National Institute for Health and Care Excellence

IP1217/3 Balloon disimpaction of the baby's head at emergency caesarean during the second stage of labour

IPAC date: 13th February 2025

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1.	Consultee 1 Chelsea & Westminster Hospital NHS Foundation Trust - Chelsea and Westminster and West Middlesex Hospital sites	1.1	On behalf of the Chelsea and Westminster NHS Hospital Foundation Trust (both sites - Chelsea and Westminster and West Middlesex Hospitals), we as a Trust would like to make the following comments: 1) We agree that more research is needed but the balloon is already in use within the NHS and our Trust and is well established in many units and there is no evidence that the product is unsafe, dangerous or worsens outcomes. 2) We believe strongly that removing its use before a research study is in place or people are trained in alternative techniques is unlikely to support safe care. 3) At present, only staff trained in its use are using the balloon and therefore the balloon is unlikely to be used in an unsafe manner. 4) Many of our consultants believe strongly that the use of the balloon prevents adverse outcomes and is less likely to cause harm than the vaginal disimpaction push method. Many consultants have also seen significant maternal and fetal adverse outcomes in their clinical experience when the balloon has not been used. 5) We also believe that a number of alternative products being offered currently including the Tydeman tube should be formally reviewed and commented on by NICE before they come into wider use.	Thank you for your comment The committee considered this comment but decided not to change the main recommendation. They agreed that there was a lack of high quality peer-reviewed evidence that showed benefits of the procedure, and that more research is needed. The draft guidance does state that there are no major safety concerns. A recommendation has been added stating that 'Centres already using this procedure may continue to do so but are encouraged to collect data or do further research on the outcomes listed in recommendation 1.5.'

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2.	Consultee 2 Northampton General Hospital	1.1	**Conclusion** In conclusion, NGH are happy to follow nationally produced guidance if there is evidence that the fetal pillow causes harm, however whilst the potential benefits are being re-explored, and the fetal pillow has not demonstrated harm at NGH, we would advocate its continued use in obstetric practice. At NGH the fetal pillow is perceived to be beneficial to patients in reducing the chance of physical harm to both mother and baby. Removal of the fetal pillow would result in a group of less experienced obstetric staff not having access to a medical device to help them achieve a safe delivery, especially in situations where a senior obstetrician is not available at the time of need. Whilst our regular training in these emergencies does help staff confidence and competence, a fetal pillow is far easier to implement in real life compared to complex invasive delivery methods such as reverse breech extraction. [The full text of this submission was available in the committee pack]	Thank you for your comment. The committee considered this comment but decided not to change the main recommendation. They agreed that there was a lack of high quality peer-reviewed evidence that showed benefits of the procedure, and that more research is needed. The draft guidance does state that there are no major safety concerns. A recommendation has been added stating that 'Centres already using this procedure may continue to do so but are encouraged to collect data or do further research on the outcomes listed in recommendation 1.5.'
3.	Consultee 3 Consultant obstetrician and gynaecologist	1.1	While I totally understand the need for robust research for a new medical device, the fetal pillow has been used now for years by a full cohort of trainees who have audited its use up and down the UK and found it a very useful adjunct to managing an acute obstetric emergency. My view would be that it should / could be used as part of local audit and governance review at each Obstetric unit. I believe the new guidance will be a retrograde step to a new cohort who have trained using the pillow regularly as part of their	Thank you for your comments. The committee considered this comment but decided not to change the main recommendation. They agreed that there was a lack of high quality peer-reviewed evidence that showed benefits of the procedure, and that more

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			protocol for head impaction. I would urge the committee to please reassess the wording of their recommendations.	research is needed. The draft guidance does state that there are no major safety concerns. A recommendation has been added stating that 'Centres already using this procedure may continue to do so but are encouraged to collect data or do further research on the outcomes listed in recommendation 1.5.'
4.	Consultee 4 Consultant in obstetrics and gynaecology	General	I have personally used Fetal PIllow and can say that it makes delivery of IFH easy during C.S.. Use of fetal pillow is specially useful for specialist trainees at intermediate grade, whenever there is anticipation of IFH such as after a failed instrumental delivery. Use of fetal pillow helps by negating the need for pushing fetal head vaginally, thus minimising risk of fetal head injuries as well as use of wrong technique in push method causing more damage than benefit. It will also prevent injury to surgeons wrist, shoulder and finger that many of my colleague obstetricians have suffered after a severely imapcted fetal head delivery- leading to loss of sickness days and some never coming back to on calls. Simultaneous use of GTN and Terbutaline should be encouraged as Patwardhan technique as well as reverse breech extraction are not easy in a contracted uterus over the baby.	Thank you for your comment. Section 3.7 of the draft guidance states 'The committee was told that the balloon disimpaction device may be useful for less experienced staff.'
5.	Consultee 5 CooperSurgical Company	General	The intended use of the balloon cephalic elevation device is to elevate the fetal head and facilitate delivery of the fetus in women requiring cesarean section at full dilation or those requiring a cesarean section after a failed instrumental vaginal delivery in gestational age greater than or equal to 37 weeks.	Thank you for your comment. Section 2.4 of the draft guidance states: 'The aim of balloon

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			The evaluation and decision to use the device should be based on the approved intended use to elevate the fetal head and facilitate delivery.	disimpaction is to elevate the baby's head and make a caesarean delivery during the second stage of labour less traumatic and quicker.'
6.	Consultee 5 CooperSurgical Company	**1**	Based on all available real-world data and global published evidence, the Fetal Pillow has been demonstrated to be safe and effective for the intended use to elevate the fetal head and facilitate delivery of the fetus in women requiring cesarean section at full dilation or those requiring a cesarean section after a failed instrumental vaginal delivery in gestational age greater than or equal to 37 weeks. Furthermore, a randomized control trial performed at Harvard University in the United States demonstrated clinicians find the device overwhelmingly easy to use, would use the device again, and would recommend use of Fetal Pillow to colleagues. The study additionally demonstrated efficacy in reducing severe uterine extensions and hysterotomy to delivery time with inflated Fetal Pillow. These findings were statistically significant (Lassey 2020). Given that Fetal Pillow has been approved in the UK since 2011 and utilized widely in the UK since recommendation for standard use in 2022 without safety issues, it is of utmost importance the committee revises this draft recommendation to ensure the continued safe, effective, and equitable delivery of care to all patients. CooperSurgical recommends that Fetal Pillow remain in the "can be used" designation. Given the committee's concerns about maternal and fetal outcomes beyond the intended use of the	Thank you for your comments. The committee considered this comment but decided not to change the main recommendation. They agreed that there was a lack of high quality peer-reviewed evidence that showed benefits of the procedure, and that more research is needed. The draft guidance does state that there are no major safety concerns. The overview states that clinical studies were included with emphasis on identifying good quality studies. Abstracts were excluded if they did not report clinical outcomes. Reviews, editorials, and laboratory or animal studies, were also excluded and so were conference abstracts, because of the difficulty of appraising study methodology, unless they reported specific

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			device, CooperSurgical may consider additional evidence collection if advised by the committee. This procedure has been widely used in the NHS since its introduction to the UK in 2011. Between July 2018 and October 2024, a total of 155,779 Fetal Pillow devices have been sold globally. Of these, 74,041 devices were purchased by the UK and Australia. Currently, 175 institutions in EMEA and APAC are active users of the Fetal Pillow, including 43 institutions in EMEA, with 35 located in the UK. Over the past year alone, these UK institutions have purchased 1,299 devices. Real-world evidence and published literature does not support restricting this procedure to research use only as no safety or efficacy concerns have been noted. Based on clinical use globally, the device is able to elevate the fetal head to facilitate delivery in women requiring a cesarean section at full dilation or following a failed instrumental vaginal delivery at greater than or equal to 37 weeks gestation. 37 weeks of gestation as is the device's Indication for Use ("IFU"). CooperSurgical is unaware of any safety or efficacy concerns that support limiting the use of this product solely to research settings. Indeed since acquiring the Fetal Pillow in 2021, CooperSurgical has engaged in numerous discussions with scientific thought leaders supporting the benefits of this device for patients, trainees, and providers (Barbieri 2020). No clinical study demonstrates that the labeled indication of the Fetal Pillow - to elevate the fetal head to facilitate delivery -has not been met. There are currently more than 45 non-retracted studies measuring outcomes from use of Fetal Pillow which consist of randomized controlled trials, prospective interventional trial, prospective observational studies, comparative case control,	adverse events not available in the published literature. Lassey (2020) is included in the key evidence in the overview. Barbieri (2020) was not identified in the literature search (the journal is not currently indexed for MEDLINE). It is an editorial and so does not meet the criteria to be included in the overview. Hanley (2022) was not identified in the literature search. It describes a UK survey of management of managing an impacted fetal head at caesarean section and does not report safety or efficacy outcomes for the procedure. The study has been added to table 5 of the overview. Romano (2021) and Romano (2023) were not identified in the literature search. Neither of them report safety and efficacy outcomes for the procedure.

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			retrospective cohort studies, case reports, surveys, and simulation which support the safe and effective use of the device. The literature that NICE reviewed consisted of Cornthwaite 2024, Sadler 2024, Sacre 2021, Hanley 2020, Chooi 2023, Safa 2016, Lassey 2020, Dutta 2019, Barman 2015, Jordan 2022, and Mumtaz 2023. All except Sadler 2024 were included in the systematic review. It should be recognized that in Jordan 2022 and Mumtaz 2023, the device was utilized in pregnant patients with prior cesarean deliveries, where safety and effectiveness have not been established as is clearly stated in the Fetal Pillow IFU Warning section. Furthermore, this review fails to recognize relevant data including manuscripts by Hanley 2022, Romano 2021, Romano 2023, another Sadler 2024 article on Obstetrician Views, Singh 2008, and Walker 2023. Additionally, other relevant published global data was also not considered, from Elbarbary 2023, Fung 2021, Ganapathy 2015, Gopal 2018, Gopal 2019, Hepburn 2017, Ho 2019, Johns 2018, Kalburgi 2018, Kalburgi 2015, Laverick 2019, Mufti 2015, Mufti 2013, Papanikolaou 2009, Rahim 2018, Sarkar 2018, and Tussey 2022. The review performed by the Committee fails to recognize this additional relevant data which supports the safe and effective intended use of the device. Since NICE developed the recommendation of standard use of Fetal Pillow in 2022, there have been no product complaints to the Company from UK providers. Indeed the only 2 (two) product complaints from the UK since 2022 were both complaints from the Mumtaz 2023 article and were not reported by the providers but instead found via literature review In Mumtaz 2023, the device was utilized in a pregnant patient with prior cesarean delivery, where safety and effectiveness have not been established as is clearly	Sadler (2024b) is included in table 5 of the overview. Singh (2008) was not identified in the literature search. It describes a pilot study of 30 women and has been added to table 5 of the overview. Walker (2023) is included in table 5 of the overview. Fung (2021), Hepburn (2017), Kalburgi (2018), Kalburgi (2015), Laverick (2019), Mufti (2015), Papanikolaou (2009), Sarkar (2018) are conference abstracts. From the information given, Elbarbary (2023), Ganapathy (2015), Gopal (2018), Ho (2019), Johns (2018) and Mufti (2013) appear to be conference abstracts. Gopal (2019), Rahim (2018) and Tussey (2022) are poster presentations.

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			stated in the Fetal Pillow IFU Warning section. In both cases, other independent clinical factors were identified in the article as potential contributors to the adverse events. A definitive link between the Fetal Pillow and uterine rupture was not established, and a causal relationship is not confirmed and is considered unlikely. Most recent data from the Neonatal Data Analysis Unit at Imperial College London shows 2,490 infants diagnosed with brain injury in England in 2021 (Jawad 2021). Methods used to disimpact a fetal head may have a role preventing or sustaining brain injuries in neonates (Avoiding Brain Injury in Childbirth 2025). Fetal Pillow is used for an obstetrical emergency that is associated with increased risk of maternal and neonatal morbidity and mortality, therefore safe options to help disimpact the fetal head should not be restricted. This should especially be taken into consideration since there is no clear consensus on the safest and most effective methods that should be used for disimpaction. In addition, a recent systematic review and meta-analysis by Cornthwaite 2024 concluded that the certainty of evidence was low or very low for all included articles and mostly no or equivocal differences resulted across comparisons for vaginal disimpaction, reverse breech extraction, Patwardhan method, and Fetal Pillow. Thus, one method cannot be recommended over another due to lack of evidence regarding all techniques (Cornthwaite 2024). One difference between these techniques is ease of use and clinician comfort with these techniques. Indeed, in these obstetrical emergencies that are unplanned and when minutes matter, having someone present who is comfortable with the complex techniques of a reverse breech extraction or Parwardhan method is essential but unfortunately may not be the case. Clinicians have rated Fetal Pillow easy to use which, in a complex medical situation like	

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			impacted fetal head during a cesarean section, is necessary. Additionally, it is recommended for training on a range of available techniques to develop guidance on sequential order of techniques from less to more complex methods (Cornthwaite 2024). Training on all methods for disimpacting a fetal head will allow providers to determine their own competence and selection of a preferred method based on clinical scenarios (Cornthwaite 2024).	
7.	Consultee 5 CooperSurgical Company	**1.3**	Prior to any use of a device or technique, pertinent staff should always feel comfortable and competent to perform the technique. CooperSurgical provides a variety of tools for staff including virtual and hands-on resources. This includes a unique anatomical pelvic training model that can be utilized as a simulation training tool by any institution with a desire to use the Fetal Pillow device. CooperSurgical also has materials that may facilitate providers in performing informed consent of Fetal Pillow with patients. It was reported in a survey by Cornthwaite 2023, the vast majority of midwives and obstetricians (n=309, 85%) considered training in vaginal disimpaction to be essential, however most midwives (n=117, 81%) and over half of the participating obstetricians (n=92, 57%) reported not receiving any training for vaginal disimpaction (Cornthwaite 2023). It is clear, a lack of training and consensus on the proper method of disimpaction to be used persists. In addition, most participants reported to (n=380, 91%) prefer hands-on training in simulation (Cornthwaite 2023). The CooperSurgical pelvic model may be used for additional hands-on simulation training with the Fetal Pillow device.	Thank you for your comment. Section 1.3 of the draft guidance states that 'The procedure should only be done by staff trained in managing an emergency caesarean birth when the baby's head is impacted.'
8.	Consultee 5 CooperSurgical Company	**1.4**	Can the committee clarify what is being requested to provide "longer-term" safety and efficacy outcomes? Although more high-quality evidence from randomized controlled trials may be required to further substantiate additional improved	Thank you for your comment. The committee considered this comment but decided not to change the main recommendation.

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			outcomes, current evidence supports safe and effective intended use to elevate the fetal head and facilitate delivery. Many challenges persist in performing research on pregnant patients including: - Pregnancy is a protected state for clinical research and additional considerations are in place including regulations for the protection of human subject research - Cesarean section at full dilation or those requiring a Cesarean section after a failed instrumental vaginal delivery are specific clinical states and emergent situations. Informed consent for a clinical trial in these scenarios is difficult and often must be obtained at the time of admission on the labor and delivery unit. - Urgency in which intervention may need to occur may limit the opportunity for informed consent and therefore exclude participants. - Financial support for the study and potentially providing financial incentives to increase patient participation. - Inadequate research infrastructure and capabilities at an institution. - Challenges in gaining ethical approvals. - Patients may not understand the rationale for study design features such as randomization and blinding. - Patient concern for provider confidence in the technique required for research. - Patient fear around data sharing and use. As mentioned in Section 1.1, there are additional data from global publications that demonstrate both the safety but also the efficacy of the Fetal Pillow's ability to elevate the fetal head during a cesarean section at full dilation or after a failed vaginal delivery.	They agreed that there was a lack of high quality peer-reviewed evidence that showed benefits of the procedure, and that more research is needed. The draft guidance does state that there are no major safety concerns. Section 1.4 has been changed to state that longer term means beyond the immediate postpartum period and after hospital discharge.

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9.	Consultee 5 CooperSurgical Company	**2.3**	A recent systematic review and meta-analysis by Cornthwaite 2024, concluded that the certainty of evidence was low or very low for all included articles and mostly no or equivocal differences resulted across comparisons for vaginal disimpaction, reverse breech extraction, Patwardhan method, and Fetal Pillow. Thus, one method cannot be recommended over another due to lack of evidence regarding all techniques (Cornthwaite 2024). The publication recommended for training on a range of available techniques to develop guidance on sequential order of techniques from less to more complex methods. Training on all methods for disimpacting a fetal head will allow providers to determine their own competence and selection of a preferred method based on clinical scenarios (Cornthwaite 2024).	Thank you for your comment. Cornthwaite (2024) is included in the key evidence in the overview.
10.	Consultee 5 CooperSurgical Company	**2.4**	Fetal Pillow meets the unmet need. The increased risk of maternal and fetal complications from impacted fetal head are well-established; this includes uterine incision extensions, hemorrhage, umbilical artery acidosis, skull or limb fracture, and hypoxic ischemic encephalopathy. Evidence is limited and there is no clear consensus on the safest and most effective technique for disimpacting a fetal head (Cornthwaite 2024), yet none of the other techniques are limited to research only. Thus, a potentially valuable tool should not be limited to research only when it may be assistive in an emergency caesarean delivery. The aim and intended use of the ballon is to elevate the fetal head and facilitate delivery of the fetus in women requiring cesarean section at full dilation or those requiring a cesarean section after a failed instrumental vaginal delivery at gestational age greater than or equal to 37 weeks. The evaluation and decision to use the device should be based on the intended use of the device.	Thank you for your comment. Section 2.4 of the draft guidance states that ‘There is no clear consensus on the safest and most effective technique to support disimpacting the baby’s head before or at an emergency caesarean.’
11.	Consultee 5	**2.6**	The aim and intended use of the ballon is to elevate the fetal head and facilitate delivery of the fetus in women requiring cesarean	Thank you for your comment.

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	CooperSurgical Company		section at full dilation or those requiring a cesarean section after a failed instrumental vaginal delivery at greater than or equal to 37 weeks gestation. The device is proven to be safe and effective for the intended use of the device. The NICE recommendations should be based on the intended use of the device.	The committee bases its recommendation on safety and efficacy outcomes for the procedure published in peer-reviewed literature.
12.	Consultee 5 CooperSurgical Company	**3**	Considerations for the final draft should be made regarding possible repercussions of his draft guidance to recommend formal research use only, including: - The unique situation where clinicans currently have and do access the device for clinical care of patients. The impact on current users of Fetal Pillow who do not have access or means to utilize Fetal Pillow for clincial care when restricted to a resarch only status - The creation of inequitable care for patients and development of a health care disparity. - The hinderance of the education and training of future generations of health care providers. Additional considerations prior to the decision on final recommendations: - The device is shown to be safe and effective for the intended use to elevate the fetal head and facilitate delivery - All other methods such as reverse breech, vaginal push, or Patwardhan techniques lack quality evidence and no one method may be recommended over another when compared to Fetal Pillow.	Thank you for your comment. The committee considered this comment but decided not to change the main recommendation. They agreed that there was a lack of high quality peer-reviewed evidence that showed benefits of the procedure, and that more research is needed. The draft guidance does state that there are no major safety concerns. The committee did not agree that the research recommendation will lead to inequitable care for patients or development of a healthcare disparity.
13.	Consultee 5 CooperSurgical Company	**3.1**	We concur with NICE that Fetal Pillow has been well-established as safe to use without any major safety concerns. The draft recommendations for use of Fetal Pillow appear to focus the decision based on a requirement of improved maternal and fetal	Thank you for your comment.

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			outcomes with the use of Fetal Pillow. However, what the draft recommendations fail to consider is that per the labeling, the device is intended to elevate the fetal head and facilitate delivery. Although more high-quality evidence from randomized controlled trials may be required to further substantiate additional improved outcomes, current evidence supports safe use of the device and effective intended use to elevate the fetal head and facilitate delivery. There are currently more than 45 non-retracted studies measuring outcomes from use of Fetal Pillow which consist of randomized controlled trials, prospective interventional trial, prospective observational studies, comparative case control, retrospective cohort studies, case reports, surveys, and simulation which support the safe and effective use of the device. The literature that NICE reviewed consisted of Cornthwaite 2024, Sadler 2024, Sacre 2021, Hanley 2020, Chooi 2022, Safa 2016, Lassey 2020, Dutta 2019, Barman 2015, Jordan 2022, and Mumtaz 2023. All except Sadler 2024 were included in the systematic review. It should be recognized that in Jordan 2022 and Mumtaz 2023, the device was utilized in pregnant patients with prior cesarean deliveries, where safety and effectiveness have not been established as noted in the device's Warnings. Additionally, this review fails to recognize relevant data including that from manuscripts by Hanley 2022, Romano 2021, Romano 2023, another Sadler 2024 article on Obstetrician Views, Singh 2008, and Walker 2023. Other relevant published global data was also not considered, from Elbarbary 2023, Fung 2021, Ganapathy 2015, Gopal 2018, Gopal 2019, Hepburn 2017, Ho 2019, Johns 2018, Kalburgi 2018, Kalburgi 2015, Laverick 2019, Mufti 2015, Mufti 2013, Papanikolaou 2009, Rahim 2018, Sarkar 2018, and	In accordance with the IP programme manual, efficacy data will only be presented to the committee if it has been published in peer-reviewed literature. The committee considered this comment but decided not to change the main recommendation. They agreed that there was a lack of high quality peer-reviewed evidence that showed benefits of the procedure, and that more research is needed. The draft guidance does state that there are no major safety concerns.

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			Tussey 2022. The review performed by the Committee fails to recognize additional relevant data which supports the safe and effective intended use of the device.	
14.	Consultee 5 CooperSurgical Company	**3.2**	It is reported that three professional expert questionnaires for the procedure were submitted, however only one questionnaire, from Dr. Rita Arya, appears to be published on the NICE website. It is unclear if all three submissions were considered in development of the draft recommendations. For transparency, all expert questionnaire submissions should also be shared and it should be clarified to all stakeholders if all expert submissions were included in consideration of development for the recommendations.	Thank you for your comment. Although the committee were provided with 3 professional expert questionnaires as part of the evidence, only 1 expert gave permission for their questionnaire to be published on the NICE website at the time of consultation. All 3 questionnaires will be available when the guidance is published.
15.	Consultee 5 CooperSurgical Company	**3.3**	The intended use of the balloon cephalic elevation device is to elevate the fetal head and facilitate delivery of the fetus in women requiring cesarean section at full dilation or those requiring a cesarean section after a failed instrumental vaginal delivery at greater than or equal to 37 weeks gestation. The device is proven to be safe and effective for the intended use of the device.	Thank you for your comment. IP guidance makes recommendations for a procedure rather than a specific device.
16.	Consultee 5 CooperSurgical Company	**3.4**	The submission received by the Birth Trauma Association reports having received accounts from thousands of women about their birth experiences and even from one patient that “the balloon device is not used enough.” Based on the response, “women have told us that the balloon device could have made the birth easier” and “we have also heard from a few women who had experience of the balloon device being used. These were all positive stories.” Even though data has been retracted the patient organization still feels “all maternity units should have a fetal pillow so that it is	Thank you for your comment. The committee considered this comment but decided not to change the main recommendation. They agreed that there was a lack of high quality peer-reviewed evidence that showed benefits of the procedure, and that more

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			available to clinicians as an option." This reinforces that even patients prefer to have Fetal Pillow as an option for all clinicians. If the drafted guidance is published, the decision to limit use of Fetal Pillow for formal research dismisses the valuable opinion of the Birth Trauma Association and the thousands of patients who have provided feedback. This will further impact all patients in the UK who may endure cesarean delivery with an impacted fetal head in the future. Health care disparity may be prevented by a change in the guidance decision prior to publication. The device has been shown to be safe and effective to elevate the fetal head and facilitate delivery as intended and therefore as recommended by the Birth Trauma Association "would benefit those women at higher risk of experiencing impacted fetal head." If NICE values quality care for mothers and babies in the UK, the draft recommendations should be changed to incorporate and reflect the opinion of patients.	research is needed. The draft guidance does state that there are no major safety concerns. NICE produces useful and usable guidance for health and care practitioners by providing rigorous, independent assessment of complex evidence for new health technologies. If new evidence is published that reduces the uncertainty about the efficacy of this procedure, the IP guidance may be reviewed.
17.	Consultee 5 CooperSurgical Company	**3.5**	The new programme called Avoiding Brain Injury in Childbirth (ABC) is developed to make considerable strides in training on how to manage impacted fetal head. Training should include the use of Fetal Pillow as an option for safe and effective elevation of the fetal head to facilitate delivery. It should be remembered that there is no clear consensus on the safest and most effective technique for disimpacting a fetal head when comparing vaginal disimpaction, reverse breech extraction, Patwardhan method, and Fetal Pillow, andFetal Pillow is proven to be safe and effective, has been rated by clinicians as easy to use. Thus, Fetal Pillow should be used for training in this programme in addition to all other methods, especially since an available pelvic simulation model is available for use with Fetal Pillow.	Thank you for your comment. The consultee notes that the procedure should be part of the programme called Avoiding Brain Injury in Childbirth (ABC), which is referred to in section 3.5 of the guidance.
18.	Consultee 5	**3.6**	The definition and manner in which a fetal head is impacted is highly subjective and difficult to clearly identify.	Thank you for your comment.

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	CooperSurgical Company			Section 3.6 of the draft guidance states 'The committee noted that some of the evidence described the balloon disimpaction device being used at a caesarean during the second stage of labour but not necessarily when there was impaction of the baby's head.' Section 2.1 of the draft guidance states that 'The definition of impaction of a baby's head is subjective.'
19.	Consultee 5 CooperSurgical Company	**3.7**	Oftentimes a senior provider with more experience may not be available to a trainee in these emergent cases. It has been reported that trainees like Fetal Pillow, are more likely to use the device, and to have used it more than five times when compared to consultant obstetricians. If the draft guidance moves forth, equitable care for future generations of providers will be hindered since universal training of the device at all institutions is unlikely to continue. In a survey of UK trainees and consultant labour ward leads, providers with <5 years of experience were significantly less confident managing impacted fetal head than those with 6-10 years and >10 years of experience, highlighting an increased need for training on managing an impacted fetal head. In the same survey Fetal Pillow was the second most common option as the number one technique to assist delivery of an impacted fetal head, appearing only after lowering the operating table and prior to that of reverse breech extraction, extend incision, tocolytics, head down	Thank you for your comment. Section 3.7 of the draft guidance states 'The committee was told that the balloon disimpaction device may be useful for less experienced staff.'

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			tilt, vaginal push up, and use of non-dominant hand. It is evident Fetal Pillow may be a preferred method by trainees. Prior to any use of a device or technique, pertinent staff should always receive proper training and determine competency to perform the technique. CooperSurgical provides a unique pelvic anatomical training model that can be utilized as a simulation training tool by any institution with a desire to use the Fetal Pillow device. The training model is simply requested for use from CooperSurgical. CooperSurgical also has materials that may facilitate providers in performing informed consent of Fetal Pillow with patients. It was reported in a survey by Cornthwaite 2023, the vast majority of midwives and obstetricians (n=309, 85%) considered training in vaginal disimpaction to be essential, however most midwives (n=117, 81%) and over half of the participating obstetricians (n=92, 57%) reported not receiving any training for vaginal disimpaction. It is clear, a lack of training and consensus on the proper method of disimpaction to be used persists. In addition, most participants reported to (n=380, 91%) prefer hands-on training in simulation (Cornthwaite 2023). The CooperSurgical pelvic model may be used as an opportunity for additional hands-on simulation training with the Fetal Pillow device. Bibliography 1. Lassey SC, Little SE, Saadeh M, et al. Cephalic Elevation Device for Second-Stage Cesarean Delivery: A Randomized Controlled Trial. Obstet Gynecol. 2020;135(4):879-884. 2. Cornthwaite K, van der Scheer JW, Kelly S, et al. Management of impacted fetal head at cesarean birth: A systematic review and meta-analysis. Acta Obstet Gynecol Scand. 2024;103(9):1702-1713.	

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			3. Barbieri RL. The Fetal Pillow: A new option for delivery the deeply impacted fetal head. OBG Management. 2020; 32(7):8-11. 4. Sadler LC, Thompson JMD, Alsweiler JM, et al. Maternal and neonatal morbidity associated with Fetal Pillow® use at full dilatation caesarean: A retrospective cohort. BJOG: An International Journal of Obstetrics and Gynaecology. 2024a;131(9):1240-1248. 5. Sacre H, Bird A, Clement-Jones M, Sharp A. Effectiveness of the fetal pillow to prevent adverse maternal and fetal outcomes at full dilatation cesarean section in routine practice. Acta Obstet Gynecol Scand. 2021;100(5):949-954. 6. Hanley I, Sivanesan K, Veerasingham M, Vasudevan J. Comparison of outcomes at full-dilation cesarean section with and without the use of a fetal pillow device. Int J Gynaecol Obstet. 2020;150(2):228-233. 7. Chooi KYL, Deussen AR, Louise J, Cash S, Dodd JM. Maternal and neonatal outcomes following the introduction of the Fetal Pillow at a tertiary maternity hospital: A retrospective cohort study. Australian and New Zealand Journal of Obstetrics and Gynaecology. 2023;63(3):360-364. 8. Safa H, Beckmann M. Comparison of maternal and neonatal outcomes from full-dilatation cesarean deliveries using the Fetal Pillow or hand-push method. Int J Gynaecol Obstet. 2016;135(3):281-284. 9. Barman S, Chakraborty B, Saha S, Sahana R, Maity S, Roy D. Use of Fetal Pillow during cesarean section in deeply engaged head: a comparative study with Patwardhan's technique. Indian Journal of Clinical Practice. 2015;26(4):375. 10. Jordan A, Herbert N, Rundle-Thiele D, Holland S, Wong A. Foetal Pillow associated uterine and bladder rupture. J Obstet Gynaecol. 2022;42(5):1551-1552.	

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			26. Kalburgi S, Oyekan E, Bagtharia S, Ikomi A. Impact of the fetal pillow device on maternal morbidity. BJOG: An International Journal of Obstetrics and Gynaecology. 2018;125:61. 27. Kalburgi S, Sahare A, Ikomi A. Initial experience with the fetal pillow in South West Essex and comparison with historical cohort of 2nd stage caesarean sections. Paper presented at: BJOG: An International Journal of Obstetrics and Gynaecology. 2015. 28. Laverick B, Berg L, Chandrakumar D, Parisaei M. Outcomes of caesarean section at full dilatation, difficulty delivering the fetal head and the impact of the introduction of the fetal pillow. BJOG: An International Journal of Obstetrics and Gynaecology. 2019;126:134. 29. Mufti N, Beaton L, Sircar S. Re-audit of the fetal pillow (FP): a novel intervention to reduce maternal and fetal complications at caesarean section at full dilation (CSFD). Paper presented at: BJOG: An International Journal of Obstetrics and Gynaecology. 2015. 30. Mufti NM, Thomas TT, Sircar SS. The fetal pillow (FP): A novel intervention to reduce maternal and fetal complications in caesarean sections at full dilatation (CSFD). Archives of Disease in Childhood: Fetal and Neonatal Edition. 2013;98. 31. Papanikolaou N, Tillisi A, Louay L, Singh M, Ikomi A, Varma R. O737 Reducing complications related to Caesarean section (CS) in second stage: UK experience in the use of fetal disimpacting system (FDS). Int J Gynaecol Obstet. 2009(107):S304. 32. Rahim A, Cotzias T, Page L, Girling J. A retrospective analysis of fully dilated caesarean sections at West Middlesex Hospital. BJOG: An International Journal of Obstetrics and Gynaecology. 2018;125:70.	

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			33. Sarkar P, Das S. Prospective study evaluating the role of fetal pillow in caesareans section at full dilatation in reducing maternal and fetal morbidity. American Journal of Obstetrics and Gynecology. 2018;218(1):S242. 34. Tussey C, Ruck LB, McCluskey K, Wallen TT, Rigali K, Wolf MJ. How a Fetal Elevation Device Assists the Birth of a Neonate With a Deeply Impacted Head in the Pelvis. Journal of Obstetric, Gynecologic & Neonatal Nursing. 2022;51(4):S58-S59. 35. Jawad S, Webbe J, Ougham K, Uthaya S, Modi N, Gale C. Brain injury occurring or soon after birth: annual incidence and rates of brain injuries to monitor progress against the national maternity ambition: 2021 national data. The Neonatal Data Analysis Unit, Imperial College London. 2021; 1-37. 36. Avoiding Brain Injury in Childbirth (ABC). RCOG.org.ukc. Accessed January 23, 2025. https://www.rcog.org.uk/about-us/quality-improvement-clinical-audit-and-research-projects/avoiding-brain-injury-in-childbirth-abc/ 37. Cornthwaite K, Hewitt P, van der Scheer JW, et al. Definition, management, and training in impacted fetal head at cesarean birth: a national survey of maternity professionals. Acta Obstet Gynecol Scand. 2023;102(9):1219-1226. doi:10.1111/aogs.14600 38. Cornthwaite K, Bahl R, Lenguerrand E, Winter C, Kingdom J, Draycott T. Impacted foetal head at caesarean section: a national survey of practice and training. J Obstet Gynaecol. 2021;41(3):360-366. doi:10.1080/01443615.2020.1780422	
20.	Consultee 6 NHS Forth Valley	General	I work in a District general hospital in Scotland with a delivery rate of 2,600 babies/year. We routinely use the fetal pillow for caesarean sections at full dilatation. We have excellent results locally and a small local audit had no maternal or fetal complications and reduced the rate of blood loss, time to delivery	Thank you for your comment. The committee considered this comment but decided not to change the main recommendation.

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			and maternal trauma. Operator findings were that delivery was easier and made a significant difference in 100% cases. We anticipate continued use.	They agreed that there was a lack of high quality peer-reviewed evidence that showed benefits of the procedure, and that more research is needed. The draft guidance does state that there are no major safety concerns. A recommendation has been added stating that 'Centres already using this procedure may continue to do so but are encouraged to collect data or do further research on the outcomes listed in recommendation 1.5.'
21	Consultee 7 Specialist society British Maternal & Fetal Medicine Society	General	No comments but agree with the recommendations	Thank you for your response. Consultee agrees with recommendations.

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."

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