



2023 exceptional surveillance of intrapartum care for healthy women and babies (NICE guideline CG190)

Surveillance report

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Surveillance decision

We will update the <u>recommendations on choosing planned place of birth in NICE's</u> guideline on intrapartum care for healthy women and babies.

We will not update the recommendations for water birth (recommendations 1.8.4 to 1.8.6 and 1.13.23) at this time but will reconsider the evidence base once the <u>POOL study</u> has published (expected 2024).

Reasons for the exceptional review

The NICE surveillance team were contacted by the multiple obstetric guidelines update committee during the update of the NICE guideline on intrapartum care for healthy women and babies, and asked to consider the need to update recommendations on choosing planned place of birth. In particular, they submitted new evidence around the risks of home births for nulliparous and multiparous women and discussed that the section of the guideline on place of birth may be out of date and warrant an update. Subsequent to this an enquirer contacted NICE to highlight a new study on water birth. Each of these issues is discussed in turn below.

Planning place of birth

Methods

The exceptional surveillance process consisted of:

- Considering intelligence from the <u>Multiple Obstetric Guidelines Update Committee</u>
 (Obstetrics committee)
- Considering the evidence used to develop the guideline.
- Considering relevant information from previous surveillance reviews of the guideline.
- Literature searches for new evidence.
- Examining related NICE guidance and quality standards.

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- Examining the NICE event tracker for relevant ongoing and published events.
- Assessing the new evidence and the Obstetrics committee feedback against current recommendations to determine whether or not to update the topic areas in the guideline.

For further details about the process and the possible update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Information considered when developing the guideline

Section 1.1 in the NICE guideline has recommendations covering choosing planned place of birth.

The recommendations on place of birth generally date to 2014 and were developed based on a comparison of the different settings (home, freestanding midwifery unit, alongside midwifery unit, and obstetric unit). The review included a range of studies depending on the comparison, but there was a heavy reliance on the large UK based <u>Birthplace in England Collaborative Group study</u> from 2011. This was a prospective cohort study of 64,538 women in England with a singleton pregnancy powered for a composite primary outcome of perinatal mortality and intrapartum related neonatal morbidities (stillbirth after start of care in labour, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus, or fractured clavicle).

The committee noted that the evidence suggested giving birth is generally very safe for women and babies across all settings with very low incidences of mortality or severe morbidity reported. There was consistent evidence that for women at low risk of complications in birth, giving birth in an obstetric unit is associated with a higher incidence of obstetric intervention and its associated morbidity when compared with planning birth in other settings. Furthermore, there was evidence of an increase in neonatal unit admissions for babies born in obstetric units, but no difference in other neonatal outcomes between planning birth in an obstetric unit, an alongside midwifery unit or a freestanding midwifery unit.

Cost effectiveness analysis based on all low risk women also indicated that planning to give birth outside an obstetric unit is more cost-effective than planning to give birth in an obstetric unit owing to a reduced incidence of adverse perinatal outcomes. There were important differences seen for neonatal outcomes when subgroup analyses by parity were

undertaken. These data were drawn largely from the UK Birthplace study and thus were felt to be highly relevant. These findings indicated that, for babies born to nulliparous women planning birth at home, there was an increased risk of an adverse composite neonatal outcome when compared with planning birth in all other settings, although the absolute risk of a poor outcome remains small. There was no difference seen between settings for babies born to multiparous women. The committee noted that this would likely impact on the cost effectiveness of each setting. As a result, while they recognised that offering both home and midwifery-led settings for multiparous women would be cost-effective, they felt less certain about the cost effectiveness of home birth for nulliparous women.

For these reasons, coupled with the fact that planning to give birth in an obstetric unit was found to be associated with increased maternal morbidity, the committee felt it appropriate to recommend that nulliparous women be advised to give birth in either a freestanding or alongside midwifery unit and multiparous women be advised to give birth either at home or in a freestanding or alongside midwifery unit. However, alongside this advice, the committee felt it imperative that women be given a choice of all birth settings and evidence-based information in an easily accessible format of the key risks and benefits associated with each birth setting in order to help them decide the most appropriate place for them to plan to give birth.

The group therefore developed a decision-aid as an example of how this information might be presented to women in a format that facilitates discussion between the woman and the midwife and which the woman can use for future reference and as a basis for ongoing discussions. The committee believed it is important that the information given be as individually relevant as possible and so recommended that local data be provided wherever possible, and that data relating to nulliparous women and parous women be provided separately. Because of this, while the conclusions that inform the recommendations are based on a synthesis of findings from all studies reviewed, the data included in the recommendations are drawn largely from the Birthplace UK study.

The committee also drafted a recommendation for research to investigate the impact on women's choices and decision-making of using an evidence-based decision-aid and a less risk-based approach to discussions around place of birth. When considering the evidence for each birth setting a number of gaps in the evidence were noted by the committee which prompted the drafting of recommendations for research. In particular, they drafted a recommendation for research to investigate the difference in long term outcomes associated with birth in the different settings and what components of care in midwifery-

led settings that contribute to lower intervention rates. They were also aware that the new recommendations would lead to a shift towards more women giving birth outside an obstetric unit than is currently the case. Recommendations for research were made to look at the staff training needs associated with this shift and to develop a commissioning tool to examine the impact this would have on planning service provision.

Information considered in previous surveillance of this guideline

The <u>2019 surveillance review</u> found a systematic review of 15 studies (n=215,257), which examined the proportion of transfers from a planned home birth setting to hospital and the reasons behind the transfers. The review suggested that rates of transfer from a home birth setting may be lower than the guideline currently states. However, the new evidence was deemed to have a lower applicability to the guideline and UK practice than the Birthplace study that was used to inform this section of the guideline and, as such, was not deemed to impact on the guideline.

Information considered in this exceptional surveillance review

The NICE surveillance team were contacted by the multiple obstetric guidelines update committee during the update of the NICE guideline on intrapartum care for healthy women and babies, and asked to consider the need to update the topic area on place of birth for low risk women. The <u>current update of NICE's guideline on intrapartum care</u> is not updating the area of choosing planned place of birth for all low risk women but only for women at different body mass index (BMI) thresholds. As such, the committee submitted 2 new studies comparing planned home birth with planned hospital birth.

A meta-analysis (Reitsma et al. 2020) comparing the occurrence of birth interventions and maternal outcomes among low risk women who begin labour intending to give birth at home compared to women intending to give birth in hospital was found (n=16 studies; approximately, 500,000 intended home births). The study found that among low risk women, those intending to give birth at home experienced fewer birth interventions and adverse maternal outcomes, such as maternal infection or third or fourth degree tear. Pooled results for postpartum haemorrhage showed women intending home births were either less likely or did not differ from those intending hospital births. However, the review included studies from a non-UK setting which have very different maternity systems that might reduce generalisability to the UK.

A second meta-analysis (Hutton et al. 2019) comparing the occurrence of fetal or neonatal

loss among low risk women who begin labour intending to give birth at home compared to low risk women intending to give birth in hospital was found (n=14 studies; approximately, 500,000 intended home births). The study found that the risk of perinatal or neonatal mortality was not different when birth was intended at home or in hospital, for either multiparous women or nulliparous women. However, the confidence intervals of the effect estimates were wide, and the review also included studies from a non-UK setting which might reduce generalisability to the UK. The authors did acknowledge that there was a trend towards favouring hospital birth and that the generalisability of findings should be undertaken cautiously.

While both of these studies may have issues with generalisability to UK clinical practice, the NICE multiple obstetric guideline committee considered that even a small change in the risks of the different settings would be important to reflect in the NICE guideline. As such, they considered that these 2 studies should be considered alongside the Birthplace UK study and any other new evidence available.

Searches for other new evidence

A search was conducted to check for other new evidence related to planning place of birth that had published since the 2 meta-analyses above were undertaken. A total of 2,554 studies were found that had published between 2018 and February 2023. The review question on planning birth from the full guideline was used and we limited inclusion to randomised controlled trials (RCTs), systematic reviews, cohort studies and economic evaluations to identify the key evidence. From this 11 additional studies were included, which are briefly summarised below.

There were 8 studies looking at effectiveness and safety of various birth settings in a range of countries (Merz et al. 2020; Morr et al. 2021; Wiegerinck et al. 2020; Nethery et al. 2021; Stephenson-Famy et al. 2018; Scarf et al 2019; Rossi et al. 2018; Isaline et al. 2019), which generally found all settings studied to be safe, although there may be a lack of generalisability to the UK for some of the studies. Additionally, there were 2 costing studies in Australia (Scarf et al. 2020, Scarf et al. 2021) that compared the cost of birth in a birth centre, hospital or home setting. The studies found little difference in the cost of birth for uncomplicated vaginal births at home, in a birth centre or in a hospital setting.

There is also a Cochrane review of planned hospital birth versus planned home birth (Olsen et al. 2023) which only found 1 small RCT in the area eligible for inclusion (n=11 women). However, the authors acknowledged that there is observational data in the area

and stated that 'the International Federation of Gynaecology and Obstetrics and the International Confederation of Midwives collaboratively conclude that there is strong evidence that out-of-hospital birth supported by a registered midwife is safe'. They also noted that further RCTs may be unfeasible.

Impact of new evidence on the guideline

There is a body of new evidence around planning place of birth. The NICE multiple obstetric guideline committee particularly noted the studies by Reitsma et al. 2020 and Hutton et al. 2019, which found evidence that home birth may be as safe and effective as hospital birth, albeit these studies may have issues with generalisability to a UK setting. However, the committee considered that even a small change in the risks of the different settings would be important to reflect in the guideline. The wider body of evidence found by the searches appeared consistent with the studies submitted by the committee. However, the interpretation of this new evidence would need careful consideration alongside the UK based Birthplace study, which is a large study and highly reflective of UK maternity care. As such, it appears warranted for a committee to consider an update of recommendations on planning place of birth, considering the validity of the new evidence and if the UK Birthplace study is still the most applicable to UK current maternity practice.

It was also acknowledged that planning place of birth recommendations currently sit within NICE's guideline on intrapartum care. However, in clinical practice discussions on planning place of birth generally take place in the antenatal period and thus planning place of birth recommendations do not naturally sit within this guideline.

NICE's guideline on antenatal care currently has recommendation 1.3.14 which states: Before 28 weeks, start talking with the woman about her birth preferences and the implications, benefits and risks of different options (see the section on choosing planned place of birth in the NICE guideline on intrapartum care for healthy women and babies and the section on planning mode of birth in the NICE guideline on caesarean birth).

As such, an update of planning place of birth recommendations would be an opportunity to consider how best to link up and present place of birth recommendations within the NICE guidelines. An update would also be a chance to consider whether tables of risks (tables 1 to 5 in the NICE guideline) of the different birth settings are helpful in practice, particularly when considering local variation and the need to ensure the data are up to date.

Water birth

Methods

The exceptional surveillance process consisted of:

- · Considering evidence submitted by an enquirer to NICE.
- Considering the evidence used to develop the guideline.
- Considering relevant information from previous surveillance reviews of the guideline.
- Literature searches for new evidence.
- Examining related NICE guidance and quality standards.
- Examining the NICE event tracker for relevant ongoing and published events.
- Assessing the new evidence against current recommendations to determine whether or not to update sections of the guideline.

For further details about the process and the possible update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Information considered when developing the guideline

The NICE guideline on intrapartum care for healthy women and babies has recommendations 1.8.4 to 1.8.6 that relate to water birth for pain relief in labour. The guideline also has recommendation 1.13.23 that advises: Inform women that there is insufficient high-quality evidence to either support or discourage giving birth in water. These recommendations date to 2007.

In relation to recommendations 1.8.4 and 1.8.5, there was 1 Cochrane review and 1 RCT, which found that labour in water reduced pain and also reduced the use of regional analgesia. There were no significant differences regarding adverse outcomes when comparing labours with and without the use of water. There was insufficient evidence on timing of use of water in labour, nor hygiene measures for water birth.

Recommendation 1.13.23 was informed by 1 Cochrane review, 1 RCT and 1 cross-sectional

study, which were deemed insufficient evidence to recommend the use of water birth in the second stage of labour, particularly with regards to neonatal outcomes.

Information considered in previous surveillance of this guideline

The <u>2019 surveillance review</u> found an update of a <u>Cochrane review</u> that was previously included in the guideline. The updated review included 15 trials that evaluated the effects of water immersion during labour and/or birth, compared with no immersion in water. Results indicated that immersion in water seemed to have no significant impact on rates of instrumental vaginal birth, caesarean section, blood loss or perineal tears. However, there was a small reduction in the risk of using regional analgesia for women immersed in water. There was limited evidence in the second stage of labour. The authors concluded that the available evidence is limited by clinical variability and heterogeneity across trials, and no trial has been conducted in a midwifery-led setting. The surveillance review also noted the ongoing <u>POOL study</u>: establishing the safety of waterbirth for mothers and babies (due to publish 2024).

Given the ongoing POOL study, the surveillance review concluded that there was no impact but began tracking it so that the results could assessed once they were available.

Information considered in this exceptional surveillance review

An enquirer submitted a systematic review on maternal and neonatal outcomes following immersion in water during labour (Burns et al. 2022), which aimed to synthesise the evidence that compared the effect of water immersion during labour or water birth on intrapartum interventions and outcomes to standard care with no water immersion. The review included 36 studies (n=157,546) and found that water immersion significantly reduced use of epidural (k=7, n=10,993, odds ratio [OR] 0.17, 95% confidence interval [CI] 0.05 to 0.56), injected opioids (k=8, n=27,391, OR 0.22, 95% CI 0.13 to 0.38), episiotomy (k=15, n=36,558; OR 0.16, 95% CI 0.10 to 0.27), maternal pain (k=8, n=1,200, OR 0.24, 95% CI 0.12 to 0.51) and postpartum haemorrhage (k=15, n=63,891, OR 0.69, 95% CI 0.51 to 0.95). There was an increase in maternal satisfaction (k=6, n=4,144, OR 1.95, 95% CI 1.28 to 2.96) and odds of an intact perineum (k=17, n=59,070, OR 1.48, 95% CI 1.21 to 1.79) with water immersion. Water birth was associated with increased odds of cord avulsion (OR 1.94, 95% CI 1.30 to 2.88), although the absolute risk remained low (4.3 per 1,000 versus 1.3 per 1,000). There were no differences in any other identified neonatal outcomes. The authors concluded that intrapartum water immersion for healthy women and their newborns has clear benefits. However, they acknowledged that most included studies

were conducted in obstetric units.

Searches for other new evidence

A search was conducted to check for other new evidence related to water birth to give a brief overview of the likely evidence base that has published since the review above was conducted. The original NICE guideline did not have a specific review question in this area, so a new search strategy was developed, and the inclusion criteria limited to RCTs, systematic reviews, cohort studies and economic evaluations to identify the key evidence.

A total of 169 studies were found that had published between 2021 and February 2023. From this, 12 additional studies were included (Zhang et al. 2022; Cristina et al. 2022; Edwards et al. 2023; Nikodem et al. 2022; Ghasemi et al. 2021; Carpenter et al. 2022; Aughey et al. 2021; Papoutis et al. 2021; Ulfsdottir et al. 2022; Bovbjerg et al. 2022; Lanier et al 2021; Seed et al. 2023). The studies showed some benefits of water birth but some potential safety issues such as cord avulsion, risk of water aspiration and uterine infection. Several of the studies advocated for further research.

In addition to this, the POOL study, which was identified in previous surveillance, was noted as still ongoing (due to publish 2024).

Impact of new evidence on the guideline

There is a body of new evidence around water birth which showed some benefits but some potential safety issues. As such, the evidence base still seems uncertain and it appears warranted to wait until the POOL study has published and consider the body of evidence again in light of this additional study.

Other relevant NICE guidance

NICE's guideline on antenatal care currently has recommendation 1.3.14 which states: Before 28 weeks, start talking with the woman about her birth preferences and the implications, benefits and risks of different options (see the section on choosing planned place of birth in the NICE guideline on intrapartum care for healthy women and babies and the section on planning mode of birth in the NICE guideline on caesarean birth).

<u>Statement 1 in NICE's quality standard on intrapartum care</u> states that women at low risk of complications during labour are given the choice of all 4 birth settings and information

about local birth outcomes.

Equalities

No equalities issues were identified specifically related to planning place of birth.

Searches related to water birth identified a retrospective cohort study in England (<u>Aughey et al. 2021</u>) that noted that white women from higher socioeconomic backgrounds were more likely to be recorded as giving birth in water. The study recommended that maternity services should focus on ensuring equitable access to water birth.

See appendix A for the full equality and health inequalities assessment.

Overall decision

We will update recommendations on choosing planned place of birth in the NICE guideline on intrapartum care for healthy women and babies.

We will not update the recommendations for water birth but will reconsider the evidence base once the POOL study has published (expected 2024).

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