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.
	E-mail to Alan Blighe and NHS England general to enquire about the Paul Ayuk study and whether NHS England could shed any light on it.	Response from Alan Blighe – nothing to add Response from Stephanie Heath: The authors below co-wrote both reports with other input. Dr Paul Ayuk Consultant Obstetrician Newcastle upon Tyne Hospitals NHS Foundation Trust Prof S C Robson Consultant Obstetrician Newcastle upon Tyne Hospitals NHS Foundation Trust Dr Allison Farnworth Senior Research Midwife Newcastle upon Tyne Hospitals NHS Foundation Trust Unfortunately we do not have their contact details. We would suggest you could directly contact Newcastle upon Tyne Hospitals NHS Foundation Trust or if you'd prefer to get in touch with your local AHSN network they might be able to assist.	Author details for the report were identified and authors contacted.
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	
	3. Do you have any issues with scissors going missing, needing to be replaced?	Autoclaved in the central sterilisation department	
	4. Could you estimate an average number of scissors per year?	infrequently	
	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?	1-2	
	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?	There is no tracking system for either type of scissors	
	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 Scissors are returned for sharpening when considered to be blunt by users. Unavailable for 3 weeks	

		Cost unknown to me	
	10. Could you provide an estimate of the cost of standard episiotomy scissors	Yes 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? 6. If you were using an alternative reusable scissors, how does the number of uses per scissors compare?	Don't know Don't know	
	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?	60-70	

	If you were using an alternative reusable scissors, how does the number of uses per scissors compare?	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? 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?	All reusable scissors Goes to medical device for sharpening, couple of weeks for each scissor Not sure	
	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	We have contacted Lou directly via email. We told him that their poster published in BJOG	

	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).	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.	
Allison Farnworth	E-mail sent to ask whether there were any plans to publish the Ayuk report in a peer reviewed paper.	Yes this data has been submitted for publication with the International Urogynecology Journal – I believe that Dr Ayuk has made some revisions based on reviewer comments and is awaiting the outcome of this. The study was funded by the Patient Safety Collaborative programme in the AHSN North East North Cumbria – the AHSN were supportive of Trusts in the region adopting this technology and saw it as an opportunity to (a) promote uptake, and (b) gather good quality before and after data – this study was led by Dr Ayuk. It was also an opportunity to look at barriers and facilitators to adoption of innovation in maternity units in the NENC region and so I was also funded to complete a project looking at this in 2017/18. I don't have any personal experience of using episcissors-60 but	A pre-proof version of the paper is available on the journal website and has been reviewed by the EAC

		collected views about usage from clinicians as part of my project.	

A number of additional e-mails from the company were sent to the EAC at various points in the process following submission of the report. The EAC did not directly respond to these e-mails, responses were handled by NICE directly however a copy of the correspondence received is listed below for information.

	Additional communications from the company	EAC Response
E-mail Communications from Company	As per the attached schedule, NICE reverts to us tomorrow, and we have to reply by Friday. Could you please confirm if this is the case? Also, as has been repeatedly mentioned to the NICE team, for commercial and other reasons (like a huge UK wide switch to disposable birth packs) we will not be producing the reusable EPISCISSORS-60 any more beyond what stock is left with us. We will be switching to the single use version when the NICE guidance is published next year. The application to make it available on the NHS Supply Chain is under evaluation. I would be grateful if this fact has been acknowledged. The NICE MTG will be referred to for years to come. It would make little sense to base the MTG on a product that is no longer made, and would be a wasted effort for all parties concerned. I only ask this because of your query today re: trays.	I can confirm that we are on schedule to return our Assessment Report to NICE. NICE will be able to confirm the dates that you will receive and return the report and comment on the other issues you raise.

	In your report on the EPISCISSORS-60, you have included a non-peer reviewed study called Ayuk 2018, which is published on a AHSN website.
	
	You clearly mention that the quality of data in Ayuk 2018 cannot be verified (page 44) as this is an unpublished study.
	
	You do not report any attempts to contact the authors' for the quality, methods and conclusions. You have accepted them at their word. Without any critical analysis.
	
	In contrast, you have rightfully contacted the authors of the peer-reviewed systematic reviews published in peer-reviewed scientific journals that are listed in recognised medical databases.
	
	Yet to my complete shock and dismay, you chose to include their data in your meta-analysis. You assigned it a weightage of 28% in all 'reported' studies on the EPISCISSORS-60, and 94% weightage on all studies without other OASIS reduction measures.
	
	Please could you explain the rationale for this? If I put up a study that I have personal information from doctors' feedback of 10,000 patients that EPISCISSORS-60 reduced OASIS by 100%, would you include this, if I published this on the Medinvent website ?
		The EAC responded directly to NICE with answers to the specific queries raised by the company:
		• Could you detail the search strategy used to obtain the Ayuk study? (I know that the medline search is outlined in the AR, but given this is not peer-reviewed I am presuming it did not come up in this search strategy?)
		  ○ The Ayuk study was found during grey literature searches, it came up when looking for general background literature for topic and when checking for literature to confirm the rates used in the economic model which is a standard part of what we do. You are correct that it wasn't a formal literature search that identified, hence we have the box on the PRISAM diagram "literature from other sources" and we do state in the report that it was not a peer reviewed publication.
		
		• I note that the Ayuk study is published on the AHSN website and is publically available. Would it hence be classified as a published, non peer reviewed article rather than unpublished?
		  ○ Yes the study is publically available and therefore would be classed as a published non-peer reviewed article however this would also apply to all abstracts which are published and in the public domain. The reason these get listed as

		unpublished in the tables is really to indicate that they are not peer-reviewed as the NICE template indicates that peer reviewed publications should go under published and other studies under unpublished. Perhaps we could change the table title to be more clear about this but I do think that we have made it clear through the report what the situation with the Ayuk data is. ○ • From your review of the study, is the study methodologically sound? Could you detail the rationale in including this in the meta-analysis? ○ The methods of the study are as good as any of the peer reviewed publications but we have attached a critical appraisal table for it if you think it would help? We included it in the meta-analysis because is real-world, UK data which we considered to be relevant to the question at hand. The purpose for us was to try an identify the possible scenarios which may happen if Episcissors is introduced and the more data we have in the meta-analysis, the more reflective it is of the possibilities and that the clinical experts should be the ones to discuss whether the introduction of Episcissors-60 could lead to a possible increase in OASIS (which I presume is the concern Dharmesh has about including this data?)
	I have now received a copy of the Ayuk publication which I attach here for your convenience. As you will note: Table 3 breaks the data down into before and after for all episiotomies. However, the denominator is not clear. Is it just spontaneous vaginal deliveries (SVD) or all vaginal births? The UK national OASIS rate as per the Gurol-Urganci (2013) paper is 5.9% in the study of 1.2 million first vaginal births from 90 UK hospitals. Table 3 (last rows) also describes nulliparous women having a SVD. This means that OVD are excluded. OVD are the highest risk of OASIS. There is no mention of why this group is excluded. Van Roon (2015) and Mohiudin (2018) clearly describe this group separately. In	The EAC did not respond directly to this e-mail Response from NICE: Thank you for your 2 communications below, I have forwarded onto the NICE team for their information. Nevertheless, in order for your points to be considered by the Committee, please do submit them as consultation comments once the consultation opens on the Draft guidance, currently planned for 4 October. We will not be able to consider them if not submitted in this way. Thank you for forwarding in advance.

	fact, the highest OASIS reductions are seen in this group in those studies. It is baffling why this high risk OASIS group was deliberately excluded from the analysis. The authors go on to say that the "introduction of Episcissors-60 does not influence the association between episiotomy and OASI". Normally, if one is unable to find a difference between two groups, especially before and after, one would check if the study was powered to do so. I would be grateful if the EAC would assess whether it was 'powered' to detect differences between the groups. On the last line of page 96 and first lines of page 97, authors state: "the surgical anatomy of the perineum means that longer and more lateral episiotomies are more likely to disrupt branches of the internal pudendal vessels". They fail to provide any scientific reference to this claim. The angled episiotomy at 60 degrees has been practiced in Finland and Scandinavia for 50 years. Fodstad and Laine showed that there was no difference in blood loss between lateral, mediolateral and midline episiotomies (2014). On page 97, the authors state: "The recommendation that episiotomies should be made at an angle of 45-60 degrees from the midline when the perineum is distended [14], and the subsequent design of the Episcissors-60 with a 60 degree cutting angle does not appear to take full account of the surgical anatomy of the perineum and the need to protect major blood vessels". Although the NICE Intrapartum guidance is unclear whether 45-60 degrees is the cutting or sutured episiotomy angle, the above statement challenges even that recommendation. Please bear in mind there is a significant trade-off between blood loss (even if it were true) without any impact on patient recovery, and OASIS, which is a long-term debilitation.	

	A 45 degree angled episiotomy results in a suture angle of about 25 degrees, which has 10X higher OASIS than an episiotomy of sutured angle 45 degrees (Eogan 2006, Kalis 2008, Kalis 2011, Stedenfeldt 2012, El-Din 2014). Are the authors suggesting a return to a more acutely angled episiotomy? I would be grateful if NICE/EAC could ask the authors' for these clarifications.	
	I had a long conversation with the Christina Farrow, the Senior ITP manager at NHSE and her colleague Alan Blighe today. Among the points discussed was the role of HES data for episiotomy and OASIS rates in hospitals that adopted the EPISCISSORS-60 before and after the introduction of the EPISCISSORS-60. NHSE confirmed that their own data sets show a significant OASIS decline after the ITP for the EPISCISSORS-60. However, they cannot guarantee that all the episiotomies were performed with the EPISCISSORS-60, as there is no mandatory field in the electronic labour ward data capture systems. Also, they cannot be sure if perineal protection played a role. I have requested them to urgently release their dataset or the HES data with the aim that it is available during the NICE consultation period. My own belief is that the EAC will be able to assess the methodological quality and assign it a weightage accordingly. The sample size will be more than 50,000 births compared to the 1100 size of the next sample size of a study, and it will be able to provide trend-lines that are valuable. Perineal protection will impact 100% of vaginal deliveries in contrast to episiotomy (15-25% of vaginal births), and the effect will be equal in both episiotomy and non-episiotomy groups. I would be grateful if you could let me know if NICE policies allow the introduction of this dataset at the consultation stage.	The EAC did not respond directly to this e-mail Response from NICE: Thank you for the information below which I have passed onto the NICE team and my apologies for the delay in replying while I consulted my colleagues. I would advise to make these and other points during the consultation period. NICE won't be proactively looking to obtain the HES dataset and additional evidence needs to be submitted transparently through the consultation. Should the Committee determine that it requires further information or analysis to enable it to determine final guidance recommendations then it will request that NICE/ EAC undertake this work at that point.

	If you so wish, I am happy to place you in direct contact with Christina and Alan.	
	I would be grateful for some clarifications on the MTEP process here onwards. Once the public consultation phase closes on 1 November, will there be a publication of the comments received on the website? And what is the purpose of the scheduled 15th November meeting? The schedule says 'resolution' starts on 16th December. Will the final recommendations be made public at this point? Or will we get to know what public comments were received and the final recommendations only on the publication date of 30th January?	The EAC did not respond directly to this e-mail Response from NICE: Once the Consultation closes, NICE collates all the comments for presentation to the Committee at the meeting on 15 November. The Committee will go through all the submitted consultation comments in the meeting. The comments are shown on the screens in the meeting room. The Committee may ask the Experts/ EAC/ company questions in connection with the comments. As with the first meeting attendees are there to respond to questions from the committee only. Some comments may only be discussed in the private part of the meeting if they have the potential to change the guidance. At the start of the resolution process anyone who has submitted a consultation comment can ask to see the final guidance before it is published on the NICE website. After signing a confidentiality agreement those who register for resolution receive the final guidance and the consultation comments and responses. They have 3 weeks to confirm if they want to raised a resolution request if they have an issue with the process that has been followed or the facts within the guidance. If a resolution request is raised, NICE will consider and make a determination on any request before the guidance is published on the NICE website.