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:	Dr Rita Arya
Job title:	Consultant Obstetrician and Gynaecologist
Organisation:	Warrington and Halton Teaching Hospitals NHS Foundation Trust
Email address:	Click here to enter text.
Professional organisation or society membership/affiliation:	British Maternal and Fetal Medicine Society until Jun 2024, Cheshire and Merseyside LMNS Deputy Clinical Director
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 4180515

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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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 am familiar with the product and have launched its use 4 years ago in the Trust where I work. I have used the product multiple times as per the product licence. I am not aware that this product is used in any other speciality other than obstetrics. I am aware that most obstetricians are familiar with the use and the product has been shown to reduce the risk of maternal complications such as extended tears, haemorrhage, need for blood transfusion and length of operation. The use of the product is widespread. The product is favoured by less experienced obstetricians e.g. specialist trainees as it avoids the need to use manual disimpaction of the fetal head per vagina which can increase the risk of skull fracture. There is a need for national guidance on patient selection and consent. Women are unaware unless the operator explains to them.

	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. See references in the questionnaire included in responses, I was not involved in research on this procedure.
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):	It is new within the last approximately 7 years. The first in a new class of procedure.
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?	Addition to existing standard of care.

Current management

5	Please describe the current standard of care that is used in the NHS.	If product is not in use, options include, disimpaction of fetal head vaginally by an assistant with subsequent risk of neonatal skull

		injury and lack of training in this procedure for midwives. Note RCOG retracted its scientific oimpact paper dated June 2023 RETRACTED: Management of Impacted Fetal Head at Caesarean Birth - Cornthwaite - 2023 - BJOG: An International Journal of Obstetrics & Gynaecology - Wiley Online Library Other options are extension of uterine incision to assist delivery of the baby, with subsequent increased blood loss potentially.
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 have heard of the Tyndenman Tube, this is not widespread in use and has undergone a pilot, I believe.

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?	Reduced maternal complication and skull injury.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Women who require an emergency caesarean section who have cervix with is fully dilated (10cm) or nearly fully dilated.
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?	Yes , less need for blood transfusion, less operating time, reduced hospital stay. Mentioned in RCOG
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)	According to product specialist, reduces costs overall when look at complications, but units will require to do a business case as new product.
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)?	Less in terms of care overall. Additional equipment resource.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Training for units who do not currently use the product.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Basic training for obstetricians and theatre staff – takes 30 mins

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	Anecdotal Neonatal sepsis, failure, time to insert, increase
15	Please list the key efficacy outcomes for this procedure/technology?	Time taken to use, ease of use, reduction in maternal haemorrhage, reduction in neonatal injury, admission to neonatal unit
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Effectiveness of the fetal pillow to prevent adverse maternal and fetal outcomes at full dilatation cesarean section in routine practice - Sacre - 2021 - Acta Obstetricia et Gynecologica Scandinavica - Wiley Online Library Research does not show clear benefit
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Maybe only one product option Obstetrician views on Fetal Pillow® device use and research in Aotearoa New Zealand: A cross-sectional survey - Sadler - Australian and New Zealand Journal of Obstetrics and Gynaecology - Wiley Online Library

		RCT would be best way forward to demonstrate benefits to mother and neonate versus any potential risks
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	All hospitals with a maternity unit and obstetric services.

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.	TOG article in BJOG Comparison of techniques used to deliver a deeply impacted fetal head at full dilation: a systematic review and meta-analysis - PubMed (nih.gov) Mentioned in PROMPT course RCOG, RCOG Management of the Labour ward course
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Not aware

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)?	8000 (2014 figure) maybe higher

22	Are there any issues with the usability or practical aspects of the procedure/technology?	No
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?	Financial pressure
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	No as references suggest well researched.
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: Operating time Extended uterine tears Blood loss Use of blood products Admission to neonatal unit Adverse outcome measures: None

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	None

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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
Non-financial professional	Currently use of product in unit where I work.	**2017**	
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:	**Dr Rita Arya**
Dated:	**8/3/22**