

NICE interventional procedures consultation document, November 2024

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Balloon disimpaction of the baby's head at emergency caesarean during the second stage of labour

In the final weeks of pregnancy, the baby's head moves down into the pelvis. Sometimes a problem during labour means that an emergency caesarean is needed to deliver the baby through a cut in the tummy and womb. If the baby's head is stuck (impacted) low down in the pelvis, it can be difficult to deliver the baby. This can lead to delay or injury to the woman, trans man or non-binary person giving birth, or to the baby. In this procedure, a silicone balloon is inserted into the vagina and inflated to move the baby's head (disimpaction) before starting the caesarean. The aim is to reduce the risk of injury.

This is a review of NICE's interventional procedures guidance on balloon disimpaction of the baby's head at emergency caesarean during the second stage of labour.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

**This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.**

After consultation ends, the committee will:

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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 19 December 2024

Target date for publication of guidance: April 2025

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## 1 Draft recommendations

- 1.1 [More research is needed](#) on balloon disimpaction of the baby's head at emergency caesarean during the second stage of labour before it can be used in the NHS.
- 1.2 This procedure should only be done as part of a formal research study, and a research ethics committee needs to have approved its use.
- 1.3 The procedure should only be done by staff trained in managing an emergency caesarean birth when the baby's head is impacted.

### What research is needed

- 1.4 More research, including randomised controlled trials or a registry, is needed on:
  - how the procedure compares with other options
  - patient selection, such as the characteristics of the woman, trans man or non-binary person giving birth, and risk factors
  - longer-term safety and efficacy outcomes for the woman, trans man or non-binary person giving birth, and the baby.

### Why the committee made these recommendations

Several publications that provided supporting evidence for [NICE's interventional procedures guidance on balloon disimpaction of the baby's head at emergency caesarean during the second stage of labour](#) have been retracted since the guidance was published. This includes a key study that was retracted because the journal's research integrity team found several inconsistencies in the results presented. There is now a lack of high-quality evidence to show whether the procedure improves outcomes for either the woman, trans man or non-binary person giving birth, or the baby. There is also a lack of evidence comparing the procedure with other options for

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disimpacting the baby's head. But there are no major safety concerns. So, this procedure can be used in research.

## 2 The condition, current treatments, unmet need and procedure

### The condition

2.1 A caesarean during the second stage of labour is associated with an increased risk of adverse perinatal outcomes compared with an elective caesarean or a caesarean during the first stage of labour. Delivery of the baby can be more difficult if the head is impacted deep within the pelvis, further increasing the risks to the woman, trans man or non-binary person giving birth, and to the baby. The definition of impaction of a baby's head is subjective. But a UK survey published in 2023 proposed the definition: 'A caesarean birth where the obstetrician is unable to deliver the fetal head with their usual delivering hand, and additional manoeuvres and/or tocolysis are required to disimpact and deliver the fetal head' ([Cornthwaite et al. 2023](#)).

2.2 Difficulties in disimpacting a deeply engaged baby's head can delay the birth of a baby that is already at risk. For the woman, trans man or non-binary person giving birth, there is an increased risk of complications such as:

- extension of the uterine incision
- haemorrhage
- infection
- bladder injury.

For the baby, complications include:

- umbilical artery acidosis

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- skull or limb fracture
- hypoxic ischaemic encephalopathy
- brachial plexus injury.

## **Current treatments**

2.3 Two main approaches are commonly used to disimpact an engaged baby's head. One involves the surgeon or an assistant placing fingers of a cupped hand through the vagina and pushing the baby's head back up the pelvis. This can be associated with vaginal tissue trauma. The other approach (reverse breech extraction) involves the surgeon delivering the baby's feet first through the uterine incision, and then delivering the head. The Patwardhan technique and the modified Patwardhan technique are modifications of the reverse breech extraction method. They involve delivering a shoulder or both shoulders of the baby first, followed by the body and, lastly, the head.

## **Unmet need**

2.4 Impaction of the baby's head makes a caesarean delivery more difficult and is associated with an increased risk of complications. 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. The situation is also affected by the baby's position. The aim of balloon disimpaction is to elevate the baby's head and make a caesarean delivery during the second stage of labour less traumatic and quicker.

## **The procedure**

2.5 Balloon disimpaction is usually done immediately before an emergency caesarean, at full dilation, during the second stage of labour.

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2.6 A disposable soft silicone balloon device is inserted into the vagina, using a lubricant. The balloon is pushed back towards the coccyx and placed between the pelvic floor and the baby's head. The balloon surface is placed in contact with the head. The base plate of the device rests on the posterior vaginal wall and anorectum, opposite the anococcygeal ligament. This is to prevent downward displacement when the device is inflated. Once the device is in position, the balloon is inflated using sterile saline using a tube connected to a 2-way tap. The balloon is designed to inflate only in an upward direction. Inflating the balloon helps to elevate the head out of the pelvis by a few centimetres. The intention is to:

- make the delivery easier, with less manipulation through the abdominal wound
- reduce the risk of injury.

Immediately after delivery, the balloon is deflated by opening the 2-way tap and then removed from the vagina by traction. After the caesarean, the vagina is inspected for trauma.

### **3 Committee considerations**

#### **The evidence**

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 11 sources, which was discussed by the committee. The evidence included 1 systematic review, 5 retrospective cohort studies, 2 randomised controlled trials, 1 prospective non-randomised comparative study and 2 case reports. Both the randomised controlled trials and all the cohort studies except 1 were also included in the systematic review. The evidence is presented in the

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[summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be:

- outcomes for the woman, trans man or non-binary person giving birth:
  - reduced time from the decision to have a caesarean to birth
  - reduced time from uterine incision to birth
  - reduced need for extension of uterine incision
  - less blood loss
  - fewer operative complications
- outcomes for the baby:
  - improved Apgar scores
  - improved umbilical artery pH
  - less sepsis
  - reduced need for admission to a special care baby unit or newborn intensive care unit
  - less need for intubation
  - fewer deaths.

3.3 The professional experts and the committee considered the key safety outcomes to be trauma to the vagina or baby's head, and infection.

3.4 A submission was received from a patient organisation, which was considered by the committee. This highlighted the potentially severe and long-lasting effects of having a caesarean when the baby's head is impacted. They noted that the few women who had experience of balloon disimpaction of the baby's head were positive about it and had successful outcomes.

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## **Committee comments**

- 3.5 The committee was told about a new programme funded by the Department of Health and Social Care called [Avoiding Brain Injury in Childbirth \(ABC\)](#). The aim of the programme is to improve outcomes for women, trans men or non-binary people giving birth, and their babies by implementing national clinical protocols, tools and multiprofessional training. This will include training on how to manage impaction of the baby's head during a caesarean birth.
- 3.6 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.
- 3.7 The committee was told that the balloon disimpaction device may be useful for less experienced staff.

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Chair, interventional procedures advisory committee

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