NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1217/2 Balloon disimpaction of fetal head at emergency caesarean delivery**

Your information

Name:	Mr. Ramesh Ganapathy
Job title:	Consultant Obstetrics and Fetal Medicine
Organisation:	Epsom and St. Helier University Hospitals NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	RCOG
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	5207211

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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☑ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this	I started use of this product in 2013 while I was the clinical lead of services in south-west Birmingham NHS trust and it continues to be used there. Since my move to my current trust (ESTH NHS Trust)we have used it routinely in second stage caesareans over the last 5 years. We use it routinely as standard care in second stage caesareans Although the use is established in many hospitals across the NHS in England and Scotland it use is not as widespread as would be expected – given that the tool is used in high risk caesareans to reduce poor outcomes

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	This is an innovative design and a product that helps reduce the risk associated with delivery of the fetuses in second stage of caesarean. Although caesareans in the second stage are less then 1% of all caesareans, they have a disproportionate impact on poor maternal and fetal outcomes. I started use of this product in 2013 while I was the clinical lead of services in south-west Birmingham NHS trust and it continues to be used there. Since my move to my current trust (ESTH NHS Trust)we have used it routinely in second stage caesareans over the last 5 years. Although the use is established in many hospitals across the NHS in England and Scotland it use is not as widespread as would be expected – given that the tool is used in high risk caesareans to reduce poor outcomes The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or	In addition to standard operative care

	would it be used as an addition to existing standard care?	

Current management

5	Please describe the current standard of care that is used in the NHS.	The management of second stage caesareans has not changed for decades- the techniques use to reduce risk and poor outcomes have been in place for long but the outcomes have not changed over time.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	I am not aware of any other technology

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Reduce maternal and fetal poor outcomes in second stage caesareans
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	All women who have a caesarean in the second stage of labour
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Reduce maternal and fetal poor outcomes in second stage caesareans and consequently reduce hospital stay, need for blood transfusions and neonatal admissions(which can be a consequence of delay in delivery of the fetus in second stage caesareans)
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	It will be cost effective
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Probably increase cost by around £150-200 per caesarean
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Change required in educating staff in usage and indications (which doesn't take more than 10-20 minutes)

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Change required in educating staff in usage and indications (which doesn't take more than 10-20 minutes)

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	No harm/adverse events that I am aware of
15	Please list the key efficacy outcomes for this procedure/technology?	Ease of delivery of the fetal head which is impacted in the pelvis. Consequently a reduction in maternal and fetal morbidity
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	None that I am aware of
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	None that I am aware of
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Sarah C Lassey et.al.Cephalic Elevation Device for Second-Stage Cesarean Delivery: A Randomized Controlled Trial. Obstet Gynecol . 2020 Apr;135(4):879-884.. Isaac Hanley et.al. Comparison of outcomes at full-dilation cesarean section with and without the use of a fetal pillow device. Int J Gynaecol Obstet . 2020 Aug;150(2):228-233. Raffaella Di Girolamo et.al. Outcomes of second stage cesarean section following the use of a fetal head elevation device: A systematic review and meta-analysis Eur J Obstet Gynecol Reprod Biol . 2021 Jul;262:1-6.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	None that I am aware of

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	1% of all caesarean births in the country.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	None that I am aware of
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	None that I am aware of.

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Time to delivery of the head after uterine incision. Ease of delivery (operator opinion)
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Time to delivery of the head after uterine incision. especially in cases of a failed instrumental birth Ease of delivery (operator opinion) Umbilical arterial ph Admission to NNU Maternal blood loss and transfusion events Uterine angle extension and or bladder/ureteric damage Maternal understanding /perception of the events especially in cases of a failed instrumental birth Adverse outcome measures: Outcomes in future pregnancies

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	The perception among senior obstetricians that they are skilled at second stage caesareans and hence adjuncts of tools to reduce risk are not needed. This is myopic because majority of the cases are delivered by trainee registrars will limited experience and the event doesn't lend itself to awaiting senior's arrival (out of hours). The skill sets in delivery are not easily measurable nor

		or translatable in a simulation (as the stress of the event- failure to deliver the fetal head in time- cannot be recreated in a lab environment).

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

√ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Ramesh Ganapathy**
Dated:	**01.03.2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1217/3 Balloon disimpaction of the baby's head at emergency caesarean during the second stage of labour

Your information

Name:	Zoe Thurlwell
Job title:	Consultant Obstetrician and Sub-specialist in Fetal and Maternal Medicine
Organisation:	Manchester University Foundation Trust, Oxford Road Campus, Oxford Road, Manchester, M13 9WL
Email address:	[redacted]
Professional organisation or society membership/affiliation:	RCOG, British Maternal and Fetal Medicine Society
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 7014678

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

- ✓ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own?	I am familiar with the procedure and have implemented it in my practice since 2016 when I first encountered the equipment. I have used this in my current practice when at full dilatation caesarean section. I used this when both a Registrar and Consultant. As a Registrar, from a purely observational perspective, I found that using the fetal pillow reduced the chance of a surgical uterine extension of my uterine incision. However, as I have become more experienced, the use of the fetal pillow should be balanced and compared to other methods such as disimpacting with your opposite hand, using a stool to be over the operating table and slower delivery of the fetal head and previously pushing up vaginally by another operator. When a junior is performing the procedure, I will advise them to use this, although I am aware that this is not common practice across the UK as many units do not have the equipment, especially following the recent (June 2023) retraction of the paper by Seal et al 2016 which was supported by the Scientific Impact Advisory Group RCOG June 2023.

	– If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure. Other (please comment)
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes, the title reflects the procedure Yes, the proposed indication is appropriate I find the classification of this to be difficult. Without the fetal pillow, there is the Tydeman tubing suggestive for fetal disimpaction. There are no other ways, other than being operator dependant that I know to help with the disimpaction of the fetal head. The fetal pillow was first introduced in 2016 and data was subsequently retracted in June 2023. As such, a meta-analysis of studies relating to fetal pillow should be being undertaken.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	In the unit that I work in a tertiary Obstetric unit with 9,000 delvieries (16,000 delvieries across the trust) the fetal pillow is available and it is down to the Consultant whether this is utilised.
5	Have there been any substantial modifications to the procedure technique or,	The technique remains the same from its inception. However, practice has changed in that, previously disimpaction often resulted from another operator pushing up vaginally at the same

	if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	time as the Surgeon trying to deliver the fetal head via cs. This practice does not occur readily in either my unit or indeed the NW region. There has been a significant retraction of the Seal et al paper 2016 “Randomised controlled trial of elevation for the fetal head with a fetal pillow during caesarean section delivery at full cervical dilatation” Int J Gynaecol Obstet 2016 133:178-182 The RCOG SIP No 73 as a result has been retracted for endorsing it. The authors cited that there were concerns regarding discrepancies between the retrospective trial registration and the published article.

Current management

6	Please describe the current standard of care that is used in the NHS.	Options for delivery of the fetal head at full dilatation: 1. Disimpaction vaginally by another operator 2. Delivery with the opposite hand to reduce chance of uterine angle extension 3. Maternal Head down 4. Terbutaline if hypertonic contraction 5. Breech extraction potentially with further incision on the uterus eg. Inverted T
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Tydemann tubing, presented at BMFMS 2024 Liverpool by Graham Tydemann Similar to the fetal pillow with no increased risk of fetal fractures on a small cohort.

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Lower incidence of birth trauma to the fetus and surgical site trauma resulting in uterine extensions
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Needs a true RCT comparing fetal pillow with no adjunct
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	This procedure has been around for the past 8 years with varying degree of clinical uptake.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Nil, fetal pillow requires the equipment, insertion by a skilled operator, water and 50ml syringe.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training of insertion / removal to Registrar and Consultants if utilised in their units.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:	Please see Seal et al 2016

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	As stated previously re literature included in the RCT is dubious
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Yes, as outlined above.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Cannot predict at present, although I believe that there are at least 10 units in the country whom use this product.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a	

	comprehensive reference list but it will help us if you list any that you think are particularly important.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	SIP RCOG, ?Seal et al re-analysing their data, RCOG suggests meta-analysis but unaware who is doing this.
20	Please list any other data (published and/or unpublished) that you would like to share.	nil

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	I am unable to provide a specific number for this.
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: - Successful delivery of fetus following sole fetal pillow use - Successful delivery of fetus with fetal pillow and other additional procedures (as outlined above) Adverse outcome measures: - Skull fractures - Alternative uterine incision ie Inverted T or J Incision-

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	No conflicts of interest		
Choose an item.			
Choose an item.			

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Print name:	**Dr Zoe Thurlwell**
Dated:	**08/09/2024**