent to peer-review an unpublished study as it does not have domain skills in obstetrics and gynaecology. No checks on ethical aspects of excluding other OASIS reduction measures despite being recommended by RCOG, no checks on methods, no checks on data, intention to treat, no checks on statistical methods used, no checks on why the conclusions are different from published peer reviewed data. No quality assessment tools like Newcastle-Ottawa, Cochrane, NHLI, Jada even reported, unlike in the published systematic reviews. EAC have just blindly accepted the data at the authors' word. This is in gross violation of NICE's own guidance. NICE PMG33 for the Medical Technology Evaluation Programme-MTEP states in Section 6.3.1 [Unpublished evidence]:"Unpublished data may be used to support a **narrative** review of the evidence, as well as to inform the design and conduct of new secondary research studies". https://www.nice.org.uk/process/pmg33/chapter/introduction PMG 33 does not say that unpublished data can be used by EAC for evidence synthesis or a meta-analysis. In contrast, explicit mention is made in section 6.3.4 [Section on expert advisers]: "Expert advice can also be used as part of evidence synthesis or modelling studies". Section 6.3.2 [Unpublished evidence sources] says: "the external assessment centre may identify other unpublished evidence, such as analysis of data from observational	Thank you for your comment. Please see previous comment regarding this study (Issue 5)

		research sources, including professional or company-sponsored registers." The Ayuk 2018 data has not been identified from professional or company sponsored registers. It has been identified in a Google like search. PMG 33 Section 8.1 [Main considerations in decision-makings] says: "The committee needs to be confident that the evidence is of sufficient quality, quantity and consistency to form the basis of robust recommendations." This is not possible if the committee is provided a meta-analysis by the EAC that includes evidence from non-peer reviewed unpublished studies which dramatically skew the results of published meta-analysis (43% OASIS reduction, Divakova 2019) and systematic review (50% OASIS reduction, Cole 2019). EAC's inclusion of the Ayuk study is in violation of the MTEP's own guidance, therefore, in violation of the remit they were asked to follow. We contacted NICE urgently to highlight that their own guidance on developing MTG's had not been followed by the EAC. We pointed out the relevant sections of PMG33 and asked them to clarify whether inclusion of non-peer reviewed studies and unpublished studies on a MTG meta-analysis commissioned by them was acceptable. Despite several emails and phone calls, **NICE declined to clarify.** If NICE allows inclusion of the EAC meta-analysis in the report, it raises serious concerns about NICE's commitment to evidence based medicine.	

Issue 16

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Page 51;	NICE mandated completion of the de novo cost model.	MEDINVENT did not make such conclusions. NICE mandated	Thank you for your comment. The summary accurately describes that the company submitted the cost model. The

The company concluded that the YHEC (2017) study did not include complete costs relating to OASIS, therefore a *de novo* model was required		completion of the de novo cost model.	responsibility of the sponsor to submit a cost model is stated on the MTG methods guide and is available on the NICE website. No changes made

Issue 17

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Page 55; Published data suggest that the rate of OASIS in nulliparous women who have an instrumental birth can be as high as 7.8% of women sustained OASIS in operative vaginal or instrumental deliveries (OVD) compared with 1.6% of women with spontaneous vaginal deliveries	Published data suggest that the rate of OASIS in nulliparous women who have an instrumental birth can be as high as 7.8% of women sustained OASIS in operative vaginal or instrumental deliveries (OVD) compared with **5.4%** of women with spontaneous vaginal deliveries	Wrong figures have been entered. 1.6% is the OASIS incidence in multiparous women. (RCOG-NMAO report)	Thank you for your comment. The EAC has corrected this sentence to read "Published data suggest that the rate of OASIS in nulliparous women who have an instrumental birth can be as high as 7.8% of women sustained OASIS in operative vaginal or instrumental deliveries (OVD) compared with 5.4% of nulliparous women and 1.6% of multiparous women with spontaneous vaginal deliveries."

Issue 18

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 5 & page 56 "The EAC did not identify any disposable episiotomy scissors on NHS Supply Chain and based their cost in the model on the cost of standard reusable scissors at a cost of £0.26 per use. The cost	Please re-calculate after including sterilisation and sharpening costs OR The EAC did not identify any disposable episiotomy scissors on NHS Supply Chain and based their cost in the model on the cost of standard reusable scissors at a cost of £0.26 per use. The cost per birth of a standard	Sterilisation and sharpening costs need to be added. In a single use EPISCISSORS-60, they will be included in the £16 sale price	Thank you for your comment The EAC have not made any changes. The EAC model is based on comparing 'like with like' (reusable Episcissors with reusable standard scissors). Discussion

per birth of a standard episiotomy scissors using these figures would be £0.04 per birth."	episiotomy scissors using these figures would be £0.04 per birth, although it is noted that this does not include sterilisation and sharpening costs, which could range from £1-20 per use, depending on the location of the sterilisation facilities, the choice of birth packs and other factors.		with clinical experts suggested that sterilisation and sharpening costs would be the same for any reusable scissors therefore there is no benefit to including it in the model. The EAC acknowledge the company statement that reusable Episcissors will no longer be produced and for this reason have included a scenario analysis where the cost of standard scissors is much higher than 26p. The results suggest the model is very insensitive to changes in cost, remaining cost saving. The EAC suggest that should the model compare disposable Episcissors with reusable standard scissors, then there would be a need to include the additional sterilisation and sharpening costs for the standard scissors. There are however, no reliable costs for sterilisation procedures or sharpening costs. The company has not provided a source for their estimate of £1-£20 and none of the clinical experts were able to suggest a cost. As Episcissors-60 is currently cost saving in almost all scenarios modelled by the EAC, despite no additional costs for the standard scissors, the EAC consider that any additional costs associated with comparing a reusable standard scissors with a disposable Episcissors would likely result in Episcissors being even more cost saving to the NHS however there are not enough data available to include these costs in the model at this time. The company indicated that the price of a single use Episcissors has been priced

			on a per use basis. The EAC do not agree that a single use instrument should have a sterilisation or sharpening cost included as these would not be necessary processes for a single use, disposable instrument.

Issue 19

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 7; page 58 "Thiagmoorthy et al reported a lower rate value of 0%"	Please use IQR figures	It is clinically not possible to have an OASIS rate of 0%. Thiagamoorthy 2014 data is based on self-reporting. Assuming a range for economic modelling is not ideal scientifically, We have previously suggested to EAC to use Inter-quartile ranges 25-75 (IQR's) as the range is too diverse. Most leading scientific peer-reviewed journals insist on IQR for clinically meaningful results. Similarly using 8% OASIS would also be not believed by doctors and midwives who would peruse the NICE MTG.	Thank you for your comment. The EAC cannot comment on whether an OASIS rate of 0% is clinically possible. The EAC note Thiagamoorthy 2014 reported median of 2.85% with a range of 0-8%. The EAC did seek clarity from the company regarding the discrepancy between the figures reported in the company submission 2.85% (2-4%) and those reported in the published paper, but received no response. RCOG (2016) Patterns of maternity care in English Trusts reports that rates of OASIS range from 2% to 9.3% across individual NHS trusts suggesting that there is wide variability in the rates of OASIS. Based on the range of figures reported across published literature the EAC has sought to reflect the range of possible clinical scenarios to provide the clinical experts with a broad selection of the possible outcomes.

Issue 20

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Page 59 "The EAC noted that there were no low or high values included in the model for any parameters other than OASIS rates"	The EAC noted that there were no low or high values included in the model for any parameters other than OASIS rates. However the cost model provided does not readily support changes to the unit cost of comparators, the costs of Episcissors-60 are fixed via NHS Supply Chain and the costs used for alternative treatments are nationally determined."	It is not possible to provide ranges for NHS reference costs where these are fixed. Neither has EAC provided such figures.	Thank you for your comment The EAC note that this comment relates to the sensitivity analysis, the purpose of which is to investigate how robust the results are to changing inputs. This is generally done by selecting low and high values for each of the elements included in the cost analysis. The EAC accept that while costs may be fixed there is always the potential that they will change over time and that change, whether it is an increase or decrease in cost will have an impact on the overall result. The EAC accept there is no way to know whether and how those changes might occur, therefore the EAC selects what is feels may be realistic changes. These are not definitive and are open for discussion. The EAC has ensured that all changes made are clearly documented and a rationale provided in order to facilitate this (table 9 and table 14). The EAC could not identify where the company submission has carried out the sensitivity analysis hence the comment regarding no low or high values.

Issue 21

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 9 Row 4; usage of 10 times and 50 times “	Please delete	These are irrelevant for the time the MTG will be released. We have repeatedly emphasised to NICE that the reusable scissors will no longer be produced. No of uses per scissors will not be relevant to future decision making on the use of Episcissors-60.	Thank you for your comment These represent the possibility of costs of Episcissors changing which allow the EAC to test how robust the model is to changing costs (sensitivity analysis) The EAC note that there may be some confusion in the way that the results have been reported due to the way the model template and report template work which may have resulted in Episcissors appearing to be cost incurring when in fact it is cost saving. The EAC has corrected this copy/paste error – all figures with a minus in front indicate cost incurring. (table 9 and table 14).

Issue 22

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Page 61 The EAC has searched NHS supply chain and found actual purchase costs for standard reusable episiotomy scissors of [redacted] from the catalogue (excluding VAT), giving a per patient use cost of £0.26 for [redacted] or £0.10 for [redacted].	Please include the sterilisation and blunting repair costs. Or ADD The EAC has searched NHS supply chain and found actual purchase costs for standard reusable episiotomy scissors of [redacted] from the catalogue (excluding VAT), giving a per patient use cost of £0.26 for [redacted] or £0.10 for [redacted]. It should be noted that these	It is misleading to the reader to compare the costs without providing the real inputs of sterilisation and sharpness repair when compared to the single use EPISCISSORS-60.	Thank you for your comment. The EAC have not made any changes. Discussion with clinical experts suggested that sterilisation and sharpening costs would be the same for any reusable scissors therefore there is no benefit to including it in the model.

	do not include sterilisation and sharpening costs."		

Issue 23

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 10	Please delete this table	For the birth data, we used HES data which can easily be cross-checked. EAC cannot create a model when there is no reliable data on the base rate for OASIS in deliveries with episiotomy nationwide.	Thank you for your comment. The EAC cannot delete this table as to do so would mislead the readers as to the changes made to the economic model inputs. The EAC has used a rate of 15% for episiotomies which was provided by the company to reflect the use of Episcissors-60 in the episiotomy only population rather than the whole birth population as this was the population in the scope. The EAC acknowledge in the conclusions of the report that the EAC consider their model to represent a small subset of patients and that there is a benefit to considering the costs and outcomes in the whole birth population.

Issue 24

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Disposable scissors; page 70	Please use a reliably obtained real world figure or delete.	We challenge the EAC to provide a reliable reference for this figure of 26p. By their own admission, EAC failed to find a price for single-use	The EAC has used data from NHS supply chain.

We can take the same approach for standard disposable scissors and use the cost per use of 26p		episiotomy scissors on the NHS Supply Chain. It is commercially not possible to assume a price of 26p, given the manufacturing, regulatory, packaging and sterilisation costs of single use devices in a UK accredited facility. Not presenting these figures is misleading the reader of this MTG into believing that an alternative product is available at this price.	The EAC did ask clinical experts for their input but they could not provide an estimate. The EAC acknowledges that this cost may not be reflective of the true cost due to all of the issues highlighted by the company and therefore conducted sensitivity analysis in the base case and a separate scenario analysis (Section 4.6, table 15) to investigate the impact of increasing and decreasing costs of the standard scissors. As previously noted, the model is relatively insensitive to changes in the cost of standard scissors and the EAC note that the greater the increase in the cost of standard scissors, the more cost saving Episcissors is likely to become.

Issue 25

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Page 72 Pooled analysis suggests no significant risk difference in favour of Episcissors-60 (RD= -0.02; 95% CI -0.05 to 0.01; p=0.14) for OASIS rates in women who had an episiotomy with Episcissors-60 compared with standard episiotomy scissors, though there is evidence from the pooled results of two studies, that Episcissors-60 as part of a bundle of care may significantly reduce	Please recalculate after omitting Ayuk 2018 from the analyses. Also please add: It would be reasonable to assume that the impact of these measures would be equal in both the episiotomy and no-episiotomy groups in the post-EPISCISSORS-60 adoption period. We note that the OASIS reduction in the episiotomy groups in both spontaneous and instrumental vaginal deliveries were significantly higher than in the no-episiotomy groups.	Impact of other OASIS measures must be assumed to equal in both episiotomy and no-episiotomy groups after the introduction of the EPISCISSORS-60. Please read detailed explanation in Issue 8 above. Ayuk 2018 is not a peer-reviewed study. It is not part of any medical databases as it is unpublished. Simply put up on a website, accessed by EAC via a search engine like Google. It should be excluded from the meta-analysis done by EAC. EAC admit that its quality cannot be assessed (Page 44). Neither has EAC critically analysed the data. Nor is EAC competent to peer-review an unpublished study as it does not have domain skills in obstetrics and gynaecology. No checks on ethical aspects of excluding other OASIS reduction measures despite being recommended by	Thank you for your comment. Please see previous comment regarding this study (Issue 5)

OASIS rates in women who have an episiotomy		RCOG, no checks on methods, no checks on data, intention to treat, no checks on statistical methods used, no checks on why the conclusions are different from published peer reviewed data. No quality assessment tools like Newcastle-Ottawa, Cochrane, NHLI, Jada even reported, unlike in the published systematic reviews. EAC have just blindly accepted the data at the authors' word. This is in gross violation of NICE's own guidance. NICE PMG33 for the Medical Technology Evaluation Programme-MTEP states in Section 6.3.1 [Unpublished evidence]:"Unpublished data may be used to support a **narrative** review of the evidence, as well as to inform the design and conduct of new secondary research studies". https://www.nice.org.uk/process/pmg33/chapter/introduction PMG 33 does not say that unpublished data can be used by EAC for evidence synthesis or a meta-analysis. In contrast, explicit mention is made in section 6.3.4 [Section on expert advisers]: "Expert advice can also be used as part of evidence synthesis or modelling studies". Section 6.3.2 [Unpublished evidence sources] says: "the external assessment centre may identify other unpublished evidence, such as analysis of data from observational research sources, including professional or company-sponsored registers." The Ayuk 2018 data has not been identified from professional or company sponsored registers. It has been identified in a Google like search. PMG 33 Section 8.1 [Main considerations in decision-makings] says: "The committee needs to be confident that the evidence is of sufficient quality, quantity and consistency to form the basis of robust recommendations." This is not possible if the committee is provided a meta-analysis by the EAC that includes evidence from non-peer reviewed unpublished studies which dramatically skew the results of published meta-analysis (43% OASIS reduction, Divakova 2019) and systematic review (50% OASIS reduction, Cole 2019).	

		EAC's inclusion of the Ayuk study is in violation of the MTEP's own guidance, therefore, in violation of the remit they were asked to follow. We contacted NICE urgently to highlight that their own guidance on developing MTG's had not been followed by the EAC. We pointed out the relevant sections of PMG33 and asked them to clarify whether inclusion of non-peer reviewed studies and unpublished studies on a MTG meta-analysis commissioned by them was acceptable. Despite several emails and phone calls, **NICE declined to clarify.** If NICE allows inclusion of the EAC meta-analysis in the report, it raises serious concerns about NICE's commitment to evidence based medicine.	

Issue 26

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Page 73 There is a suggestion that the reusable Episcissor-60 could be used up to 50 times before replacement. If the cost of the disposable scissors is priced to reflect a possible 50 uses then a shift to the disposable scissors may increase the cost savings associated with Episcissors-60	Please either obtain reliable national costs for per use sterilisation and sharpening or add: -although per unit sterilisation costs will vary (£1-20) depending on the location of the CSSD facilities, whether they are private or in-house. Loss of instruments to inadvertent loss or theft has been reported to the company by hospitals.	.The company's intention is to market single use Episcissors -60 at c. £16 each, based on current production costs. It should be noted that comparisons with re-usable scissors of all types should take into account per use sterilisation costs and bluntness repair/sharpening costs. This is one of prime reasons why MEDINVENT is shifting to a single use EPISCISSORS-60	The EAC used these values to investigate the possible impact of changing costs. These are not considered to be definitive costs, merely an indication of how overall cost savings may change as costs of different elements in the model change. Clinical Experts consulted by the EAC have not reported any losses of their Episcissors-60 at any rate that differs from the loss of any other instruments.

Issue 27

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Page 74; section 6 "however it is less clear whether the EPISCISSORS-60 alone is responsible or ….bundle of improvements	Please delete this statement	As previously highlighted, the benefits of other measures would be equal in both episiotomy and no-episiotomy groups in both spontaneous and instrumental vaginal births. Yet, the OASIS rate is much lower in the EPISCISSORS-60 episiotomy groups in the Van Roon 2015 and Mohiudin 2018 studies.	The EAC feel that this is best discussed between the clinical experts. This has been added to section 7 (Key Considerations)

Issue 28

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
The weightage given to Ayuk 2018, an unpublished study in the EAC meta-analysis is 28% among all reported studies. 94% weightage given to Ayuk study in deriving the impact of the EPISCISSORS-60 where no other OASIS reduction measures were included.	Ayuk 2018 has not been assesses for quality nor been peer reviewed. Therefore we are unable to add this information to the meta-analysis.	When a study is submitted to an indexed journal, the editors select 3-5 eminent practitioners with domain skills and experience in the art to peer- review the paper? Does the EAC have the skills to peer review an obstetrics and gynaecology paper? EAC quick to critique the use of quality assessment tools by published peer reviewed SR. Where is the EAC Newcastle Ottawa, Jadad or Cochrane quality assessment tools for their own meta-analysis??? Ayuk 2018 is not a peer-reviewed study. It is not part of any medical databases as it is unpublished. Simply put up on a website,	Thank you for your comment. The EAC do not assign the weighting, this is done automatically by Review Manager based on the data input. Please see previous comment regarding this study (Issue 5)

		accessed by EAC via a search engine like Google. It should be excluded from the meta-analysis done by EAC. EAC admit that its quality cannot be assessed (Page 44). Neither has EAC critically analysed the data. Nor is EAC competent to peer-review an unpublished study as it does not have domain skills in obstetrics and gynaecology. No checks on ethical aspects of excluding other OASIS reduction measures despite being recommended by RCOG, no checks on methods, no checks on data, intention to treat, no checks on statistical methods used, no checks on why the conclusions are different from published peer reviewed data. No quality assessment tools like Newcastle-Ottawa, Cochrane, NHLI, Jada even reported, unlike in the published systematic reviews. EAC have just blindly accepted the data at the authors' word. This is in gross violation of NICE's own guidance. NICE PMG33 for the Medical Technology Evaluation Programme-MTEP states in Section 6.3.1 [Unpublished evidence]:"Unpublished data may be used to support a **narrative** review of the evidence, as well as to inform the design and conduct of new secondary research studies".	

		https://www.nice.org.uk/process/pmg33/chapter/introduction PMG 33 does not say that unpublished data can be used by EAC for evidence synthesis or a meta-analysis. In contrast, explicit mention is made in section 6.3.4 [Section on expert advisers]: “Expert advice can also be used as part of evidence synthesis or modelling studies”. Section 6.3.2 [Unpublished evidence sources] says: “the external assessment centre may identify other unpublished evidence, such as analysis of data from observational research sources, including professional or company-sponsored registers.” The Ayuk 2018 data has not been identified from professional or company sponsored registers. It has been identified in a Google like search. PMG 33 Section 8.1 [Main considerations in decision-makings] says: “The committee needs to be confident that the evidence is of sufficient quality, quantity and consistency to form the basis of robust recommendations.” This is not possible if the committee is provided a meta-analysis by the EAC that includes evidence from non-peer reviewed unpublished studies which dramatically skew the results of published meta-analysis (43% OASIS reduction, Divakova	

		2019) and systematic review (50% OASIS reduction, Cole 2019). EAC's inclusion of the Ayuk study is in violation of the MTEP's own guidance, therefore, in violation of the remit they were asked to follow. We contacted NICE urgently to highlight that their own guidance on developing MTG's had not been followed by the EAC. We pointed out the relevant sections of PMG33 and asked them to clarify whether inclusion of non-peer reviewed studies and unpublished studies on a MTG meta-analysis commissioned by them was acceptable. Despite several emails and phone calls, **NICE declined to clarify.** If NICE allows inclusion of the EAC meta-analysis in the report, it raises serious concerns about NICE's commitment to evidence based medicine.	