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Extended Research Article

Establishing the safety of waterbirth for mothers and their babies: the POOL cohort study with nested qualitative component

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This article

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Abstract

Background: Intrapartum water immersion analgesia has been recommended by the National Institute for Health and Care Excellence since 2007, but high-quality evidence relating to the safety of waterbirth for mothers and their babies was lacking.

Primary study objective: To establish whether, in the case of 'low-risk' women who use water immersion during labour, waterbirth, compared to birth out of water, is as safe for mothers and their babies.

Methods: A cohort study with non-inferiority design.

Setting: Twenty-six National Health Service organisations in England and Wales.

Participants: The primary analysis included 60,402 births between January 2015 and June 2022. Primary analysis was restricted to births where the woman: (1) was without complicating medical conditions at the time of pool entry, (2) used water immersion during labour and (3) did not receive obstetric or anaesthetic interventions prior to birth. Comparisons were undertaken between women who gave birth in water and women who gave birth out of water.

Main outcome measures: Maternal primary outcome: obstetric anal sphincter injury (with planned subgroup analysis by parity); neonatal composite primary outcome: fetal or neonatal death (after the commencement of intrapartum care and prior to discharge home), neonatal unit admission with respiratory support or the administration of intravenous antibiotics within 48 hours of birth. Separate a priori sample size calculations were undertaken for the maternal and neonatal primary outcomes.

Results: After adjusting for differences in the characteristics of women who used intrapartum water immersion and gave birth in or out of water: (1) among nulliparous women, rates of recorded obstetric anal sphincter injury were no higher among women who gave birth in water than among women who left the pool before birth [730 of 15,176 women (4.8%) vs. 641 of 12,210 women (5.3%); adjusted odds ratio 0.97; one-sided 95% confidence interval, −∞ to 1.08]; (2) among parous women, rates of recorded obstetric anal sphincter injury were no higher among women who gave birth in water than among women who left the pool before birth [269 of 24,451 women (1.1%) vs. 144 of 8565 women (1.7%); adjusted odds ratio 0.64; −∞ to 0.78].

Among babies, rates of the primary outcome were no higher among babies born in water than among babies born out of water [263 of 9868 infants (2.7%) vs. 224 of 5078 infants (4.4%); adjusted odds ratio, 0.65; −∞ to 0.79].

All upper confidence intervals of the primary outcomes were lower than the prespecified margins of non-inferiority; therefore, we conclude that the rate of the primary outcomes for mothers and their babies were no higher among waterbirths than among births out of water.

Rates of the individual components of the neonatal primary outcome were: Intrapartum or neonatal death, which occurred in three babies born in water (0.3. per 1000 births) and zero in babies born out of water. Respiratory support on a neonatal unit was provided to 91 (0.9%) of babies born in water and to 104 (2.0%) of babies born out of water; (adjusted odds ratio 0.44, one-sided 95% confidence interval −∞ to 0.60). Antibiotics were administered within 48 hours of birth to 263 (2.7%) babies born in water and to 224 (4.4%) babies born out of water (adjusted odds ratio 0.65, −∞ to 0.79).

The online survey and interviews identified various factors influencing the use of birth pools in the United Kingdom and emphasised the need to address issues related to resource availability (including midwives with experience of waterbirth), unit culture and guidelines and staff endorsement. The site case studies found obstetric units less facilitating of waterbirth compared to midwifery units in relation to equipment and resources, staff attitudes and confidence, senior staff support and women's awareness of water immersion.

Limitations: Limitations of the study included the inability to reliably identify women with medical or obstetric complications recorded in their medical records and the possibility of confounding between groups that were not known or could not be adjusted for – including reason for getting out of pool.

Conclusion: For women without pregnancy and labour complexities who use water immersion during labour, birth in water was as safe for mothers and their babies as birth out of water. This study supports policy and practice to enable women with an uncomplicated pregnancy and labour, who use intrapartum water immersion, to have the choice of remaining in, or leaving, the water to give birth.

Future work: Having established the safety of waterbirth for women and their babies, future work should concentrate on methods to reduce rates of severe perineal trauma during spontaneous vaginal births; support women to access water immersion during labour; improve understanding of the psychosocial impact of birth environments, including birth pools; increase understanding of the physiological impact of labour and birth in water; and measurement of blood loss in water.

Trial registration: This trial is registered as Current Controlled Trials ISRCTN 13315580.

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Glossary

Risk classification of women The National Institute for Health and Care Research's commissioning call classified the patient group of interest as women who are defined by National Institute for Health and Care Excellence (NICE) as at 'low risk'. The criteria of 'low risk' within maternity care are ones of exclusion. The NICE Intrapartum Care Guidelines for healthy women and their babies during childbirth list conditions that, if present, should be regarded as an indication to either advise birth in an obstetric unit or offer individual assessment when considering the planned place of birth. In this report, we have regarded these conditions as intrapartum risk factors. We have used the terms 'low risk' or 'women without complexities' when referring to women without risk factors recorded in their antenatal records; we also use this term to refer women giving birth after sites opened, for whom there were also no risk factors recorded at the time of first pool use in labour. We have used the terms 'high risk' or 'women with complexities' when referring to women with identified risk factors.

Use of language We use the words 'women' and 'woman' throughout this report, recognising that this reflects the biology and identity of the great majority of those who are in childbearing stage. In this report, these terms include girls and people whose gender identity does not correspond with their birth sex or who may have a non-binary identity.We use the words 'mothers and their babies' to reflect the importance of this dyad. In this report, this term includes childbearing women who gave birth to a child on behalf of another person or couple.

Pool usage for labour and birth Women were pragmatically defined as having used water immersion for labour or birth, if this had been recorded in their maternity record. This will have included women who used a bath, specialist birth pools or any other form of water immersion. When referring to babies born into water, the terms waterbirth and birth in water are used throughout the report.

List of abbreviations

AMU	alongside midwifery unit
AOR	adjusted odds ratio
BBA	born before arrival
BMI	body mass index
CAG	Confidentiality Advisory Group
CI	confidence interval
CRP	C-reactive protein
CTG	cardiotocograph
CU	Cardiff University
DM	data manager
FMU	freestanding midwifery unit
GBS	group B streptococcus
HR	heart rate
HRA	Health Research Authority
IPW	inverse probability weighting
IRR	incidence rate ratio
IUGR	intrauterine growth restriction
IV	instrumental variable
MIS	maternity information system
MLU	midwifery-led unit
NBM	negative binomial model
NCT	National Childbirth Trust
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
NNRD	National Neonatal Research Database
NNU	neonatal unit
OASI	obstetric anal sphincter injury
OR	odds ratio
OU	obstetric unit
PPI	patient and public involvement
PPH	postpartum haemorrhage
RCT	randomised controlled trial
RDS	Research Data Storage
RECORD	Reporting of studies Conducted using Observational Routinely collected health Data
RR	relative risk
SAP	statistical analysis plan
SGA	small for gestational age
SMG	study management group
SSC	study steering committee
SSH	Secure Shell
SVB	spontaneous vaginal birth
UOR	unadjusted OR
VBAC	vaginal birth after caesarean
WS	Wellbeing Software

Plain language summary

Using a birth pool, or bath, to be immersed in warm water should be offered as a choice of pain relief to women in labour with 'low-risk' pregnancies. 'Low risk' in maternity care refers to women without medical or pregnancy complications.

Among women who use water immersion during labour, some leave the water before birth, and others remain in the water and the baby is born underwater. When a baby is born underwater, this is known as waterbirth. There have been reports of babies becoming seriously ill, or even dying, after waterbirths. Some people were concerned that mothers were more likely to have severe tears or heavy blood loss. These are important outcomes for women, as heavy blood loss can be life threatening and severe tears need to be repaired with surgery and can cause distressing longer-term problems such as pain and incontinence. We therefore undertook a study to find out if waterbirths in the United Kingdom are as safe as giving birth out of water for women and their babies at low risk of complications.

Our study, called POOL, looked at the National Health Service records of 87,040 women who used a pool in labour between 2015 and 2022, across 26 National Health Service trusts. We compared women who gave birth in water to those who left the pool for extra medical care or more pain relief. Most of the women who got out of the pool for extra medical care were first-time mothers (1 in 3 compared to 1 in 20 of the women who had previously given birth). We looked at rates of severe vaginal tears experienced by women and rates of babies dying, needing antibiotics or help with their breathing.

Overall, we found that around half of all women who used a pool in labour had a waterbirth. The rate of problems was very similar in waterbirths and births out of water. Around 1 in 20 first-time mothers, and 1 in 100 mothers having their second, third or fourth baby, had a severe tear. Around 3 in every 100 babies needed antibiotics or help with their breathing after birth, and baby deaths were rare.

Interviews and visits to maternity units found some units were more supportive of offering women the option to labour and give birth in water than others. Midwifery units were found to largely have better facilities for water immersion and waterbirths and more confident supportive staff than obstetric units.

The POOL Study concluded that among low-risk women giving birth in the National Health Service who used water immersion during labour, staying in the water and giving birth in water were as safe for them and their babies as leaving the water before birth.

Scientific summary

Objectives

The primary study objective was to establish whether, in the case of 'low-risk' women who use a pool during labour, waterbirth, compared to birth out of water, is as safe for mothers and their babies.

The secondary objectives of the study were to:

- Evaluate if the waterbirth was associated with an increase in adverse infant outcomes or treatment, including asphyxia, infection, respiratory difficulties and mortality; or maternal morbidity, particularly complex perineal trauma [obstetric anal sphincter injuries (OASIs)] and haemorrhage.
- Assess the primary safety outcomes among the subgroups of nulliparous and parous women who were 'low risk' at labour onset.
- Describe rates and treatment of haemorrhage for 'low-risk' women who, following birth in water, deliver the placenta underwater. This was also to be described for women who leave the water prior to delivery of the placenta.

The study also planned to:

- describe the proportion and characteristics of women who used a pool for labour or birth compared to women who do not use a pool
- describe the characteristics of, and outcomes for, women with identified risk factors at labour onset, who used a pool during labour
- describe the characteristics of and outcomes for women who develop labour complications who used a pool during labour, inclusive of labour interventions such as cardiotocograph (CTG) and augmetaion with oxytocin.
- explore factors associated with high and low rates of pool use in individual maternity units.

Methods

The POOL Study was a natural experiment using a cohort design with a nested qualitative component. The cohort study used a combination of retrospective and prospective data captured in electronic NHS maternity and neonatal information systems at 26 sites. The qualitative component explored factors influencing pool use and waterbirth through online chat groups, interviews and case studies.

To extract, link and analyse maternity data and data relating to babies who had been admitted to a neonatal unit (NNU), Cardiff University partnered with a maternity information system provider and the National Neonatal Research Database.

Setting

The study was set in 26 NHS maternity services with waterbirth facilities across England and Wales.

Main outcome measures

Maternal primary outcome: OASI (with planned subgroup analysis by parity); neonatal composite primary outcome: fetal or neonatal death (after the commencement of intrapartum care and prior to discharge home), NNU admission with respiratory support or the administration of intravenous antibiotics within 48 hours of birth.

Primary analysis was restricted to births where the woman: (1) was without complicating conditions in her antenatal records or recorded at the time of pool entry, (2) used water immersion during labour and (3) did not receive additional monitoring or interventions before birth. Separate a priori sample size calculations were undertaken for the maternal and neonatal primary outcomes.

Sample size

The non-inferiority of birth in water compared to birth on land on rates of OASI was examined by parity. A sample size of 15,000 nulliparous and 15,000 parous women (7500 each water and land) without antenatal complexities and who did not require additional monitoring or interventions before birth was required to obtain 90% power and a one-sided 95% confidence interval (CI) around a treatment difference of zero. A non-inferiority margin of ≤ 1% [odds ratio (OR) ≤ 1.23], and ≤ 0.6% (OR ≤ 1.38), was taken as clinically non-significant among nulliparous and parous women without antenatal complexities, respectively.

For the infant primary outcome, an estimate of 5% was used for the proportion of infants born to low-risk mothers experiencing 'adverse infant outcome or treatment'. A non-inferiority margin of ≤ 1.0% (OR ≤ 1.21) was taken as clinically non-significant. A sample size of 16,200 infants (8100 per group water/land) was required to have 90% power and a one-sided 95% CI around a treatment difference of zero.

For the infant primary outcome, an estimate of 5% was used for the proportion of infants born to low-risk mothers experiencing 'adverse infant outcome or treatment'. A non-inferiority margin of ≤ 1.0% (OR ≤ 1.21) was taken as clinically non-significant. A sample size of 16,200 infants (8100 per group water/land) was required to have 90% power and a one-sided 95% CI around a treatment difference of zero.

Participants

All women recorded as having used water immersion during labour or birth during the study period from 1 January 2015 to 30 June 2022 at 26 participating NHS organisations were eligible for inclusion. Water immersion during labour and waterbirths was identified and recorded as part of mandatory record-keeping by the attending midwives, and it included the use of baths, tubs or specialist birthing pools.

All births where care had been provided by the participating NHS organisation were included regardless of birth setting, including in obstetric units (OUs), at home or in midwifery-led units. Stillbirths, with fetal death occurring before the start of care in labour were excluded, as were births where a midwife was not in attendance, either because the women chose to give birth without professional assistance outside of a maternity unit or because of birth occurring at home or elsewhere before professional assistance arrived or could be reached.

Results

After removal of duplicates and ineligible cases, a total of 869,744 birth records were analysed, of which 87,040 (10.0%) included a record of water immersion during labour, including 46,827 (5.4%) waterbirths.

Among women without recorded antenatal risk factors or complicating factors at pool entry, 29% of nulliparous women and 5% of parous women who used a pool during labour received additional monitoring, obstetric interventions or regional analgesia, before or during birth. Among women using a pool during labour, without recorded antenatal risk factors or complicating factors at pool entry, and among nulliparous and parous women, respectively, rates of spontaneous vaginal births were 78.0% and 97.6%; rates of instrumental births were 10.9% and 1.6%; and rates of birth by caesarean section were 5.9% and 0.7%.

After adjusting for differences in the characteristics of women who used intrapartum water immersion and gave birth in or out of water: (1) among nulliparous women, rates of recorded OASI were no higher among women who gave birth in water than among women who left the pool before birth [730 of 15,176 women (4.8%) vs. 641 of 12,210 women (5.3%); adjusted odds ratio (aOR) 0.97; one-sided 95% CI, −∞ to 1.08]; (2) among parous women, rates of recorded OASI were no higher among women who gave birth in water than among women who left the pool before birth [269 of 24,451 women (1.1%) vs. 144 of 8565 women (1.7%); aOR 0.64; −∞ to 0.78] and (3) among babies, rates of the primary outcome were no higher among babies born in water than among babies born out of water [263 of 9868 infants (2.7%) vs. 224 of 5078 infants (4.4%); aOR, 0.65; −∞ to 0.79].

All upper CIs were lower than the prespecified margins of non-inferiority; therefore, we reject the null hypothesis and conclude that waterbirth is non-inferior to giving birth out of water.

Rates of the individual components of the neonatal primary outcome were: intrapartum or neonatal death – occurred in three babies born in water (0.3. per 1000 births) and in zero babies born out of water. Respiratory support on a NNU was provided to 91 (0.9%) of babies born in water and to 104 (2.0%) of babies born out of water; (aOR 0.44, one-sided 95% CI −∞ to 0.60). Antibiotics were administered within 48 hours of birth to 263 (2.7%) babies born in water and to 224 (4.4%) babies born out of water (aOR, 0.65, −∞ to 0.79).

There was a higher rate of snapped umbilical cords prior to clamping in the infants born in water compared to those born out of water (1.0% *N* = 106 vs. 0.3% *N* = 16, respectively) (aOR 3.89, one-sided 95% CI −∞ to 6.88). In 8.6% (*N* = 926) of waterbirths, the placenta was also delivered in water. Rates of postpartum haemorrhage (≥ 1000 ml) were similar when the placenta was delivered in water or out of water (aOR 0.70 one-sided 95% CI −∞ to 1.18).

The qualitative work found considerable differences between OUs and midwifery units in relation to equipment and resources, staff attitudes and confidence, senior staff support and women's awareness of water immersion and waterbirth. Findings have several implications for practice: increased exposure to care of women during water immersion and waterbirth is vital to improve the confidence of midwives working in OUs; training for obstetricians and neonatologists on the practicalities and outcomes of pool use could increase support for water immersion and waterbirths; and improved access to antenatal information would help increase awareness of the option to use a pool during labour and birth.

Limitations

Limitations of the study included the inability to reliably identify women with medical or obstetric complications recorded in their medical records and the possibility of confounding between groups that were not known or could not be adjusted for – including reason for getting out of pool.

Conclusions

The POOL Study established that among nulliparous and parous women, without antenatal complicating conditions, who used water immersion during labour, and who did not receive additional monitoring or interventions prior to birth, remaining in the water to give birth was not associated with an increase in the incidence of OASI, or the primary adverse neonatal outcome.

Current NHS midwifery practice relating to labour and birth in water is safe for women and their babies. Women, parents, families, practitioners and policy-makers should be reassured that birth in water, in the context of NHS care, is not associated with increased risks for mothers or their babies. Women considering or using water immersion during an uncomplicated labour should be informed that remaining in the water to give birth is not associated with an increased risk to themselves or their baby, and they should be supported to make evidenced-based, individualised decisions on their care.

Research priorities

1. Interventions to reduce rates of OASI during vaginal births.
2. Women's experiences of use of water during labour and birth, including impact on potential short-term and longer-term impacts, for example, maternal–infant attachment, postnatal depression, sense of control and self-efficacy. This work should focus on marginalised and culturally diverse communities.
3. Impact of waterbirth on neonatal physiology and transition to extrauterine environment.
4. Blood loss measurement in water.
5. Midwifery care during waterbirth, including in the event of non-spontaneous birth of the fetal shoulders.
6. Care of babies following cord snapping.
7. Teaching of care of women during water immersion and waterbirth to student midwives and midwives.
8. Evaluation of the cost effectiveness of waterbirth vs. births out of water.

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Chapter 1 Introduction

Background and waterbirth in the National Health Service

Water immersion during labour and birth was first introduced into NHS care in the late 1980s[1] as a method of non-pharmacological pain relief, and it has now become part of mainstream maternity care for women with uncomplicated pregnancies, particularly in midwifery-led units (MLUs) and at home births.

Water immersion during labour can be facilitated in most birth settings, and NHS maternity units usually have specialist birth pools that vary in design. All birth pools offer sufficient depth of warm water for the woman to immerse her abdomen when sitting and sufficient space for her to move and change position easily; some pools have additional features such as inbuilt lighting and thermoregulation functionality, while inflatable, portable pools, with disposable liners are available for home or hospital use. Women enter the warm water, usually once labour is established, and either remain in the pool to give birth or leave the pool prior to birth, either through choice or due to clinical concerns. For those who give birth in the pool, some remain there until after delivery of the placenta.

To support women having more choice and control over their care options during labour, in 1992, the House of Commons Health Committee (Winterton Report) recommended that hospitals should provide women with the use of a birth pool for labour '*where this is practicable*',[2] but at this time, the practice was uncommon. A 1993 survey estimated that annually around 2250 women gave birth in water in England and Wales, with an additional 1900 women using a pool during labour.[3] Births in water increased over the next decade, with surveys of maternity care in England reporting rates of 4.8% in 2006[4] and 5.1% in 2010.[5]

A Cochrane review published in 2004[6] identified eight international trials of water immersion during the first stage of labour (N = 2939) and found that there was a statistically significant reduction in the use of epidural/spinal/paracervical analgesia/anaesthesia among women allocated to water immersion during the first stage of labour compared to those not allocated to water immersion [odds ratio (OR) 0.84, 95% confidence interval (CI) 0.71 to 0.99, four trials, N = 2406]. One small trial included in the review found that women who used water immersion during the first stage of labour reported statistically significantly less pain than those not labouring in water (40/59 vs. 55/61) (OR 0.23, 95% CI 0.08 to 0.63). Pooled data from other small trials included in the review found no detrimental effect on neonatal Apgar scores at 5 minutes (five trials N = 1834), rates of neonatal unit (NNU) admission (two trials N = 1511) or rates of neonatal infection (two trials N = 1262). Just one trial[7] (N = 117) compared immersion during the second stage of labour, but it was too small to reach conclusions on the impact of birth in water for mothers or their babies.

Informed by the 2004 Cochrane review, in 2007,[8] the National Institute for Health and Care Excellence (NICE) recommended that women should be offered water immersion during the first stage of labour due to its analgesic effectiveness but recommended that there was insufficient high-quality evidence to support or discourage birth in water.

Benefits for women of warm water immersion during labour or birth have been poorly explored, but studies suggest they extend beyond pain relief. A meta-synthesis[9] included seven studies exploring experiences of women who had used water immersion during labour and/or birth. The review found that women described positive experiences of warm water immersion. The warmth provided comfort, the buoyancy facilitated women's ease of movement and change of position, and the birth pool space provided a safe space in which women could relax and claim as their own.

The availability of waterbirth facilities in the UK further increased following publication of the Birthplace in England study in 2011,[10] which found planning birth in MLUs was as safe for mothers and babies as planning birth in an OU. This led to an increase in the proportion of births in MLUs, which commonly have waterbirth facilities, to 14% between 2010 and 2016.[11] In 2015, 9% of 20,631 postnatal women who responded to a Care Quality Commission survey had experienced a waterbirth.[12] Based on 700,000 live births annually in England and Wales,[13] and a 60% spontaneous vaginal birth (SVB) rate,[14] these data suggested that up to 52,000 babies were being born into water annually.

Justification for the study

Despite the high numbers of babies born into water under NHS care, evidence of safety from randomised trials is lacking. Pilot and feasibility randomised trials of waterbirth have been undertaken,[7,15] the largest of which was conducted in Australia, recruiting 1260 participants;[16] but it concluded that a trial of sufficient size, powered to detect a difference in serious neonatal morbidity was unlikely to be feasible.

Several cohort studies have reported outcomes of births in water, but with either potential limited applicability to the UK setting,[17] insufficient size to explore rare but important outcomes,[18] or with inadequate methods to compare outcomes between women who give birth in water with a similar group who experience an uncomplicated pregnancy and labour but give birth out of water by choice rather than due to clinical need.[19]

The potential for waterbirth to cause harm to babies has been highlighted by early case reports of adverse neonatal outcomes, including neonatal water aspiration,[20] infection[21,22] and hyperthermia.[23]

Adverse neonatal outcomes resulting in perinatal deaths or survival of babies with cerebral palsy have devastating lifelong consequences for families and surviving children. They also have important economic implications to the NHS, with a daily tariff for neonatal intensive care at £1811[24] and settlements for cerebral palsy resulting from clinical negligence having expected values of £10M.[25] Case reports of adverse neonatal outcomes following, and often attributed to birth in water,[26] have continued, and despite studies suggesting no increase in rates of adverse neonatal outcomes,[17,18] widespread scepticism remains particularly among neonatal and paediatric healthcare professionals in the UK and internationally about the safety to babies of birth in water.

Clinical concern also remains around the potential of waterbirth to be associated with increased rates of severe perineal trauma.[27] Rates of identified severe perineal trauma, involving the anal sphincter, among women giving birth vaginally to their first baby in England between 2000 and 2012 tripled from 1.8% to 5.9%.[28] Although it is recognised, the increase probably reflects improved detection, and reporting[28] reducing obstetric anal sphincter injury (OASI) is important as it is associated with faecal incontinence, dignity loss, psychosexual morbidity and a compromised role as a mother.[29] It has been suggested that birth in water may be associated with increased rates of severe perineal trauma due to the inability of midwives to implement physical perineal protection[27] as recommended by the Royal College of Obstetricians and Gynaecologists.[30]

The recently published 2023 update of NICE guidance for care of women in labour stated there continues to be insufficient high-level evidence to inform whether women who use water immersion during labour should be advised to leave, or remain in, the pool for birth.[31] It is this gap in knowledge that the POOL Study was designed to address.

Study objectives

The primary study objective was to establish whether, in the case of 'low-risk' women who use a pool during labour, waterbirth, is as safe for mothers and infants as birth out of water.

The secondary objectives of the study were to:

- Evaluate if waterbirth was associated with an increase in adverse infant outcomes or treatment, including asphyxia, infection, respiratory difficulties and mortality; or maternal morbidity, particularly complex perineal trauma (OASIs) and haemorrhage.
- Assess the primary safety outcomes among the subgroups of nulliparous and parous women who were at 'low risk' at labour onset.
- Describe rates and treatment of haemorrhage for 'low-risk' women who, following birth in water, deliver the placenta underwater. This was also described for women who leave the water prior to delivery of the placenta.

The study also planned to:

- describe the proportion and characteristics of women who used a pool for labour or birth compared to women who do not use a pool
- describe the characteristics of, and outcomes for, women with identified risk factors at labour onset, who used a pool during labour
- describe the characteristics of and outcomes for women who develop labour complications, who used a pool during labour, inclusive of labour interventions such as cardiotocograph (CTG) and augmentaion with oxytocin.
- explore factors associated with high and low rates of pool use in individual maternity units.

Chapter 2 Methods 1: cohort study

Cohort study design

The cohort study was a natural experiment using a combination of retrospective and prospective data captured in electronic NHS maternity and neonatal information systems. It was designed as a non-inferiority study, and all primary comparisons were analysed and are presented on this basis.

Study participants: inclusion and exclusion criteria

Local maternity information systems (MISs) capture data on all pregnancies and births in their area, where maternity care is provided by the NHS, including births in OUs, MLU or at home. To identify women who used any form of water immersion during labour or birth, the fields, 'use of a pool during labour' and 'waterbirth', were used pragmatically. This identified women who used water immersion in a conventional bath or any form of birthing pool during labour.

All registrable births occurring at the 26 participating NHS sites between 1 January 2015 and June 30 2022 were included. Registrable births in the UK include live births at any gestation and stillborn babies, that being babies born without signs of life at or after 24 + 0 weeks of gestation. Data relating to women who opted out from the study and their babies were not received, and births recorded as being unattended by a midwife due to them being classified as 'born before arrival' (BBA), in transit or freebirths, were excluded.

Outcomes

Primary outcomes

There were two primary outcomes:

- The *maternal primary outcome* was severe perineal trauma of OASI.
- The *infant primary outcome* was a composite of 'adverse infant outcomes or treatment' to include:
  i. any NNU admission requiring respiratory support
  ii. intravenous antibiotic administration within 48 hours of birth (with or without culture proven infection)
  iii. intrapartum stillbirth and all deaths prior to NNU/postnatal ward discharge.

Secondary outcomes

Maternal intrapartum secondary outcomes

- Incidence of shoulder dystocia and required management.
- Management of the third stage of labour (including whether the placenta was intended to be, or delivered, in or out of water).
- Rates and management of postpartum haemorrhage (PPH).
- Need and reason for obstetric involvement in woman's care (including sepsis, treatment for haemorrhage).
- Incidence and management of perineal trauma.

- Maternal position at birth.
- Mode of birth.

Maternal postnatal secondary outcomes

- Duration of postnatal hospital stay.
- Breastfeeding initiation and continuation.
- Higher-level care.
- Maternal re-admission to hospital within 7 days of birth.

Infant secondary outcomes

- Snapped umbilical cord prior to clamping.
- Timing of cord clamping.
- Apgar scores at 1, 5 and 10 minutes.
- Resuscitation at birth.
- Intrapartum stillbirth or deaths prior to NNU/postnatal ward discharge.
- Cause of intrapartum stillbirth or death prior to NNU/postnatal ward discharge.
- Skin-to-skin contact at birth.
- First breastfeed within first hour.
- NNU admissions.
- Respiratory support.
- Therapeutic hypothermia.
- Brachial plexus injury.
- Treatment for jaundice.
- Successful/attempted lumbar puncture.
- Administration of intravenous antibiotics, including timing and duration.
- Highest C-reactive protein (CRP).
- Blood culture positive with a recognised pathogen (excluding skin commensal organisms).
- Neonatal deaths that occurred within 7 days of birth on a NNU/postnatal ward.
- Re-admission to hospital within 7 days of birth.

Data sources

Identification of data sources

Due to the need to identify a cohort of women who used a pool during labour and to compare outcomes between those who remained in or left the pool for birth, it was essential for the study to identify data sources that captured pool use during labour as well as separately capturing birth in water. Mapping data fields within national maternity data sets against the study objectives in 2017 confirmed that some essential data items were not exported from NHS sites to national data sets. This included a field to identify women who used water immersion during labour but not for birth. As this was central to the research question, this confirmed that national maternity data sets could not be used for this study. In addition, other data items, including some required to inform the neonatal primary outcome, were not captured at either local or national level. Therefore, to design a study to answer the National Institute for Health and Care Research (NIHR) commissioning brief questions, while meeting the requirement to maximise the use of existing routinely collected data, it became apparent that existing routinely collected data at NHS site level could be used but would need to be supplemented with additional data fields.

As local MISs are required to be adaptable to accommodate changing clinical and monitoring requirements, they have the facility for additional data items to be added or adapted. The decision was taken to add study-specific data fields to existing local NHS maternity systems completed by midwives as part of usual maternity care and for the records to be extracted at regular time points during the study. Two data sources were identified – maternity records held

in Euroking® (Magentus Maternity Software Ltd, London, England) MISs and neonatal records held by the National Neonatal Research Database (NNRD) at Imperial College London.

Partnered maternity information system

Electronic MIS forms a comprehensive maternity data set covering the antenatal, intrapartum and postnatal period. MISs provide similar functionality, but due to the complexity of data extraction, a decision was taken by the study team to collaborate with a single large electronic MIS provider. In 2016, at the time discussions began, the Euroking MIS, provided by Wellbeing Software® (WS, Magentus Maternity Software Ltd, London, England), was the most used system in the UK.[35] In 2016, the system captured data relating to 96,951 births, including 6037 (6.2%) waterbirths in NHS sites, ranging in size from approximately 1500 to 10,000+ annual births. As such, these units were able to provide the volume of data required for the planned study, could be adapted to the study need and had the advantage of being familiar to the clinically based investigators.

National Neonatal Research Database

The NNRD[36,37] holds individual patient-level data on all infants admitted for NHS neonatal care in England, Wales and Scotland. Approximately, all 200 NNUs in England, Wales and Scotland form the UK Neonatal Collaborative and contribute electronic health record data to the NNRD. The data set held by the NNRD comprises 450 clearly defined variables extracted at patient level from the electronic health record systems used by UK NNUs.

Field identification

To identify which of the existing fields would be required for the study, the statistician, with clinical support, matched the existing Euroking MIS data dictionary to those required for the POOL Study. Required fields included those to define and characterise all women, including whether a pool was used, potential confounders and outcomes.

Fields required to answer the research questions but not present in the existing data dictionary were identified, defined and developed. These fields were: maternal or pregnancy risk factors present at pool entry; the use of continuous electronic fetal monitoring in water; the administration of intravenous oxytocin for labour augmentation in water; births occurring partially in water; umbilical cord snapping prior to clamping; neonatal antibiotic administration on the postnatal ward and clinical markers for neonatal infection; and management of placental delivery following waterbirth.

To be able to compare characteristics of women who did, or did not, use a pool in labour, data were required on characteristics of women who did not use a pool in labour. The two required data sets were identified. The data set for women who did not use a pool in labour consisted of 80 variables compared to 201 variables within the data set for women who used a pool.

Data collection period

The maternal primary outcome analysis included births between 1 January 2015 and 30 June 2022. The neonatal primary outcome analysis included births from the date of individual sites opening to 30 June 2022.

Follow-up period

The duration of follow-up for the study was until discharge from maternity community postnatal care. For NNRD data, the duration of follow-up was up to NNU discharge.

Recruitment of sites

Potential NHS study sites were identified as those NHS Trusts or Health Boards with an ongoing contract with WS and with waterbirth facilities. Each potential site was contacted by the study manager, inviting them to register an interest in

study participation. The proposed NHS site principal investigator provided a Curriculum Vitae and a valid Good Clinical Practice certificate. Contracts were set up between Cardiff University (CU) and the NHS sites and once signed, a site initiation visit was undertaken. Site-specific study information materials were prepared and issued to sites.

Once contracts were in place, a statement of works was drafted, describing the required technical interaction between WS and each NHS site, which was subsequently signed off by each NHS site, CU and WS. Following signing of the statement of works, WS would approach the lead for the maternity software system and agree to a timeline for testing and implementation of the 12 additional study-specific data fields. A further approval process was required prior to implementation of the new data items, a 'Request for Change', which, in many sites, needed information governance or senior information technology team sign off. As all MISs are bespoke, prior to release into the live clinical system, testing of the new data items in their parallel system was required at each study site. Once the local lead was satisfied, the new data items were compatible with their system and staff were trained in the study, a date for their introduction into the live clinical system was agreed. The final step was for WS to compare each local site's data dictionary to their central held data dictionary to ensure that all data fields required for the study were available from the site. E-mails seeking formal study participation were sent to known prospective sites from August 2018. The first contract with study sites was signed in January 2019, and the last was signed in August 2020. The period from the date of a contract being signed between the NHS site and CU and new data fields being implemented in the NHS sites' maternity software systems ranged from 1 to 11 months, with most sites (n = 17) taking between 2 and 6 months (*Figure 1*).

Governance approvals

To ensure results were generalisable, it was important that as few women as possible were excluded, and for this reason, the study was based on an opt-out design without individual consent. The extraction and access of deidentified medical records for research is a common approach for observational studies. However, matching maternity and NNU data required the transfer of identifiable, personal data outside of the NHS. Section 251 of the NHS Act 2006, as granted by the Health Research Authority (HRA) Confidentiality Advisory Group (CAG), allows the transfer of '*confidential patient information without consent … without being in breach of the common law duty of confidentiality*'.[38]

Data protection regulations were upheld, such as ensuring women were informed and aware of the research activities and had an opportunity to opt out without any impact on their health care. The intention was for all women giving birth

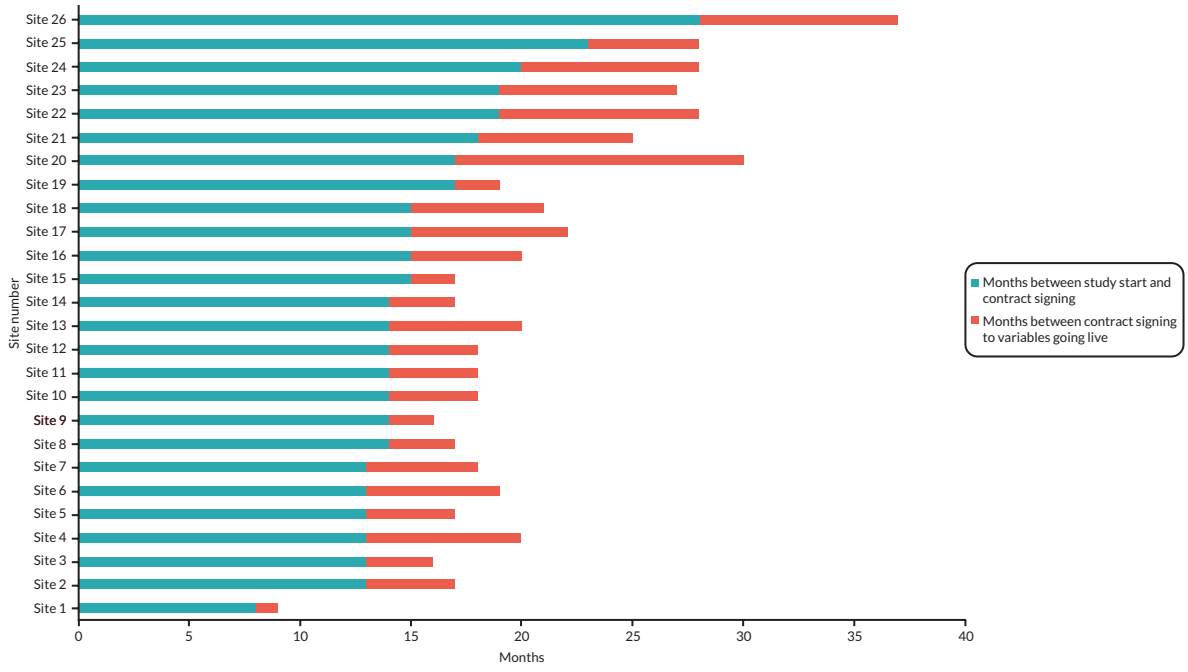

FIGURE 1 Duration of study set-up at sites.

at study sites after site opening to be informed about the study through methods selected by individual sites, including leaflets, posters, take-away cards and postings on websites (see *Appendix 1*). The application to CAG proposed that women could request to opt out of the study by informing their midwife at any point in pregnancy, around the time of birth or after consideration at home. Women who had given birth at study sites in the period from 1 January 2015 up to the date of the site opening could not opt out, as attempting to facilitate this would have been unfeasible.

Ethical approval

The protocol was approved by NHS Wales Research Ethics Committee on 18 September 2018 (18/WA/0291) and the transfer of identifiable data was approved by HRA CAG on 2 November 2018 (18CAG0153).

The approval committees accepted that women giving birth prior to site opening could not be informed that their data would be included, but they were concerned that an individual woman may feel reluctant to indicate her desire to opt out of the study to a midwife providing direct clinical care to herself or her baby. It was requested that we include the proactive provision of information to women using a pool during labour and provide alternative options for women to phone and/or e-mail the maternity unit to request that they are not included the study. For this purpose of opting out, sites were provided with posters for clinical areas and with 'business card'-sized information to give to all women who used a pool. As part of the modification to the local systems, a study opt-out tick-box was added to the local electronic maternity record, which could be ticked by any member of the clinical team with access to a record until it was closed following discharge from postnatal community maternity care. This flag was visible to the data processor, who did not extract any data related to flagged records. A list of ethical amendments to the ethics are available in *Appendix 2*.

Data management

To create a single record combining individual maternity and NNU records, without identifiable data (personal identifiers), a method of linkage was required. To ensure that data received by CU from sites and the NNRD could be linked once the identifiable data had been removed, linking numbers were created by the statistician. The linking number comprised a code for the NHS organisation, the quarter and year of data, six randomly generated digits and a flag for the mother or baby (*Table 1*). Linking fields were unique to each mother/baby and were attached to each maternity record by WS.

The POOL Study data flow is shown in *Figure 2*. After maternity (maternal and neonatal) data were extracted on a site-by-site basis, the mother and baby linking fields were sent with each baby's NHS number to the NNRD. The NNRD identified babies who had been admitted to a NNU by matching babies' NHS numbers sent to those held within the NNRD. Each baby's data, and the mother's and baby's ID (with the NHS numbers removed) were then sent to CU. The NNRD data were then linked to the maternity records via the linking field. It was not possible to identify or longitudinally link the pregnancies of women who had had more than one pregnancy during the study period.

Data access, storage and cleaning

Access and transfer of data

Data held at study sites were sent electronically to CU via Secure Shell (SSH – a public-key cryptography to authenticate a remote computer and allow it to authenticate the user). This provided WS with access to a secure folder

TABLE 1 Development of linking numbers

NHS organisation	Quarter and year	ID (Euroking pregnancy ID)	Mother/baby	Linking number
10	119	000123	Mother – 0	101190001230
10	119	000123	Baby 1 – 1 (birth order)	101190001231
10	119	000123	Baby 2 – 2 (birth order)	101190001232

ID=identifier.

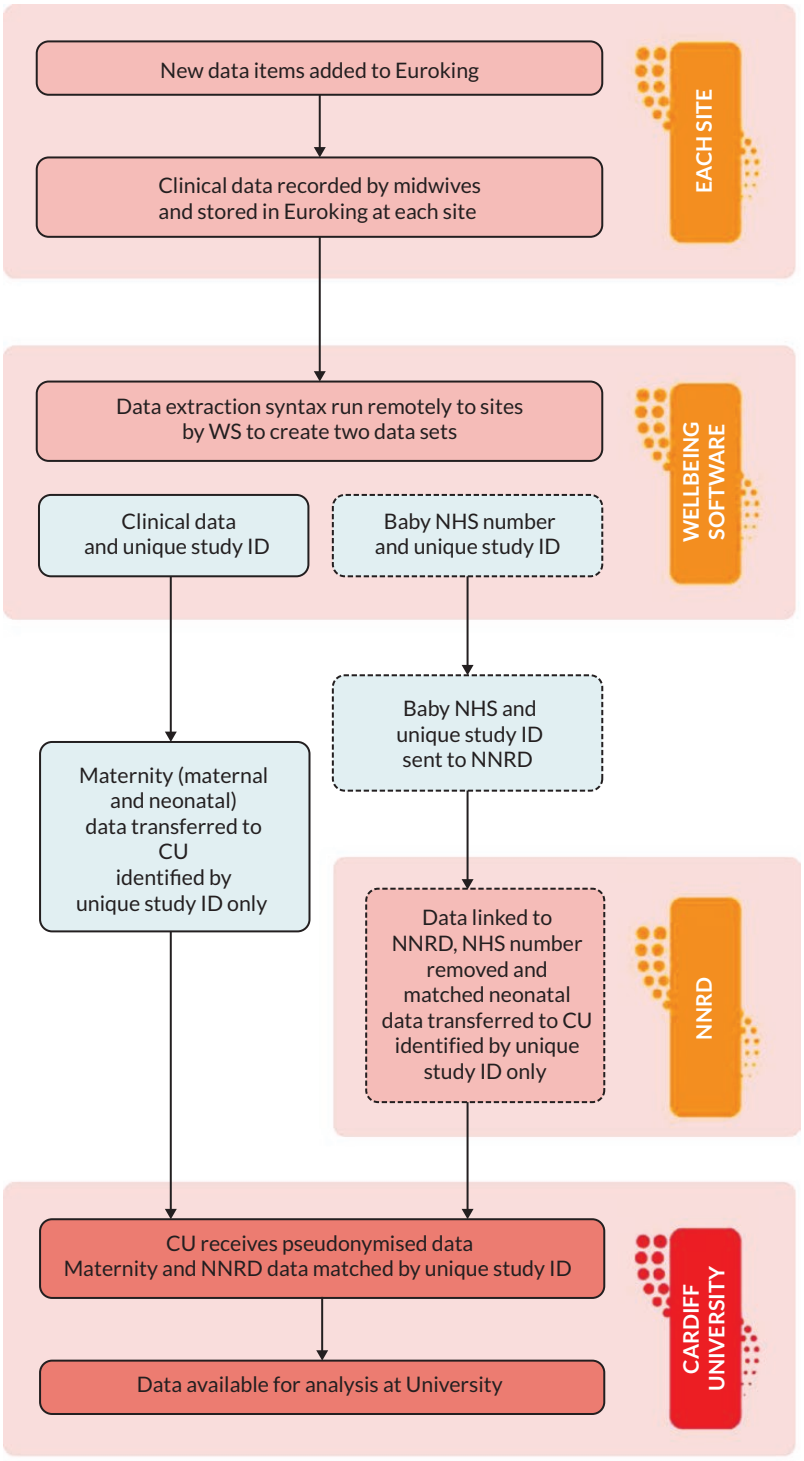

FIGURE 2 POOL Study data flow.

on CU servicers, which could only be accessed by the data manager (DM) and the account holders from WS. To ensure continued access when the COVID-19 pandemic began, additional access was granted to the study manager and statistician. To access data at participating sites, WS securely logged into the NHS site server and created the extracts. Extracts were then transferred to WS servers and formatted prior to transfer to CU and the NNRD. Once transfer had successfully occurred, extracts were deleted from the WS servers and the DM then moved the files to a folder which could not be accessed by WS staff. All NNRD data were sent to CU via the Imperial College London file exchange, a secure file transfer system.

Data storage

All data were stored in a secure study-specific data storage at CU, with access restricted to the DM and the statistician. Data sets were delivered in password-protected Comma Separated Values format and were moved to Statistical Product and Service Solutions (SPSS) (SPSS Inc., Chicago, IL, USA) via syntax. The SPSS files were then also stored in the secure space.

Data cleaning

A Microsoft Excel® (Microsoft Corporation, Redmond, WA, USA) spreadsheet detailing data cleaning for all data received from WS was maintained. Each data file received contained 3 months (one-quarter) of data. The data cleaning process was detailed in a data cleaning plan (see *Appendix 3*). Once each file was imported into IBM SPSS, the initial check was to ensure records with pool use or no pool use could be identified. This quality check doubled up as a check to ensure that the data extracts had been created correctly. Data received from the NNRD were only received on two occasions, firstly during a pilot stage and at the end of data collection. The data cleaning process for NNRD was also detailed in the data cleaning plan; once all files were imported into IBM SPSS, the initial check was to ensure that all variables were received and then to match the identifiers with the WS data.

The second stage of data cleaning was changing the width of all variables so that they were consistent throughout the data set; this meant that when it came to merging the data sets, they could be merged without problems. Following this, the link IDs assigned were checked to ensure that they matched the prescribed format set out by the statistician. A check was made on each data batch received to ensure that they contained the correct variables and that the following variables derived by WS were within feasible or expected ranges: maternal age at delivery, gestational age at birth, parity, deprivation quintile, duration of rupture of the fetal membranes to birth, duration from head delivered to birth (in cases of shoulder dystocia) and duration of postnatal stay. Data outside feasible ranges or not as expected were set to missing. Frequencies were run on all variables and were visually checked for any outlying data or potentially identifiable information within free text fields. The identification of such data by the DM did not need to be reported as a data protection breech, as following a similar breech in the pilot, it was confirmed by the sponsor that the DM would be permitted to check for, and redact, identifiable data. The linking numbers were visually checked to ensure that they were in the correct format and that the mother and baby IDs were identical except the final number. Data sets were checked for duplicate records, and any duplicate record found was deleted. Data set quarters were merged into years and variable labels were added. Once all cleaning was completed for a site, the data files were merged to produce two files per site, one relating to pool use and one to non-pool use.

Full details of pilot work to assess the planned data management processes are described in *Appendix 4*.

Chapter 3 Methods 2: study populations

Identification of women who used a pool during labour

Women who used any form of water immersion during labour were pragmatically defined as any women for whom water immersion analgesia, or a waterbirth, had been recorded in the maternity record.

Identification of women who gave birth in water

Women were pragmatically defined as having given birth in water if this was recorded in their maternity record. To capture births commenced in, but completed, out of water, such as in the event of shoulder dystocia or previously unrecognised breech presentation, 'waterbirth' was defined in the study as 'a birth in which the fetus is partially or totally expelled under water'. A field recording 'partial births' in water was only available from records after site opening. Partial births in water occurring prior to site opening were identified from text entries in the records.

Identification of women with complexities

The criteria of 'low risk' within maternity care is one of exclusion. The NICE Intrapartum Care Guidelines[39] list conditions that, if present, should be regarded as an indication to either advise birth in an OU (see *Appendix 5*, *Tables 30* and *31*), or that suggest individual assessment should be undertaken prior to making a recommendation on the planned place of birth (see *Appendix 5*, *Tables 32* and *33*).

To identify women with any of the conditions listed by NICE indicating recommended birth in an OU, or individual care planning, fields held in the 'medical and surgical history' section, and other antenatal sections of records completed during the pregnancy were mapped to the NICE guidelines. For births after site opening, midwives also completed the new fields providing information on complexities present at the time of pool entry.

In combination, these fields were used to identify women with an identified complexity who used a pool in labour.

It was anticipated that the classification of risk may have differed between these two sources.

Risk classification categorisation based on the existing MIS antenatal fields is likely to provide a lower threshold for risk, potentially identifying women who experienced a complication in the past or during pregnancy, but for whom this was no longer present at pool entry, for example, a woman with an episode of hypertension during pregnancy, but who was later normotensive. Risk classification categorisation used by the midwife at pool entry is likely to provide a more pragmatic definition reflecting the opinion of the midwife providing intrapartum care.

For women who gave birth prior to site opening, for whom complexities relating to the time of pool entry were not available, if there was any record of a relevant factor in the antenatal notes, the woman was classified as complex.

For women who gave birth after site opening, if factors that cannot change over time were recorded in the antenatal notes, the woman was classified as complex regardless of whether this was also identified by the midwife providing intrapartum care, for example, a previous caesarean section.

For women who gave birth after site opening and where factors that can change over time were recorded in the antenatal notes, when these were not identified by the midwife providing intrapartum care, the woman was classified as without complexity, for example, hypertension, suspected macrosomia.

Medical and surgical information storage within Euroking

Magentus (formerly WS) notified users of the MIS, in a service bulletin dated 2 July 2023, of issues within their system in the management of pregnancy-specific data which, when carried over to the next pregnancy, overwrite the data relating to past pregnancies. These data included the data held within the 'Medical & Surgical History' menu. It was subsequently confirmed that all Euroking MISs, across all dates, were similarly affected.

Implications for the POOL data set

For convenience, when a woman 'books' for a second or subsequent pregnancy, the medical and surgical history section is opened, showing the entries from the previous pregnancy. This saves time and duplication of entry, as only required changes need to be entered. As the medical and surgical history had been stored as a single record at patient level, the original medical and surgical history, as recorded in the previous pregnancy, was overwritten.

By July 2023, when the study team became aware of how the data in the medical and surgical menu were held, all study data had been extracted and received by the study team and these data were used to risk classify women.

The fields contained in the 'Medical & Surgical History' were:

- cardiac problem
- haematological problem
- respiratory problem
- hepatic problems
- renal problems
- endocrine problem
- neurological problem
- musculoskeletal problem
- gynaecological problem
- operations
- infections
- mental health problem
- thromboembolic disorder
- genetic disorder
- thyroid problems
- deep-vein thrombosis risk assessment.

The POOL Study spans births occurring between 1 January 2015 and 30 June 2022. Many of the cohorts will have had more than one pregnancy during this period. As each woman is allocated with a different ID for each pregnancy, and due to the anonymised nature of the data, women with more than one pregnancy could not identified.

As a result, it was not possible to determine whether the medical and surgical history section contained within each maternity record received was correct or related to a future pregnancy for the same woman. For example, if a woman had three pregnancies and births within the POOL Study data set and was detected to carry group B streptococcus (GBS) only on her third pregnancy, as the medical and surgical data were held at patient level, within the POOL data set, the woman would be identified as a GBS carrier for all three pregnancies.

Impact on analysis relating to women without risk factors who used a pool in labour

The impact of the overwriting of medical and surgical information in the MIS was that factors recorded or developing during subsequent pregnancies were included in the history of all past pregnancies. As all women with factors identified in their records were excluded from the primary analysis, the impact of this was that more women than were necessary were excluded from the without complexity groups.

It is also possible that a medical problem recorded as present during one pregnancy will have been removed from the record during a future pregnancy. However, as the history taken at booking captures the 'current or past medical

and surgical history', conditions would normally be expected to remain in the record even if those are no longer an active concern.

Impact on analysis relating to women with risk factors who used a pool in labour

One of The POOL Study objectives was to establish the characteristics of, and outcomes for, women with identified complexities at labour onset, who used a pool during labour. Complexities recorded outside of the medical and surgical history menu in the antenatal record, and in the new field relating to the time of pool entry, were not compromised. All data held within the medical and surgical history fields were considered to be potentially compromised.

The impact was that women who had been classified as having complexities solely based on data in the potentially compromised fields needed to be removed from this analysis. This objective was answered using the prospective data only.

Impact on analysis relating to women who did not use a pool in labour

One of the POOL Study objectives was to describe the proportion and characteristics of women who used a pool for labour or birth compared to women who do not use a pool. It had been planned to identify women without risk factors who had not used a pool in labour, but this was not undertaken.

Study population groups

Women were separated into groups, depending on (1) their pool use for labour and/or birth; (2) the presence of complexities in antenatal records; (3) whether transfer to obstetric care for additional monitoring or interventions occurred prior to birth and (4) among women not transferred to obstetric care prior to birth, whether any midwife concerns were present before birth (*Figure 3* and *Table 2*). Records were categorised into the following groups:

- *Group 1* – without antenatal complexity – waterbirths

This comprised women who used a pool in labour, with no risk factors in their antenatal record or recorded at pool entry, without additional monitoring or interventions before birth, who had a waterbirth.

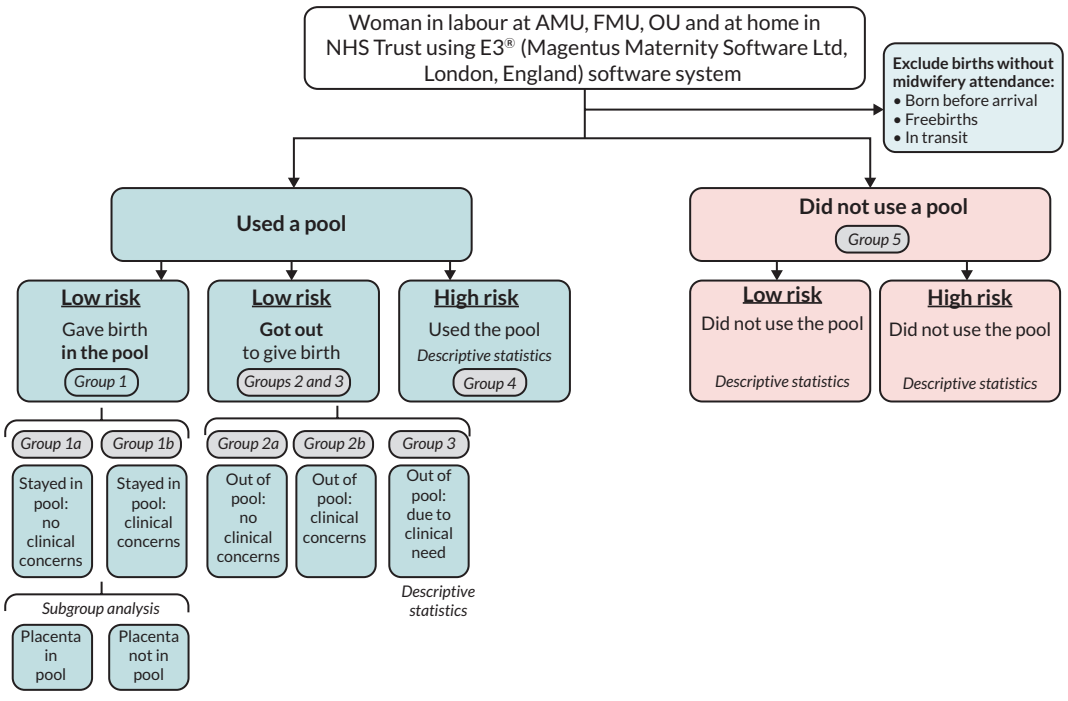

FIGURE 3 Study population: the five study groups. AMU, alongside midwifery unit; FMU, freestanding midwifery unit; OU, obstetric unit.

- 1a – no clinical concern recorded by the midwife as being present prior to birth.
- 1b – clinical concern recorded by the midwife as being present prior to birth.

- *Group 2* – without antenatal complexity – births out of water

This comprised women who used a pool in labour, with no risk factors in their antenatal record or recorded at pool entry, without additional monitoring or interventions before birth, who gave birth out of water.

- 2a – no clinical concern recorded by the midwife as being present prior to birth.
- 2b – clinical concern recorded by the midwife as being present prior to birth.

- *Group 3* –without antenatal complexity – with additional monitoring or interventions before birth

This comprised women who used a pool in labour, without risk factors in their antenatal record or recorded at pool entry, with additional monitoring or interventions before birth, including women who were transferred to obstetric care during labour.

- *Group 4* – with antenatal complexity

This comprised women who used a pool in labour with recorded risk factors in their antenatal record or recorded at pool entry.

- *Group 5* – women who did not use a pool during labour or birth, without antenatal complexity and with complexity.

Identification of women in group 1

Group 1 included women who used a pool in labour, with no risk factors in their antenatal record or recorded at pool entry, without additional monitoring or interventions before birth, who had a waterbirth.

Women were allocated to group 1 if all the following points applied:

- an absence of risk factors in their antenatal record
- an absence of risk factors at pool entry (for births after site opening)
- record of pool use in labour
- record of a waterbirth
- an absence of any record of an intervention which would move the woman to group 3.

Women allocated to group 1 remained in group 1 if any of the following were recorded:

- non-significant meconium (also described as light, or grade 1 or not described)
- women with recorded delay in the first stage of labour (but without the use of augmentaion with oxytocin)
- CTG monitoring performed with normal findings and discontinued
- significant meconium (or similar description) only seen at, or after, delivery of the fetal head
- partial births in water with breech presentation or shoulder dystocia
- tight nuchal cord
- any third-stage complications, for example PPH.

Women were identified by using a combination of the waterbirth field in maternity records (for all records); and, to capture births commenced in, but completed, out of water (such as in the event of shoulder dystocia or previously unrecognised breech presentation), the new waterbirth field was used: 'A birth in which the fetus is partially or totally expelled under water'. This information was only available from records after site opening. For the period of data collection where these additional data was not available, we took any recording of waterbirth as such. A small number of additional partial waterbirths were picked up in the additional field 'POOLLeftPoolNoReturn', where there was clear

evidence of a partial waterbirth recorded in the additional text (e.g. slow delivery of shoulders, stood up in pool to deliver and left pool to assist with delivering body).

Identification of women in group 2

Group 2 included women who used a pool in labour, without complexities recorded in their antenatal record or recorded at pool entry, without transfer to obstetric care during labour, who gave birth out of water.

Women were allocated to group 2 if all the following points applied:

- An absence of risk factors in their antenatal record.
- An absence of risk factors at pool entry (for births after site opening).
- Record of pool use in labour.
- No record of a waterbirth
- For women giving birth after site opening, the 'Reason for leaving pool before birth' is recoded as:
  - **I.** left pool for vaginal examination/use bathroom and did not return'
  - **II.** maternal decision to leave pool and did not return
  - **III.** left pool for further analgesia and did not return
  - **IV.** planned to labour but not give birth in water.

- An absence of any record of an intervention which would move the woman to group 3.

Women allocated to group 2 remained in that group if any of the following points were recorded:

- Non-significant meconium (also described as light, or grade 1 or not described).
- Women with recorded delay in the first stage of labour (but without augmentaion with oxytocin).
- CTG monitoring performed, but it was normal and discontinued
- Significant meconium (or similar description) only seen at, or after, delivery of the fetal head.
- Partial births in water with breech presentation or shoulder dystocia.
- Tight nuchal cord.
- Any third-stage complications, for example PPH.

Identification of women in groups 1a and 2a

Groups 1a and 2a were subgroups of groups 1 and 2. Women in groups 1 and 2 were eligible to be in group 1a or 2a, respectively, if there were no recorded clinical concerns prior to birth.

Identification of women in groups 1b and 2b

Groups 1b and 2b were subgroups of groups 1 and 2. Women in groups 1 and 2 were eligible to be in group 1b or 2b, respectively, if midwives recorded that there had been some midwife concern occurring before or during some births, but these either did not require, or had no time for, transfer to obstetric care.

To identify midwife concern present before birth, but that did not result in recorded obstetric involvement in a woman's care, we used a combination of existing fields (e.g. maternal/fetal intrapartum problems: 'Were there any maternal/fetal problems during labour?') and a new field (POOLLabourComplications), both with an option for open text comments.

Groups 1b and 2b included women where the midwife recorded that, prior to birth, there was:

- an abnormal fetal heart rate (HR) (fetal compromise, bradycardia, decelerations, fetal tachycardia, irregular heartbeat, rise in fetal heart baseline and fetal distress)
- some delay in second-stage progress (without instrumental birth)
- blood-stained liquor
- significant meconium-stained liquor (thick) seen prior to delivery of the fetal head
- intrapartum haemorrhage

- maternal hypertension/tachycardia/pyrexia/suspected infection (without treatment)
- reduced fetal movements
- other concern.

Identification of women in group 3

Women who used a pool during labour, without complexities identified in the antenatal records/or by the midwives at the time of pool entry, and who received additional monitoring or obstetric interventions before or during birth formed group 3.

Women were allocated to group 3 if all the following points applied:

- an absence of risk factors in their antenatal record
- an absence of risk factors at pool entry (for births after site opening)
- record of pool use in labour
- record of any of the following:
  - pain relief incompatible with use in water (e.g. epidural, remifentanil and pudendal block) before birth
  - Oxytocin augmentation of labour
  - CTG described as pathological, suspicious, abnormal or non-reassuring
  - breech presentation identified during labour with obstetric involvement in care
  - caesarean section or instrumental birth
  - transfer from home or a MLU during first or second stage of labour.
  - maternal pyrexia with investigation or treatment
  - receipt of instrumental variable (IV) fluids
  - antibiotics for suspected chorioamnionitis/sepsis
  - placental abruption
  - intrapartum eclampsia
  - additional obstetric monitoring or treatment.

Identification of women in group 4

Women who used a pool in labour, who had recorded risk factors in their antenatal record or (for births after site opening) recorded at pool entry, formed group 4.

TABLE 2 Study populations allocations

		Complexities in antenatal record or at pool entry				
	Pool use in labour	Present – high risk	Absent – low risk	Record of an intervention during labour	Clinical concern prior to birth	Birth in water
Group 1	✔	✗	✔	✗	–	✔
1a	✔	✗	✔	✗	✗	✔
1b	✔	✗	✔	✗	✔	✔
Group 2	✔	✗	✔	✗	–	✗
2a	✔	✗	✔	✗	✗	✗
2b	✔	✗	✔	✗	✔	✗
Group 3	✔	✗	✔	✔		[a]
Group 4	✔	✔	✗			[a]
Group 5	✗	✔	✔			✗

a Some women from groups 3 and 4 may also have given birth in water.

Identification of women in group 5

Women with no record of pool use during labour or birth were allocated to group 5.

Study populations for primary analysis

Two primary analyses were undertaken, as it was considered to be important to report 'real life', where concerns may be present prior to birth, and also to report on any impact of giving birth in water in the absence of any midwife concerns (*Table 3*).

Pooling of investigational sites

Records from all sites were pooled for the analysis. Sites were identified by their site ID number (and not named) and were included in the regression models as a random factor.

Study opt-out

Data held in a site's MIS relating to women who had opted out of the study were not extracted. The number of women who opted out per site over the study period are reported. Where sites changed their MIS supplier during the period of the study, births recorded in the new MIS were also not extracted.

Statistical analysis

Prior to commencement of the analysis, a statistical analysis plan (SAP) was produced (https://osf.io/pqadm), reviewed by the study management group (SMG), signed off by the chief investigator and statistician and approved by the Study Steering Committee (SSC) before data collection was completed and examined.

Sample size

The non-inferiority of birth in water compared to birth on land on rates of OASI was examined by parity. The Birthplace in England study[10] found that 4.6% and 1.6% of 'low-risk' nulliparous and parous women in spontaneous labour, respectively, sustained OASI. A sample size of 15,000 nulliparous and 15,000 parous women (7500 each water and land) without antenatal complexities, and who did not require additional monitoring or interventions before birth, was required to obtain 90% power and a one-sided 95% CI around a treatment difference of zero. Non-inferiority margins of ≤ 1% (OR ≤ 1.23) and ≤ 0.6% (OR ≤ 1.38) were taken as clinically non-significant among nulliparous and parous women without antenatal complexities, respectively. Since nulliparous women birthing in water are regarded as the least prevalent of the four groups, a data collection period providing data on 7500 nulliparous women giving birth in water ensured adequate numbers in the other three, more prevalent groups. These data were combined to assess the effects averaged across both strata at an increased power, with a combined required sample size of 30,000 women without complexities. We have assumed that 25% of the 6600 waterbirths recorded in Euroking in 2015 were nulliparous women (1650/annum). Allowing for staggered site set-up, 6 years of combined retrospective and prospective data collection was required (January 2015–June 2022). With potential study sites, collectively undertaking

TABLE 3 Study populations used in the primary analysis

Analysis	Pros	Cons
Primary: group 1 vs. 2 Groups 1b and 2b remain in primary analysis	This analysis 'reflects real life', including that on occasions clinical concern occur before or during birth, but these either did not require, or without time for, transfer for obstetric care	Potential bias in favour of waterbirth group as women asked to leave the water where concerns became apparent before birth
Sensitivity: group 1a vs. 2a Groups 1b and 2b were excluded from primary analysis	This analysis answers the question: 'Does birth in water (in the absence of any clinical concerns) influence maternal and neonatal outcomes?'	Potential to underestimate adverse effects across the whole primary analysis

TABLE 4 Maternal and infant characteristics to be summarised

	Group				
	5	4	3	2	1
Maternal characteristics					
Age at birth (years)[a]	✔	✔	✔	✔	✔
Maternal ethnicity	✔	✔	✔	✔	✔
Lead professional at labour onset	✔	✔	✔	✔	✔
Smoker at time of booking	✔	✔	✔	✔	✔
Issues with language/literacy	✔	✔	✔	✔	✔
Deprivation quintile (based on the UK Townsend Deprivation Score[40])[b]	✔	✔	✔	✔	✔
Risk factor	✔	✔	✔	✔	✔
Type of condition					
VBAC	✔	✔	✔	✔	✔
Induction	✔	✔	✔	✔	✔
Previous OASI	✔	✔	✔	✔	✔
Gestational diabetes	✔	✔	✔	✔	✔
Para 4+	✔	✔	✔	✔	✔
Multiple pregnancy	✔	✔	✔	✔	✔
Thyroid disease[c]	✔	✔	✔	✔	✔
Other	✔	✔	✔	✔	✔
Complications per woman (none, 1, 2, 3,4+)	✔	✔	✔	✔	✔
Parity (primiparous/multiparous)[a]	✔	✔	✔	✔	✔
BMI (height/weight)[a]	✔	✔	✔	✔	✔
Gestational age at birth (weeks)[a]	–	✔	✔	✔	✔
Duration of labour[a]	–	✔	✔	✔	✔
Complications of labour	–	✔	✔	✔	✔
MROP	–	✔	✔	✔	✔
Mode of birth	–	✔	✔	✔	✔
Meconium-stained liquor at birth[c]	–	✔	✔	✔	✔
How was fetal HR monitoring performed?	–	✔	✔	✔	✔
CTG use in pool	–	✔	✔	✔	✔
Oxytocin administered in the pool following waterbirth	–	✔	✔	✔	✔
Birth position	–	✔	✔	✔	✔
Reason for leaving pool prior to birth (maternal/infant intrapartum problems)	–	✔	✔	✔	✔
Intrapartum or neonatal deaths	–	✔	✔	✔	✔
Maternal and infant outcomes (for women with risk factors who use a pool)	–	✔	–	–	–

TABLE 4 Maternal and infant characteristics to be summarised (*continued*)

	Group				
	5	4	3	2	1
Infant					
Birthweight (g)[a]	–	✔	✔	✔	✔
SGA (< 10th centile)[c]	–	✔	✔	✔	✔
Infant head circumference (cm)[a]	–	✔	✔	✔	✔
Sex of baby[c]	–	✔	✔	✔	✔
Duration of ROM to birth in hours[c]	–	✔	✔	✔	✔
Intrapartum fever recorded in record[c]	–	✔	✔	✔	✔
Fetal HR concerns in labour	–	✔	✔	✔	✔

BMI, body mass index; MROP, manual removal of placenta; ROM, rupture of membranes; SGA, small for gestational age; VBAC, vaginal birth after caesarean.
a Potential confounders for maternal primary outcome.
b Indices of multiple deprivation (IMD) is a measure of relative deprivation for small, fixed geographic areas of the UK. IMD classifies these areas into five quintiles based on relative disadvantage, with quintile 1 being the least deprived (most affluent) and quintile 5 being the most deprived.
c Potential confounders for infant primary outcome.

6037 waterbirths in 2016, it was believed that the study would have sufficient power to answer this important clinical question.

Based on estimates from the Birthplace in England study for the infant primary outcome, an estimate of 5% was used for the proportion of infants born to low-risk mothers experiencing 'adverse infant outcome or treatment'. A non-inferiority margin of ≤ 1.0% (OR ≤ 1.21) was taken as clinically non-significant. A sample size of 16,200 infants (8100 per group water/land) was required to have 90% power and a one-sided 95% CI around a treatment difference of zero.

Descriptive analysis

The numbers of records received from all sites, as well as the total number of women and babies for groups 1–5, were described and depicted in a flow chart. We have described opt-outs by each NHS site alongside the number and rate of women not using a pool (group 5), using a pool (groups 1–4), by risk status (low risk, groups 1–3 and underlying condition, group 4) and waterbirth (group 1). Maternal and infant characteristics, such as age, parity and ethnicity of all women giving birth in the study sites during data collection, were summarised by study population group (*Table 4*).

Primary analysis

The primary analyses were based on a non-inferiority test of births occurring in water (group 1) versus births occurring out of water (group 2) (reflecting real life practice) comparing:

1. the proportion of mothers who have OASI (based on retrospective and prospective maternity data)
2. the proportion of infants with a composite outcome of 'adverse infant outcome or treatment' (based on prospective maternity and NNRD-provided data).

Non-inferiority testing explored whether birth in water was not worse than birth out of water by more than the predefined non-inferiority margin and established at the 5% (one-sided) of the upper limit of the CI for the difference between groups.

- *Maternal outcome:* Non-inferiority would be concluded if the upper limit of the 95% CI for the difference in the proportion of OASI between the groups is < 1.0% (OR ≤ 1.23) in nulliparous low-risk women and < 0.6% (OR ≤ 1.38) in parous women. The data were then combined to assess the effects averaged across both strata.
- *Infant outcome:* Non-inferiority would be concluded if the upper limit of the 95% CI for the difference in infant outcome between the groups is < 1.0% (OR ≤ 1.21).

To test the primary hypothesis of non-inferiority between babies born in water versus leaving the pool before birth, both the maternal and infant primary outcomes were evaluated for non-inferiority using logistic regression models. All analyses used a mixed-effects two-level regression model to allow for clustering of outcomes by site. We did not account for the clustering of infants within mothers within site, as we anticipated a small number of multiple births.

Three sets of ORs were presented: unadjusted OR (UOR), adjusted OR (aOR) for selected confounders (no imputation) and aOR for selected confounders (with imputation). ORs were presented alongside a one-sided 95% CI (−∞ to upper limit), where the upper limit was compared to the predefined non-inferiority margins.[41] Confounders of interest were year of birth, ethnic group, maternal age, deprivation quintile, parity, gestational age, BMI, birthweight and midwife concern present at birth (post hoc adjustment).

Unit of analysis

For maternal outcomes, women were the unit of analysis (denominator), and those who left the pool to give birth were used as the reference group for all comparative analyses. For infant outcomes, babies were the unit of analysis (denominator), and those with mothers who left the pool to birth were used as the reference group for all comparative analyses.

Secondary analyses

If non-inferiority was demonstrated, then a superiority analysis was conducted as a secondary analysis of the primary outcomes, again using logistic regression and presented as UORs and aORs, alongside a two-sided 95% CI.

Further secondary analyses of components of the infant primary composite outcome were undertaken using both retrospective and prospective maternity and NNRD data for the following outcomes: NNU admissions requiring respiratory support and intrapartum stillbirth or early neonatal death, as these were captured over both periods of data collection in both sources. This was done to increase the sample size and the power of these analyses. However, this outcome did not include administration of intravenous antibiotic within 48 hours of birth among babies not admitted to a NNU, nor babies that died without admission to a NNU.

Subgroup analysis

Parity

A planned and powered subgroup of the primary maternal outcome was conducted to compare rates of OASI separately for primiparous and multiparous women. The relationship between the proportion of women using a pool during labour at individual sites and the incidence of adverse maternal and infant primary outcomes were described and explored. A planned subgroup analysis of the primary infant composite outcome was also conducted to compare rates separately for infants born to primiparous and multiparous women. These preplanned analyses were conducted by the inclusion of appropriate interaction terms (waterbirth exposure × parity) in the regression models. Results were presented using interaction coefficients, 95% CI and *p*-value.

Delivery of placenta in water

To explore potential risks of delivery of the placenta in water, an important subgroup was that of women who birthed in water, by whether the placenta was delivered in water, or the woman left the pool during the third stage. We examined the primary maternal and infant outcomes and PPH of ≥ 1000 ml between these two groups.

Sensitivity analyses

For both maternal and infant primary outcomes, several sensitivity analyses were performed to assess the robustness of the results to factors which may introduce bias (i.e. definition of risk and the study populations, maternal characteristics associated with waterbirth and fetal HR concerns).

Clinical need

The study has reported outcomes reflecting clinical practice, including where a risk was described as having been present at the time of pool entry as its primary analysis. It also reports outcomes among women without any risk factors in either antenatal records or at pool entry as a sensitivity analysis among group 1a (birth in pool + no midwife concerns) versus group 2a (birth in/out of pool + no midwife concerns).

Propensity score analysis

In addition to adjusting for maternal and infant characteristics for each outcome as in our primary analysis approach, we reweighted on the propensity score using inverse probability weighting (IPW) so that no controls were excluded. Incorporating propensity scores, that is the 'propensity' of a woman to choose a waterbirth, in the analysis is a way of controlling for this bias and can produce estimates with greater precision. Propensity scores were derived from logistic regression models, with waterbirth as the outcome and this included all maternal predictors of waterbirth.

Instrumental variable analysis

The proportion of women using water for labour or birth at each unit was used as an IV in this analysis, and the assumptions were tested that the IV variable was (1) associated with the exposure (i.e. remaining in water for birth) and (2) not associated with the outcome.

Missing data

Empty cells were distinguished by:

1. sites not collecting certain fields (partial or full study period) or entirely halting data collection (e.g. ceasing to use the Euroking MIS)
2. cells that were expected but were empty (coded as NULL).

For (2), fields were separated into those:

a. Expected to be well completed (e.g. mode of birth, birthweight and breastfeeding). Empty cells were defined as truly missing and imputation considered (see Case study findings).
b. Likely to only be completed when an event has occurred (e.g. hypertension). Empty cells were defined as an absence of event
c. Only expected when relevant prescreening questions are used (e.g. duration of antibiotics only applicable for those that receive antibiotics). Empty cells were defined as 'not applicable' unless the screening question was positive in which case an empty field would be defined as missing.

Where appropriate, we used multiple imputation methods [using the mi command in Stata® (StataCorp LP, College Station, TX, USA)], assuming that data were are missing at random or were missing completely at random. To assess the effect of missing data on the results of the primary analysis, a sensitivity analysis was planned using multiple imputation techniques to impute missing data for each of the potential confounders included in the adjusted regression models under the assumption that the data were missing at random. This assumes that the reason data are missing is not dependent on the value of the missing data if it were known. Missing outcome data would not be imputed since no information is gained, since the standard errors from imputation are likely to be larger than those of the complete case analysis.

Multiple imputation with chained equation[42] was used to impute values for the missing data (10 imputations) under the missing at random assumption, with parameter estimates and their standard errors combined using Rubin's rules.

Secondary outcomes

Secondary outcomes underwent non-inferiority testing as for the primary outcomes, and these are listed in *Appendix 6* alongside the study population used and analysis approach taken. In brief, the method of analysis is dependent on the outcome type, for example, binary (yes/no, presence or absence of events), continuous, ordinal and count data. Binary outcomes were modelled using logistic regression models and effect estimates, presented as ORs comparing the odds of an event in waterbirth compared to land. For continuous outcomes, multilevel linear models were fitted, and the results were presented as a difference in means (waterbirth minus birth on land). Ordered categorical data, such as perineal trauma, were modelled using ordinal regression. Count data were analysed using a Poisson multilevel model. If the distribution of events displayed signs of overdispersion (greater variance than might be expected in a Poisson distribution), then a negative binomial model (NBM) was used; estimates were presented as the incidence rate ratio (IRR) in waterbirth compared to on land. All parameter estimates were accompanied by a one-sided 95% CI and *p*-value.

The rate of PPH was compared for women who had their placenta delivered in water and those leaving the pool during the third stage, and results were presented as an aOR accompanied by a two-sided 95% CI.

Bias

There is a potential for reporting bias of the risk categorisation at pool entry collected by midwives after site opening, as this will usually be recorded after the outcome of the baby/mother was known. To examine this bias, we planned to examine trends in the incidence of overall risk and by categories over the study period and by the data sources (Euroking existing fields and midwives' entry) to detect any increases caused by 'diagnostic drift'. Due to the issue with the risk classification categorisation in Euroking, this analysis could not be undertaken.

Exploratory analyses

Several exploratory analyses were planned and prespecified in the SAP:

- Examination of the impact of the COVID-19 pandemic on the rates of pool use, waterbirths and other procedures that might have been altered by the pandemic (such as the rate of women under obstetric care, inductions, use of oxytocin augmenation of labour, etc.) by examining trends overall and by sites.
- Examination of the trends in antibiotic use in neonates and whether change in trends can be attributed to a change in use of guidelines (from NICE to sepsis calculator). We also examined the association with the factors associated with rates of antibiotic use.
- Examination of the factors associated with rates of pool use in individual maternity units.
- Characterisation of sites and mothers for pool use in low-risk women.
- The women with risk factors recorded in the maternity notes (group 4) who used a pool during labour were characterised by whether they gave birth in the pool or not.

Software

Data analysis was conducted in IBM SPSS Statistics version 26 (IBM Corporation, Armonk, NY, USA) and Stata version 16.

Reporting guidelines

The reporting of The POOL Study follows the REporting of studies Conducted using Observational Routinely collected health Data (RECORD) guidelines (see *Appendix 7*) and also Consolidated Standards of Reporting Trials (CONSORT) guidelines on reporting for equivalence and non-inferiority trials.[43]

Changes to statistical methods from the protocol and statistical analysis plan

A summary to the changes to the outcomes and approach to analyses are given in *Appendix 8*, and modifications made by the approach to analyses are given in *Appendix 6*.

Chapter 4 Results 1: study population

Site participation

All 26 eligible NHS study sites agreed to participate. Records were received from all 26 sites relating to births that had occurred over the period from 1 January 2015 to 30 June 2022. The number of sites reduced during the study period, as some sites changed their MIS. Participating sites across the UK are shown in *Figure 4*, and their characteristics are shown in *Table 5*.

Women opting out of the study

Sites were requested to provide the number of women who had opted out, and 24 sites provided these data. Sixty-five women (range 0–16 women per site) opted out of the study after site opening, with 11 (42%) sites recording no opt-outs during the data collection period.

Pool use and waterbirths throughout the study period

Figure 5 provides information on the proportions of women using a pool for labour, and the proportions of waterbirths, at all study sites from quarter 1, 2015 to quarter 2, 2022. The proportion of women using a pool during labour was highest in quarter 3, 2016, when 11.9% of women used a pool during labour and 6.0% of woman gave birth in water; in quarter 2, 2022, the proportions were 7.7% and 4.0%, respectively.

Study populations

The primary study aim was to compare the maternal and infant outcomes for 'low-risk' women who gave birth in water (group 1) against 'low-risk' women who left the water prior to birth for reasons other than clinical need (group 2). Since the secondary study objectives were to set pool use and waterbirth in the context of NHS care, we also defined:

- group 3 – women who used a pool during labour, with no complexities identified in the antenatal records/or by the midwives at the time of pool entry, and who were transferred to obstetric care during labour
- group 4 – women who used a pool in labour, who had recorded complexities in their antenatal record or (for births after site opening) recorded at pool entry
- group 5 – women with no record of pool use during labour or birth.

The flow chart of birth records by these groupings are shown in *Figure 6*.

A total of 956,307 records were received from 26 sites relating to births from 1 January 2015 to 30 June 2022. A total of 87,450 (9%) birth records had a record of using water immersion as labour analgesia/alternative pain relief, or for birth (groups 1–4: women who used a pool); and 868,857 (91%) birth records had no record of water immersion (group 5: women who did not use a pool). After exclusions for duplicate records, missing data within records, intrauterine deaths prior to labour and unattended births [410 (0.2%) women who used a pool; 85,065 (9.8%) women who did not use a pool], 87,040 (99.8%) birth records of women who used a pool and 783,792 (90.2%) women who did not use a pool remained for analysis. Linkage to the NNRD occurred in 5659 birth records (6.5% of all women who used a pool). Few records were true duplicates in the same data set. For some sites, data relating to births without pool use, in one or more period, were sent to the study team more than once.

From 87,040 eligible birth records for women who used a pool, at least one POOL study field was completed in 24,911 (28.6%) records, indicating that the birth occurred after the site opened to the study.

Pool (groups 1–4) and non-pool (group 5) users

The study planned to describe the proportion and characteristics of women who used a pool for labour or birth compared to women who do not use a pool. The characteristics of women (and their infants) who used water during labour or birth and those that did not are summarised in *Table 6*. Women using water immersion for analgesia were more likely to come from a White ethnic background than women not using a pool for analgesia (81.0%

FIGURE 4 Participating study sites.

TABLE 5 Site characteristics

Site name	*N* births 2021–2[a]	OU	AMU	FMU	Level of[b] NNU
Manchester (South)	15,925[c]	✔	✔	✗	3
Cardiff and Vale University Health Board	5023	✔	✔	✗	3
Bolton NHS Foundation Trust	5750	✔	✔	✗	3
Stockport NHS Foundation Trust	3330	✔	✔	✗	2
West Suffolk NHS Foundation Trust[d]	2190	✔	✔	✗	1
Medway NHS Foundation Trust	4525	✔	✔	✗	3
South Tees Hospitals NHS Foundation Trust	4630	✔	✔	✔	3
Isle of Wight NHS Trust[e]	965	✔	✔	✗	1
Maidstone and Tunbridge Wells NHS Trust	5680	✔	✗	✔	2
The Hillingdon Hospitals NHS Foundation Trust	3990	✔	✔	✗	2
North Bristol NHS Trust	5510	✔	✔	✔	3
Royal Cornwall Hospitals NHS trust	4035	✔	✔	✔	2
East Kent Hospitals University NHS Foundation Trust	6160	✔	✔	✗	3
University Hospitals of Leicester NHS Trust	9330	✔	✔	✔	3
The Newcastle upon Tyne Hospitals NHS Foundation Trust	5935	✔	✔	✗	3
Wrightington, Wigan and Leigh NHS Foundation Trust	2025	✔	✗	✗	2
Norfolk and Norwich University Hospitals NHS Foundation Trust	4955	✔	✔	✗	3
Pennine Acute Hospitals NHS Trust	2445	✔	✔	✗	2
Barking, Havering and Redbridge University Hospitals NHS Trust	7205	✔	✔	✗	2
St George's University Hospitals NHS Foundation Trust	4560	✔	✔	✗	3
Frimley Health NHS Foundation Trust	9140	✔	✔	✗	2
Blackpool Teaching Hospitals NHS Foundation Trust	2565	✔	✔	✗	2
James Paget University Hospitals NHS Foundation Trust	1730	✔	✔	✗	1
Dartford and Gravesham NHS Trust	4720	✔	✔	✗	1
Northumbria Healthcare NHS Foundation Trust	3150	✔	✔	✔	1
Salisbury NHS Foundation Trust	2085	✔	✗	✗	2

AMU, alongside midwifery unit; FMU, freestanding midwifery unit.
a Birth data source sites in England: https://digital.nhs.uk/data-and-information/publications/statistical/nhs-maternity-statistics/2021-22.
b Level 1: special care baby unit, level 2: local NNU, level 3 or tertiary: neonatal intensive care unit; where sites have multiple NNUs, the highest level is listed.
c Whole Manchester.
d Ended data collection in April 2021.
e Ended data collection in October 2021.

vs. 70.1%, respectively), with disparities seen in women of an Asian or Asian British ethnic background (4.2% vs. 12.6%, respectively) and in women of a Black, Black British, Caribbean or African ethnic background (1.3% vs. 4.0%, respectively). Women who used a pool were also more likely to understand the English language (85.0% vs. 81.0%, respectively). There was some indication that women who used a pool were more likely to reside in more affluent areas than women who did not use a pool (least deprived quintile = 20.7% vs. 15.2%, respectively). Pool and non-pool users

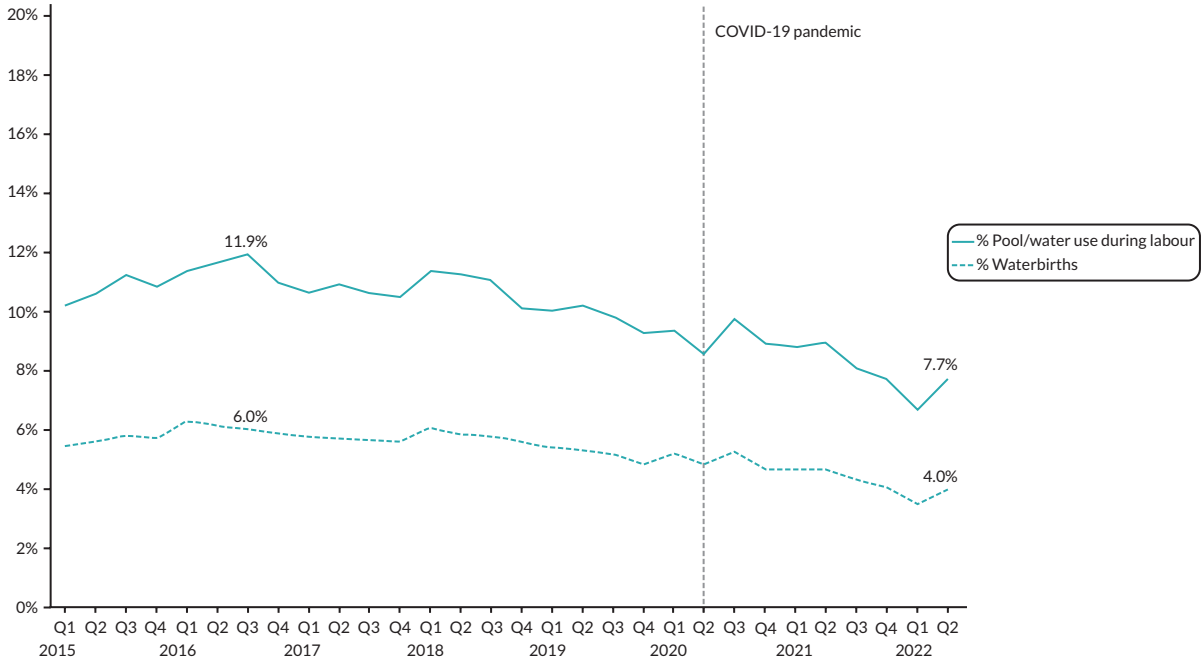

FIGURE 5 Rates of pool use and waterbirth across the study period.

were comparable for maternal age at birth (mean 30 years), gestational age at birth (39–40 weeks), infant's sex (51% male) and head circumference (mean 34.6 cms).

Group 4: women with complexities recorded during pregnancy or at the time of pool entry

Defining women with complexities

Complexities (or risk factors) were defined using a combination of data sources, using (1) the existing historic fields and (2) the new 'POOL' fields completed by the midwife following birth, to ensure a consistent definition of risk in study populations across all outcomes.

1. When the existing historic maternity fields were applied to the cohort of 87,040 birth records, 12,787 (14.7%) were deemed as having a recorded risk factor (see *Appendix 9*). The number of women identified as high risk from historic records was likely to have included some women unnecessarily, and for this reason, no further analysis was undertaken for group 4 identified by the existing fields in the maternity records.
2. From the 24,199 birth records completed after the site opened to the POOL Study, by the midwife following birth, a total of 23,800 (98.4%) birth records had utilised the new POOL fields to record risk factors present at the time of pool entry [recording either condition(s) were present or that no risk was present (no/none)] (*Table 7*). A total of 2725 (11.4%) records were flagged as the mother having at least one complexity at pool entry.

When historic and new midwife-completed fields were used in combination, alongside any mention of conditions identified from other fields, 13,811 (15.9%) of the whole cohort were found to have at high-risk conditions (group 4), with 73,229 (84.1%) remaining in groups 1–3 (see *Figure 6*).

Characteristics of women with complexities

The study planned to establish and describe the characteristics of, and outcomes for, women with known risk factors, who used a pool during labour. For these 2725 births flagged by the midwives as the mother having at least one risk factor at pool entry ('high-risk'), 1310 (48.1%) had a waterbirth recorded and 1415 (51.9%) did not, indicating that they had left the pool to birth (*Table 8*). These proportions differed by parity; nulliparous women were less likely to have a waterbirth than multiparous women (29.8% vs. 59.8%, respectively). Eighty-three per cent of women (*n* = 2270) had a spontaneous birth, although this rate was lower for nulliparous women when compared to multiparous women (68.8% vs. 92.6%, respectively). A higher proportion of nulliparous women had an emergency caesarean section and forceps

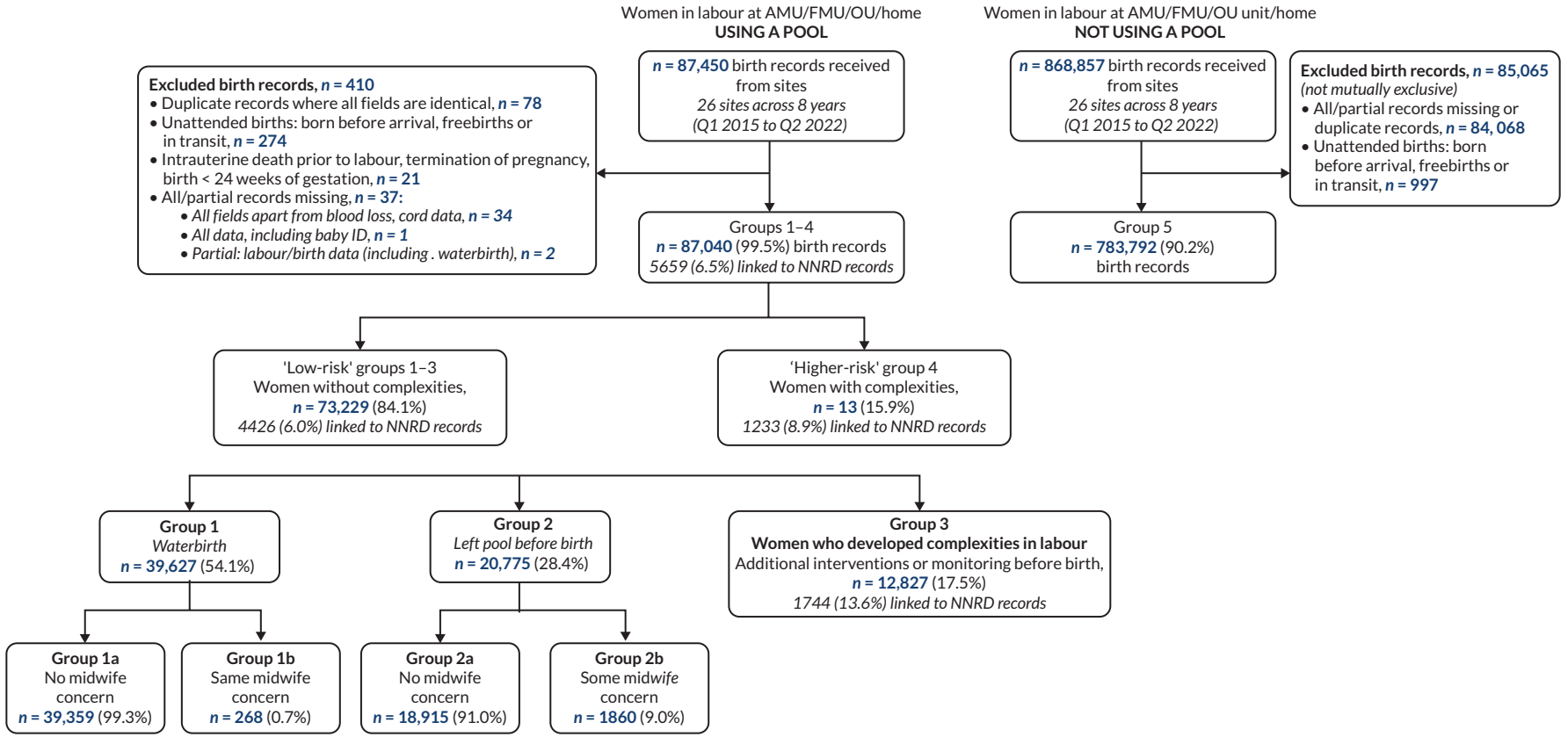

FIGURE 6 Flow chart of the study. AMU, alongside midwifery unit; FMU, freestanding midwifery unit; Q, quarter.

TABLE 6 Characteristics of pool and non-pool using women and their infants

	Used a pool in labour,[a] groups 1–4	Did not use a pool in labour,[a] group 5
Total *N* birth records	**87,040**	**783,792**
Maternal characteristics		
Maternal age at birth (years), mean (SD)	29.7 (5.1)	30.4 (5.6)
< 20 years	2395 (2.8)	20,659 (2.6)
20–24 years	12,072 (13.9)	106,373 (13.6)
25–29 years	25,821 (29.7)	214,305 (27.3)
30–34 years	31,331 (36.0)	255,316 (32.6)
35-39 years	14,003 (16.1)	149,123 (19.0)
40+ years	1418 (1.6)	38,016 (4.9)
Maternal ethnicity[b]		
White (including English, Welsh, Scottish, Northern Irish or British, Irish, Gypsy or Irish Traveller, Roma, any other)	70,484 (81.0)	549,107 (70.1)
Asian or Asian British (including Indian, Pakistani, Bangladeshi, Chinese, any other)	3669 (4.2)	98,501 (12.6)
Black, Black British, Caribbean or African (including any other)	1360 (1.6)	31,529 (4.0)
Mixed or multiple ethnic groups (White and Black Caribbean, African, White and Asian, including any other)	1242 (1.4)	11,890 (1.5)
Other ethnic group (including Arab and any other)	2544 (2.9)	31,832 (4.1)
Declined to answer/not recorded	7741 (8.9)	60,933 (7.8)
Mother still smoking at booking		
Yes (including current use of e-cigarettes)	6079 (7.0)	90,575 (11.6)
Ex-smoker (stopped before/during pregnancy)	7532 (8.7)	67,599 (8.6)
Non-smokers	73,429 (84.4)	625,618 (79.8)
Understanding of English language		
No issues (fluent)	73,962 (85.0)	634,971 (81.0)
Limited/no ability to understand, speak or read English	1527 (1.8)	43,347 (5.5)
Not recorded	*11,551 (13.3)*	*105,474 (13.5)*
Deprivation score quintile (Townsend)		
1 – least deprived (most affluent)	18,011 (20.7)	119,149 (15.2)
2	20,185 (23.2)	135,608 (17.3)
3	18,913 (21.7)	149,626 (19.1)
4	15,727 (18.1)	164,147 (20.9)
5 – most deprived	12,572 (14.4)	193,039 (24.6)
Not recorded	*1635 (1.9)*	*22,223 (2.8)*
Parity at booking		
Nulliparous (parity = 0)	44,045 (50.6)	330,687 (42.2)

TABLE 6 Characteristics of pool and non-pool using women and their infants (*continued*)

	Used a pool in labour,[a] groups 1–4	Did not use a pool in labour,[a] group 5
Multiparous (parity 1+)	42,995 (49.4)	453,105 (57.8)
BMI, mean (SD)	24.4 (4.1)	26.7 (6.1)
Not recorded	8566 (9.8)	*94,697 (12.1)*
Gestational age at birth (weeks), mean (SD)	40.2 (1.0)	39.2 (2.2)
Not recorded	*276 (0.3)*	*3642 (0.5)*
Infant		
Head circumference (cm), mean (SD)	34.5 (1.4)	34.3 (1.7)
Not recorded/not valid	*20,150 (23.2)*	*253,966 (32.4)*
Sex of baby		
Male	44,669 (51.3)	401,912 (51.3)
Female	42,299 (48.6)	380,930 (48.6)
Indeterminate	3 (0.0)	295 (0.0)
Not recorded	*69 (0.1)*	*655 (0.1)*

SD, standard deviation.
a Excluding unattended births, duplicates and records with no valid data.
b Following Office for National Statistics (ONS) categories' list of ethnic groups – GOV.UK (ethnicity-facts-figures.service.gov.uk).

Note
All data are *n* (%) unless otherwise stated.

(11.0% and 13.7%) compared to 3.3% and 2.8%, respectively, of multiparous women. A higher proportion of nulliparous women (with a spontaneous birth) experienced OASI compared to multiparous women (with a spontaneous birth) (25.7% vs. 1.9%, respectively). Similar patterns were observed, with their infants experiencing 'adverse infant outcomes or treatment' (6.8% vs. 4.2%, respectively).

Group 3: women using a pool without complexities ('low risk'), but with additional monitoring or interventions before birth

Of the 73,229 women without antenatal complexities, 12,827 (17.5%) received additional monitoring or interventions before or during birth. These included women who received analgesia incompatible with pool use and left, or did not return to the pool for clinical indications, and were recorded as receiving additional monitoring, obstetric and/or anaesthetic interventions prior to birth (*Table 9*).

Groups 1 and 2: intervention – women giving birth in water and comparator – leaving the pool to give birth

Women who used a pool in labour, with no risk factors in their antenatal record or recorded at pool entry, without additional monitoring or interventions before birth, who had a waterbirth, were allocated to group 1.

Women who used a pool in labour, with no risk factors in their antenatal record or recorded at pool entry, without additional monitoring or interventions before birth, who gave birth out of water, were allocated to group 2.

Of 60,402 birth records that formed groups 1 and 2, 39,627 (65.6%) were recorded as waterbirths (group 1) and a total of 20,775 (34.4%) were recorded as leaving the pool before giving birth (group 2). As only 0.4% (n = 234) had null entries for waterbirth, and with no other indication of a waterbirth recorded in other fields, these women were assumed to have given birth out of water. Births partially born into water (e.g. head/buttocks) were recorded for 323 (3.0%) of

TABLE 7 Risk factors identified at pool entry as recorded by midwives following birth

Conditions		Based on midwife report at pool entry, *N* = 24,911
Primary conditions		
1	ROMs > 24 hours	260 (1.0)
3	Significant meconium-stained liquor	42 (0.2)
4	Abnormal fetal HR	16 (0.1)
5	Hypertensive	29 (0.1)
6	Clinical or ultrasound suspicion of macrosomia	59 (0.2)
7	IUGR/SGA – confirmed on ultrasound	33 (0.1)
8	Para 4 or more	83 (0.3)
9	Breech presentation identified before onset of labour	8 (0.0)
10	Labour outside of 37^{+0} and 41^{+6}	102 (0.4)
11	Induction of labour	583 (2.3)
12	GBS carrier (including any history of GBS positive testing)	475 (1.9)
13	Twins/triplets	3 (0.0)
14	Fetal abnormality	9 (0.0)
16	Placenta praevia	1 (0.0)
17	Haemoglobin < 85 g/l	0 (0.0)
18	Confirmed intrauterine death	0 (0.0)
19/39	Gestational diabetes/diabetes	186 (0.8)
20	BMI at booking of > 35 kg/m^2	152 (0.6)
21/34	Thrombocytopenia platelet count < 100 × 10^9/l	9 (0.0)
22	VBAC	183 (0.7)
23	Previous PPH with blood transfusion	35 (0.1)
24	Previous baby weight > 4.5 kg	30 (0.1)
Secondary conditions		
26	Major gynaecological/uterine surgery	8 (0.0)
27	Cone biopsy or large loop excision of the transformation zone	69 (0.3)
28	Fibroids	56 (0.2)
29	Substance misuse	14 (0.1)
30	Asthma requiring an increase in treatment or hospital treatment	3 (0.0)
31	Cystic fibrosis	0 (0.0)
32	Haemoglobinopathies – sickle cell disease, beta-thalassaemia major	1 (0.1)
33	History of thromboembolic disorders	22 (0.1)
35	Von Willebrand's disease	4 (0.0)
36	Bleeding disorder in the woman or unborn baby	2 (0.0)
37	Atypical antibodies with risk of HDN	12 (0.1)
38	Hyperthyroidism	45 (0.2)
40	HIV	0 (0.0)

TABLE 7 Risk factors identified at pool entry as recorded by midwives following birth (*continued*)

Conditions		Based on midwife report at pool entry, *N* = 24,911
41	Toxoplasmosis – women receiving treatment	0 (0.0)
42	Current active infection of chicken pox/rubella/genital herpes	2 (0.0)
43	Tuberculosis under treatment	0 (0.0)
44	Systemic lupus erythematosus	1 (0.0)
45	Abnormal renal function	7 (0.0)
46	Epilepsy	13 (0.1)
47	Myasthenia gravis	0 (0.0)
48	Previous cerebrovascular accident	1 (0.0)
49/58	Liver disease and HBV/HCV	10 (0.0)
50	Psychiatric disorder requiring current inpatient care	0 (0.0)
51	Previous stillbirth/neonatal death	14 (0.1)
52	Previous baby with neonatal encephalopathy	0 (0.0)
53	Previous uterine rupture	0 (0.0)
54	Previous shoulder dystocia	23 (0.1)
55	Previous third/fourth degree or other complex tear	80 (0.3)
56	Sickle cell trait	14 (0.1)
57	Thalassaemia trait	18 (0.1)
59	Non-specific connective tissue disorders	4 (0.0)
60	Spinal abnormalities	29 (0.1)
61	Previous fractured pelvis	5 (0.0)
62	Neurological deficits	0 (0.0)
63	Crohn's disease	27 (0.1)
64	Ulcerative colitis	23 (0.1)
–	Other conditions noted by midwife	334 (1.4)
At least one complexity at pool entry		**2725 (10.9)**

HBV, hepatitis B virus; HCV, hepatitis C virus; HDN, Haemolytic Disease of the Newborn; HIV, human immunodeficiency virus; IUGR, intrauterine growth restriction; ROM, rupture of membranes; SGA, small for gestational age; VBAC, vaginal birth after caesarean.

all waterbirths recorded after site opening, including 142 woman who stood up between birth if their baby's head and body without shoulder dystocia.

Groups 1b/2b: 'low-risk' women with midwife concerns prior to birth

To identify women in groups 1b/2b, we used a combination of existing fields (e.g. maternal/fetal intrapartum problems during labour) and a new MIS field ('If the woman left pool prior to birth – did any of the following develop between leaving the pool and birth'). A total of 2128 of 60,402 (3.5%) records [group 1b: 268/39,603 (0.7%); group 2b: 1860/20,565 (9.0%)].

Groups 1a/2a: 'low-risk' women with no midwife concerns prior to birth

Within these groups were women for whom midwives had not recorded clinical concerns that were present prior to birth (groups 1a/2a).

TABLE 8 Select outcomes for women with risk factors at pool entry (group 4) by parity

	All women with at least one risk factor[a]	Nulliparous	Multiparous
***N* birth records with at least one risk factor at pool entry**	**2725**	**1065 (39.1)**	**1660 (60.9)**
Birth in or out of water			
Left pool	1415 (51.9)	748 (70.2)	667 (40.2)
Waterbirth	1310 (48.1)	317 (29.8)	993 (59.8)
Mode of birth			
SVB	2270 (83.3)	733 (68.8)	1537 (92.6)
Forceps	192 (7.0)	146 (13.7)	46 (2.8)
Emergency caesarean section	171 (6.3)	117 (11.0)	54 (3.3)
Ventouse	86 (3.2)	66 (6.2)	20 (1.2)
Vaginal breech birth	6 (0.2)	3 (0.3)	3 (0.1)
Primary maternal outcome: OASI *(spontaneous births only)*	*N* = 2270 71 (3.1)	*N* = 733 42 (5.7)	*N* = 1537 29 (1.9)
Primary infant outcome: adverse infant outcome or treatment[b]	141 (5.2)	72 (6.8)	69 (4.2)

a As recorded by the midwives following birth.
b Any NNU admission requiring respiratory support, intravenous antibiotic administration within 48 hours of birth (with or without culture proven infection), intrapartum stillbirth and deaths prior to NNU/postnatal ward discharge.

Note
All data are *n* (%) unless otherwise stated.

TABLE 9 Obstetric care and complexities developing prior to birth among group 3

Additional monitoring or interventions before or during birth (*categories not mutually exclusive*)	***N* = 12,827**
Caesarean sections, instrumental delivery	9191 (71.7)
Analgesia incompatible with pool use (epidural, GA, remifentanil, pudendal block)	6852 (53.4)
Labour augmented with oxytocin.	3.494 (27.2)
Recorded transfer to an OU during labour	2022 (15.8)
Breech identified during labour	59 (0.5)
Pathological/suspicious/abnormal/non-reassuring CTG	5174 (40.3)
Pyrexia/suspected infection with investigation/treatment	719 (5.6)

GA = general anaesthetic

Site variation

Table 10 shows the number and rate of women who did not use a pool (group 5), those using a pool by risk status (groups 1–4) and the rate of waterbirth by sites. After data cleaning, including of duplicate records, a total of 869,744 birth records were received over the study period of which 87,040 (10.0%) related to women who used a pool and 782,704 (90.0%) were related to women who did not use a pool. The number of births that an individual site contributed to the study ranged from 6804 to 65,667. Rates of pool use varied by site (between 1.6% and 22.9%) and in the proportion of women using a pool who gave birth in water (range 32.7–82%). Overall, 15.9% of women using a pool had a risk factor recorded in their antenatal record or at the time of pool entry (group 4), although considering the issues with the MIS, this may be an overestimate as they may have included some women unnecessarily. Among women

TABLE 10 Descriptives by site

		Non-pool users[a]		Pool users[a]											
	Total births[a]	Total		Total		Waterbirths		Risk factors (G4)		No risk factors, additional monitoring or interventions before birth (G3)		No risk factors, no additional monitoring or interventions + birth out of water (G2)		No risk factors, no additional monitoring or interventions + waterbirth (G1)	
Site	*N*	*n*	% births	*n*	% births	*n*	% pool users	*n*	% pool users	*n*	% pool users	*n*	% pool users	*n*	% pool users
1	41,033	36,484	88.9	4549	11.1	1934	42.5	516	11.3	795	17.5	1514	33.3	1724	37.9
2	33,643	30,674	91.2	2969	8.8	1548	52.1	262	8.8	524	17.7	775	26.1	1408	47.4
3	71,418	67,688	94.8	3730	5.2	3059	82.0	438	11.7	282	7.6	262	7.0	2748	73.7
4	43,791	40,676	92.9	3115	7.1	1398	44.9	416	13.4	486	15.6	1007	32.3	1206	38.7
5	65,667	60,545	92.2	5122	7.8	2924	57.1	870	17.0	438	8.6	1425	27.8	2389	46.6
6	44,306	37,988	85.7	6318	14.3	3045	48.2	1013	16.0	1241	19.6	1443	22.8	2621	41.5
7	30,164	26,968	89.4	3196	10.6	1694	53.0	584	18.3	469	14.7	763	23.9	1380	43.2
8	52,818	47,768	90.4	5050	9.6	3263	64.6	553	11.0	411	8.1	1162	23.0	2924	57.9
9	38,479	32,775	85.2	5704	14.8	3032	53.2	715	12.5	723	12.7	1586	27.8	2680	47.0
10	22,018	20,737	94.2	1281	5.8	622	48.6	292	22.8	197	15.4	279	21.8	513	40.0
11	39,967	35,590	89.0	4377	11.0	2454	56.1	667	15.2	726	16.6	822	18.8	2162	49.4
12	14,821	12,823	86.5	1998	13.5	905	45.3	225	11.3	320	16.0	652	32.6	801	40.1
13	38,688	32,306	83.5	6382	16.5	3823	59.9	746	11.7	1003	15.7	1212	19.0	3421	53.6
14	40,900	35,714	87.3	5186	12.7	2393	46.1	1138	21.9	829	16.0	1247	24.0	1972	38.0
15	23,054	19,041	82.6	4013	17.4	1955	48.7	896	22.3	871	21.7	717	17.9	1529	38.1
16	19,454	18,797	96.6	657	3.4	320	48.7	80	12.2	137	20.9	155	23.6	285	43.4
17	17,984	13,860	77.1	4124	22.9	2414	58.5	781	18.9	469	11.4	892	21.6	1982	48.1
18	32,799	32,278	98.4	521	1.6	350	67.2	72	13.8	67	12.9	77	14.8	305	58.5
19	46,563	40,936	87.9	5627	12.1	2900	51.5	931	16.5	888	15.8	1417	25.2	2391	42.5
20	36,523	32,863	90.0	3660	10.0	1233	33.7	1038	28.4	488	13.3	1186	32.4	948	25.9
21	7496	6809	90.8	687	9.2	291	42.4	99	14.4	125	18.2	210	30.6	253	36.8
22	15,643	13,986	89.4	1657	10.6	758	45.8	433	26.1	299	18.0	338	20.4	587	35.4

continued

TABLE 10 Descriptives by site (*continued*)

		Non-pool users[a]		Pool users[a]											
	Total births[a]	Total		Total		Waterbirths		Risk factors (G4)		No risk factors, additional monitoring or interventions before birth (G3)		No risk factors, no additional monitoring or interventions + birth out of water (G2)		No risk factors, no additional monitoring or interventions + waterbirth (G1)	
Site	*N*	*n*	% births	*n*	% births	*n*	% pool users	*n*	% pool users	*n*	% pool users	*n*	% pool users	*n*	% pool users
23	20,550	19,224	93.5	1326	6.5	716	54.0	160	12.1	232	17.5	301	22.7	633	47.7
24	6804	6221	91.4	583	8.6	338	58.0	107	18.4	90	15.4	105	18.0	281	48.2
25	34,831	32,097	92.2	2734	7.8	1608	58.8	400	14.6	324	11.9	630	23.0	1380	50.5
26	30,330	27,856	91.8	2474	8.2	1310	53.0	379	15.3	393	15.9	598	24.2	1104	44.6
Total	**869,744**	**782,704**	**90.0**	**87,040**	**10.0**	**46,827**	**53.2**	**13,811**	**15.9**	**12,827**	**14.7**	**20,775**	**23.9**	**39,627**	**45.5**

G, group.
a Non-pool and pool users exclude unattended births, duplicates and records with no valid data.

TABLE 11 Maternal and infant characteristics across pool users

	Risk factors in antenatal record or recorded at POOL entry (G4)	Risk factors relating to POOL entry only (G4)	No risk factors, additional monitoring or interventions before birth (G3)	No risk factors, no additional monitoring or interventions + birth out of water (G2)	No risk factors, no additional monitoring or interventions + waterbirth (G1)
N birth records (% of all records, N = 87,040)	13,811 (15.9)	2,725 (3.1)	12,827 (14.7)	20,775 (23.9)	39,627 (45.5)
Records linked to NNRD	1233 (8.9)	276 (10.1)	1744 (13.6)	1212 (5.8)	1470 (3.7)
N birth records after site opening	4992 (36.1)	2725 (100.0)	3696 (28.8)	5463 (26.3)	10,760 (27.2)
Concern flagged (G1 and G2 only)	–	–	–	1860 (9.0)	268 (0.7)
Waterbirth	6581 (47.7)	1310 (48.1)	62 (0.5)[a]	0 (0.0)	39,627 (100.0)
Maternal characteristics					
Maternal age at birth (years), mean (SD)	30.5 (5.2)	31.4 (5.0)	29.6 (5.0)	28.8 (5.2)	29.9 (5.0)
< 20 years	283 (2.0)	35 (1.3)	395 (3.1)	854 (4.1)	863 (2.2)
20–24 years	1647 (11.9)	223 (8.2)	1628 (12.7)	3726 (17.9)	5071 (12.8)
25–29 years	3756 (27.2)	660 (24.2)	3821 (29.8)	6597 (31.8)	11,647 (29.4)
30–34 years	4999 (36.2)	1072 (39.3)	4943 (38.5)	6757 (32.5)	14,632 (36.9)
35–39 years	2670 (19.3)	620 (22.8)	1886 (14.7)	2619 (12.6)	6828 (17.2)
40+ years	456 (3.3)	115 (4.2)	154 (1.2)	222 (1.1)	586 (1.5)
Not recorded	0	0	0	0	0
Maternal ethnicity[b]					
White (including English, Welsh, Scottish, Northern Irish or British, Irish, Gypsy or Irish Traveller, Roma, any other)	11,502 (83.3)	2187 (80.3)	10,167 (79.3)	16,395 (78.9)	32,420 (81.8)
Asian or Asian British (including Indian, Pakistani, Bangladeshi, Chinese, any other)	514 (3.7)	119 (4.4)	506 (3.9)	1006 (4.8)	1643 (4.1)
Black, Black British, Caribbean or African (including any other)	201 (1.5)	45 (1.7)	122 (1.0)	351 (1.7)	686 (1.7)
Mixed or multiple ethnic groups (White and Black Caribbean, African, White and Asian, including any other)	192 (1.4)	50 (1.8)	175 (1.4)	280 (1.3)	595 (1.5)

continued

TABLE 11 Maternal and infant characteristics across pool users (*continued*)

	Risk factors in antenatal record or recorded at POOL entry (G4)	Risk factors relating to POOL entry only (G4)	No risk factors, additional monitoring or interventions before birth (G3)	No risk factors, no additional monitoring or interventions + birth out of water (G2)	No risk factors, no additional monitoring or interventions + waterbirth (G1)
Other ethnic group (including Arab and any other)	370 (2.7)	54 (2.0)	467 (3.6)	611 (2.9)	1096 (2.8)
Declined to answer/not recorded	1032 (7.5)	2740 (9.9)	1390 (10.8)	2132 (10.3)	3187 (8.0)
Lead professional at labour onset					
General practitioner	20 (0.1)	4 (0.1)	20 (0.2)	40 (0.2)	54 (0.1)
Midwife	5186 (37.5)	1006 (36.9)	5634 (43.9)	10,544 (50.8)	19,028 (48.0)
Obstetrician	4317 (31.3)	915 (33.6)	2563 (20.0)	3683 (17.7)	6277 (15.8)
Null/not recorded	4288 (31.0)	800 (29.4)	4410 (35.9)	6508 (31.3)	14,268 (36.0)
Mother smoker at booking					
Yes (including current use of e-cigarettes)	1069 (7.7)	158 (5.8)	722 (5.6)	1759 (8.5)	2529 (6.4)
Ex-smoker (stopped before/during pregnancy)	1202 (8.7)	230 (8.4)	1207 (9.4)	2029 (9.8)	3094 (7.8)
Non-smoker	11,540 (83.6)	2337 (85.8)	10,898 (85.0)	16,987 (81.8)	34,004 (85.8)
Understanding of English language					
No issues (fluent)	12,483 (90.4)	2599 (95.4)	11,185 (87.2)	17,658 (85.0)	32,636 (82.4)
Limited/no ability to understand, speak or read English	162 (1.2)	35 (1.3)	227 (1.8)	530 (2.6)	608 (1.5)
Not recorded n (%)	1166 (8.4)	91 (3.3)	1415 (11.0)	2587 (12.5)	6383 (16.1)
Deprivation score quintile (Townsend)[c]					
1 – least deprived (most affluent)	2787 (20.5)	537 (19.7)	2731 (21.7)	3887 (19.2)	8605 (22,1)
2	3148 (23.1)	674 (24.7)	3023 (24.0)	4579 (22.6)	9435 (24.2)
3	3093 (22.7)	648 (23.8)	2896 (23.0)	4435 (21.9)	8488 (21.9)
4	2507 (18.4)	479 (17.6)	2402 (19.1)	3913 (19.3)	6905 (17.7)
5 – most deprived	2087 (15.3)	333 (12.2)	1537 (12.2)	3472 (17.1)	5475 (14.1)
Not recorded, n (%)	189 (1.4)	54 (2.0)	238 (1.9)	489 (2.4)	719 (1.8)

TABLE 11 Maternal and infant characteristics across pool users (*continued*)

	Risk factors in antenatal record or recorded at POOL entry (G4)	Risk factors relating to POOL entry only (G4)	No risk factors, additional monitoring or interventions before birth (G3)	No risk factors, no additional monitoring or interventions + birth out of water (G2)	No risk factors, no additional monitoring or interventions + waterbirth (G1)
Parity at booking					
Nulliparous (para 0)	5520 (40.0)	1065 (39.1)	11,139 (86.8)	12,210 (58.8)	15,176 (38.3)
Multiparous (para 1–3)	8291 (60.0)[d]	1660 (60.9)	1688 (13.2)	8565 (41.2)	24,451 (61.7)
BMI	25.8 (5.4)	25.4 (5.0)	24.0 (3.6)	24.0 (3.8)	24.3 (3.7)
Not recorded, n (%)	1078 (7.8)	285 (10.5)	984 (7.7)	1802 (8.7)	4702 (11.9)
Gestational age at birth (weeks), mean (SD)	40.3 (1.3)	39.8 (1.2)	40.4 (1.0)	40.2 (1.0)	40.1 (1.0)
Not recorded, n (%)	47 (0.3)	3 (0.1)	34 (0.3)	60 (0.3)	135 (0.3)
Place of birth					
AMU	6257 (45.3)	1217 (44.7)	349 (2.7)	14,503 (69.8)	30,265 (76.4)
FMU	286 (2.1)	53 (1.9)	18 (0.1)	1171 (5.6)	2953 (7.5)
Home	502 (3.6)	146 (5.4)	0 (0.0)	466 (2.2)	1966 (5.0)
Obstetric	6716 (48.6)	1304 (47.9)	12,455 (97.1)	4593 (22.1)	4412 (11.1)
Elsewhere in hospital	50 (0.4)	5 (0.2)	5 (0.0)	42 (0.2)	31 (0.1)
Mode of birth					
SVB	11.595 (84.0)	2270 (83.3)	3575 (27.9)	20,729 (99.8)	39,623 (100.0)
Forceps	915 (6.6)	192 (7.0)	4134 (32.2)	–	–
Vaginal breech birth	19 (0.1)	6 (0.2)	16 (0.1)	45 (0.3)	4 (0.0)
Emergency caesarean section	829 (6.0)	171 (6.3)	2541 (19.8)	–	–
Elective caesarean section	1 (0.0)	0 (0.0)	6 (0.05)	–	–
Ventouse	450 (3.3)	86 (3.2)	2554 (20.0)	–	–
Not recorded	2 (0.01)	0 (0.0)	1 (0.0)	1	0 (0.0)
MROP	311 (2.3)	70 (2.6)	438 (3.4)	518 (2.5)	710 (1.8)

continued

TABLE 11 Maternal and infant characteristics across pool users (*continued*)

	Risk factors in antenatal record or recorded at POOL entry (G4)	Risk factors relating to POOL entry only (G4)	No risk factors, additional monitoring or interventions before birth (G3)	No risk factors, no additional monitoring or interventions + birth out of water (G2)	No risk factors, no additional monitoring or interventions + waterbirth (G1)
Meconium-stained liquor at birth					
Meconium-stained liquor – significant (grades II, III, thick/significant, significant fresh blood loss, offensive)	157 (3.2)	92 (3.4)	271 (7.5)	206 (3.9)	129 (1.2)
Meconium-stained liquor – non-significant (clear, no ROM, grade 1, thin, lightly blood-stained)	4091 (83.9)	2267 (83.2)	2913 (81.1)	4682 (88.2)	9427 (88.5)
Not recorded	628 (12.9)	366 (13.4)	409 (11.4)	418 (7.9)	1101 (10.3)
How was fetal HR monitoring performed at the beginning of labour?					
Continuous	3388 (24.5)	647 (23.7)	4177 (32.6)	784 (3.8)	456 (1.2)
Intermittent	10,032 (72.6)	2004 (73.5)	7915 (61.7)	19,375 (93.3)	38,329 (96.7)
Continuous/intermittent	134 (1.0)	31 (1.1)	552 (4.3)	218 (1.0)	29 (0.1)
Monitoring declined	3 (0.0)	3 (0.1)	1 (0.0)	0 (0.0)	0 (0.0)
Unable to monitor/not required or performed	212 (1.5)	30 (1.1)	119 (0.9)	349 (1.7)	748 (1.9)
Not recorded	42 (0.3)	10 (0.4)	63 (0.5)	49 (0.2)	65 (0.2)
CTG use in pool (collected after site opening only)					
Yes	175 (3.5)	404 (14.8)	99 (2.7)	56 (1.0)	38 (0.4)
No/null	4425 (96.5)	2321 (85.2)	3597 (97.3)	5403 (99.0)	10,722 (99.6)
Duration of ROMs to birth (hours) Median (IQR)	N = 12,856 3.15 (0.5–9.1)	N = 2529 3.5 (0.6–9.9)	N = 11,612 8.3 (4.30–14.6)	N = 18,606 2.3 (0.7–6.2)	N = 35,984 0.9 (0.2–4.2)
ROM > 24 hours	1209 (8.8)	280 (10.3)	991 (7.7)	366 (1.8)	361 (0.9)
ROM > 36 hours	731 (5.3)	85 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)
Maternal position at birth					
Semi-recumbent/sitting	5369 (38.9)	914 (33.5)	2083 (16.2)	10,141 (48.8)	15,678 (39.6)
Kneeling/leaning forward	1779 (12.9)	395 (14.5)	61 (0.5)	1438 (6.9)	9635 (24.3)

TABLE 11 Maternal and infant characteristics across pool users (*continued*)

	Risk factors in antenatal record or recorded at POOL entry (G4)	Risk factors relating to POOL entry only (G4)	No risk factors, additional monitoring or interventions before birth (G3)	No risk factors, no additional monitoring or interventions + birth out of water (G2)	No risk factors, no additional monitoring or interventions + waterbirth (G1)
All fours	1729 (12.5)	411 (15.1)	113 (0.9)	2537 (12.2)	8322 (21.0)
Lateral	439 (3.2)	106 (3.9)	209 (1.6)	1623 (7.8)	493 (1.2)
Squatting	406 (2.9)	91 (3.3)	15 (0.1)	409 (2.0)	2034 (5.1)
Lithotomy or described as 'lithotomy-like'	1804 (13.1)	382 (14.0)	7212 (56.2)	1637 (7.9)	42 (0.1)
Birthing stool/chair/toilet	84 (0.6)	20 (0.7)	10 (0.1)	768 (3.7)	174 (0.4)
Standing	255 (1.8)	61 (2.2)	19 (0.1)	878 (4.2)	462 (1.2)
Floating/mobile/lying in water	37 (0.3)	3 (0.1)	0 (0.0)	1 (0.0)	257 (0.6)
McRoberts	198 (1.4)	43 (1.6)	170 (1.3)	444 (2.1)	60 (0.2)
Supine	109 (0.8)	9 (0.3)	323 (2.5)	66 (0.3)	103 (0.3)
Unable to determine/other	1599 (11.6)	290 (10.6)	2611 (20.4)	824 (4.0)	2366 (6.0)
Infant					
Birthweight (g) mean (SD)	3580.9 (456.9)	3579.3 (451.5)	3532.7 (413.9)	3510.9 (421.1)	3517.8 (409.0)
Not recorded	44	8	66	64	71
Infant head circumference (cm)	34.7 (1.4)	34.7 (1.4)	34.6 (1.4)	34.4 (1.4)	34.4 (1.3)
Not recorded	3171	672 (24.7)	2883	4351	9736
Sex of baby					
Male	7176 (52.0)	1402 (51.4)	7093 (55.3)	9.929 (47.8)	20,036 (50.6)
Female	6612 (47.9)	1323 (48.6)	5722 (44.6)	10,831 (52.1)	19,569 (49.4)
Indeterminate	1	0	1	0	1
Not recorded	22	0	11	21	15
Intrapartum or neonatal deaths per 1000 births	7 (0.51)	2 (0.73)	12 (0.94)	6 (0.29)	7 (0.18)
Intrapartum fever	272 (2.0)	82 (3.0)	719 (5.6)	109 (0.5)	30 (0.08)

continued

TABLE 11 Maternal and infant characteristics across pool users (*continued*)

	Risk factors in antenatal record or recorded at POOL entry (G4)	Risk factors relating to POOL entry only (G4)	No risk factors, additional monitoring or interventions before birth (G3)	No risk factors, no additional monitoring or interventions + birth out of water (G2)	No risk factors, no additional monitoring or interventions + waterbirth (G1)
Outcomes					
OASI	447 (3.2)	89 (3.3)	633 (4.9)	785 (3.8)	999 (2.5)
Adverse infant outcome or treatment	343 (6.9)	202 (7.4)	434 (11.7)	234 (4.3)	278 (2.6)

AMU, alongside midwifery unit; FMU, freestanding midwifery unit; IQR, interquartile range; MROP, manual removal of placenta; ROM, rupture of membranes.
a Women recorded as having a SVB, without epidural analgesia and a waterbirth.
b Data not provided. Following ONS categories' list of ethnic groups – GOV.UK (ethnicity-facts-figures.service.gov.uk).
c IMD is a measure of relative deprivation for small, fixed geographic areas of the UK. IMD classifies these areas into five quintiles based on relative disadvantage, with quintile 1 being the least deprived (most affluent) and quintile 5 being the most deprived.
d Includes para 4+.

Note
All data are *n* (%) unless otherwise stated.

TABLE 12 Mode of birth by parity: all women who used pool groups 1–3

	Nulliparous (parity = 0)	Multiparous (parity 1–3)
Total birth records	38,525	34,704
Mode of birth, n (%)		
SVB	30,056 (78.0)	33,871 (97.6)
Forceps	3830 (9.9)	304 (0.9)
Ventouse	2315 (6.0)	239 (0.7)
Emergency caesarean section	2289 (5.9)	252 (0.7)
Vaginal breech birth	29 (0.1)	36 (0.1)
Elective caesarean section	6 (0.0)	0 (0.0)
Not recorded	0 (0.0)	2 (0.0)

without risk factors recorded, 14.7% of women who used a pool developed complications in labour with additional monitoring or interventions before birth (range between 7.6% and 21.7% by site).

Characteristics of women using a pool

The study planned to characterise and describe outcomes for women with identified risk factors at labour onset, who used a pool during labour (group 4) and women who received additional monitoring or interventions before birth (group 3) (*Table 11*). The linkage rate of infants to NNRD data was higher in infants of mothers who received additional monitoring or interventions before birth (group 3) (13.6%) than those in the antenatal period with risk factors (8.9%) (group 4) and mothers with no risk factors or monitoring or interventions (group 1: 3.7%; group 2: 5.8%). Waterbirths were recorded in 48% (n = 6581) of women with antenatal risk factors. Among the 12,827 women who had recorded additional intrapartum monitoring or interventions, including where required transfer to an OU (group 3), 62 women (0.5%) were recorded as subsequently having a waterbirth.

Maternal age, gestational age and ethnicity were comparable across all groups with lower pool useamong most deprived women. Most births without complications (groups 1 and 2) occurred in midwifery-led settings (83.9% and 75.4%, respectively), with a smaller proportion in OU (11.1% and 22.1%, respectively); there was a higher involvement of obstetric care among women in group 4 (48.6%).

Table 12 shows the breakdown of mode of birth for all low-risk mothers (groups 1–3) by parity. Nulliparous women are more likely to have an instrumental birth, with 9.9% having forceps, 6.0% vacuum extraction, with 5.9% resulting in an emergency caesarean section, compared to 0.7% of multiparous women. Rates of vaginal breech births were comparable.

Chapter 5 Results 2: primary analysis

Descriptives by parity

A total of 60,402 birth records were eligible for inclusion in the main analysis, of which 39,627 (65.6%) were waterbirths and 20,775 (34.4%) could have remained in the water but left the pool to birth on land. These births were from all low-risk women who had no current or underlying risk factor and had no complications arising in labour. Of the 27,386 nulliparous women, 15,176 (55.4%) had a waterbirth compared with 24,451 (74.1%) of the 33,016 women who had had a previous birth.

Table 13 describes the maternal and infant characteristics of waterbirths and for those who left the pool, for all births and broken down by parity. The two groups were comparable on average maternal age (years), ethnic background, BMI at booking, gestational age at birth and infant birthweight. Differences between the two groups were observed in some maternal characteristics, such as parity, where birthing in water was more prevalent in women who had previously given birth (61.7%) compared to women who had left the pool to birth (41.2%) and also in the prevalence of clinical concern identified shortly prior to birth (0.7% waterbirth vs 9.0% left pool). For this reason, we additionally adjusted for clinical concern in the regression models. Similar patterns in maternal and infant characteristics were observed for waterbirths and for those who left the pool, within the nulliparous and multiparous women with the exception, again, of clinical concern.

Primary outcomes

Maternal outcome: obstetric anal sphincter injury

Main analysis

Of the 60,402 women who were included in this analysis, 60,338 (99.9%) contributed to the analysis with perineal trauma recorded. Fewer nulliparous women in the waterbirth group had a record of OASI than in those who left the pool [730 of 15,176 women (4.8%) vs. 641 of 12,210 women (5.3%); UOR 0.91, one-sided 95% CI, −∞ to 0.99] (*Table 14*). After adjustment for covariates, the aOR was 0.97 with a one-sided 95% CI, −∞ to 1.08. Similarly, fewer multiparous women in the waterbirth group had a record OASI use than in those who left the pool [269 of 24,451 women (1.1%) vs. 144 of 8,565 women (1.7%); UOR 0.65, one-sided 95% CI −∞ to 0.77; aOR 0.64, −∞ to 0.78]. When pooled for all women, the rate of OASI in women giving birth in water was again lower than in those who left the pool [999 of 39,627 patients (2.5%) vs. 785 of 20,775 patients (3.8%); aOR 0.89, one-sided 95% CI, −∞ to 0.98].

Since the upper limit of the CIs for the difference in the proportion of OASI between the groups were less than the prespecified non-inferiority margin for both nulliparous and multiparous women of 1% (OR < 1.23) and 0.6% (OR < 1.38), respectively, non-inferiority can be concluded (*Figure 7*). This suggests that birthing in water is no worse than birthing out of water according to OASI status.

Sensitivity analyses

A number of planned sensitivity analyses were performed to assess the robustness of the results to factors that may introduce bias [i.e. imputing missing data, impact of giving birth in water in the absence of any midwife concerns (group 1a vs. 2a) and using propensity score methods]. The main findings were consistent in these prespecified sensitivity analyses (see *Table 14*).

Instrumental variable analysis

The proportion of women using water for labour or birth at each unit was chosen as an IV due to (1) being associated with exposure (significantly different for births in water compared to those out of water) and (2) not being associated with the rate of OASI. These two conditions only held for nulliparous and the pooled cohort of women; for multiparous

TABLE 13 Maternal and infant demographics and characteristics of waterbirths and birth out of water, by parity

	All birth records for all low-risk women with no complications arising in labour		Nulliparous women (para = 0)		Multiparous women (parity 1–3)	
Population	**Waterbirth**	**Birth out of water**	**Waterbirth**	**Birth out of water**	**Waterbirth**	**Birth out of water**
Number (*N*) birth records	39,627	20,775	15,176	12,210	24,451	8565
N birth records after site opening	10,760 (27.2)	5463 (26.3)	3878 (25.6)	3075 (25.2)	6882 (28.1)	2388 (27.9)
Quarter of birth						
1	9980 (25.2)	5002 (24.1)	3281 (25.2)	2878 (23.6)	6159 (25.2)	2124 (24.8)
2	10,428 (26.3)	5498 (26.5)	3805 (25.1)	3143 (25.7)	6623 (27.1)	2355 (27.5)
3	9921 (25.0)	5423 (26.1)	3915 (25.8)	3263 (26.7)	6006 (24.6)	2160 (25.2)
4	9298 (23.5)	4852 (23.4)	3635 (24.0)	2926 (24.0)	5663 (23.2)	1926 (22.5)
Year of birth						
2015	5112 (12.9)	2842 (13.7)	1939 (12.8)	1661 (13.6)	3173 (13.0)	1181 (13.8)
2016	6449 (16.3)	3350 (16.1)	2554 (16.8)	1998 (16.4)	3895 (15.9)	1352 (15.8)
2017	6069 (15.3)	3270 (15.7)	2289 (15.1)	1892 (15.5)	3780 (15.5)	1378 (16.1)
2018	6166 (15.6)	3232 (15.6)	2439 (16.1)	1969 (16.1)	3727 (15.2)	1263 (14.8)
2019	5334 (13.5)	2879 (13.9)	2121 (14.0)	1784 (14.6)	3213 (13.1)	1095 (12.8)
2020	4759 (12.0)	2318 (11.2)	1760 (11.6)	1305 (10.7)	2999 (12.3)	1013 (11.8)
2021	4206 (10.6)	2134 (10.3)	1536 (10.1)	1184 (9.7)	2670 (10.9)	950 (11.1)
2022 (Q1 and Q2 only)	1532 (3.9)	750 (3.6)	538 (3.6)	417 (3.4)	994 (4.1)	333 (3.9)
Maternal age, years – mean (SD)	29.9 (5.0)	28.8 (5.2)	28.2 (5.0)	27.6 (5.1)	31.0 (4.6)	30.4 (4.9)
< 20 years	863 (2.2)	854 (4.1)	758 (5.0)	793 (6.5)	105 (0.4)	61 (0.7)
20–24 years	5071 (12.8)	3726 (17.9)	2803 (18.5)	2624 (21.5)	2268 (9.3)	1102 (12.9)
25–29 years	11,647 (29.4)	6597 (31.8)	5143 (33.9)	4145 (33.98)	6504 (26.6)	2452 (28.6)
30–34 years	14,632 (36.9)	6757 (32.5)	4961 (32.7)	3624 (29.7)	9671 (39.6)	3133 (36.6)
35–39 years	6828 (17.2)	2619 (12.6)	1430 (9.4)	959 (7.9)	5398 (22.1)	1660 (19.4)
40+ years	586 (1.5)	222 (1.1)	81 (0.5)	65 (0.5)	505 (2.1)	157 (1.8)

continued

TABLE 13 Maternal and infant demographics and characteristics of waterbirths and birth out of water, by parity (*continued*)

	All birth records for all low-risk women with no complications arising in labour		Nulliparous women (para = 0)		Multiparous women (parity 1–3)	
Population	**Waterbirth**	**Birth out of water**	**Waterbirth**	**Birth out of water**	**Waterbirth**	**Birth out of water**
Ethnicity						
White	32,420 (89.0)	16,395 (87.9)	12,183 (88.6)	9572 (88.3)	20,237 (89.2)	6823 (87.5)
Asian or Asian British	1643 (4.5)	1006 (5.4)	590 (4.3)	554 (5.1)	1053 (4.6)	452 (5.8)
Black, Black British, Caribbean or African	686 (1.9)	351 (1.9)	268 (1.9)	178 (1.6)	418 (1.8)	173 (2.2)
Mixed or multiple ethnic groups	595 (1.6)	280 (1.5)	239 (1.7)	166 (1.5)	356 (1.6)	114 (1.5)
Other ethnic group	1096 (3.0)	611 (3.3)	467 (3.4)	372 (3.4)	629 (2.8)	239 (3.1)
Declined to answer/not recorded	3187 (8.0)	2132 (10.3)	1429 (9.4)	1368 (11.2)	1759 (7.2)	764 (8.9)
Deprivation quintile by Townsend						
1 – most affluent	8605 (22,1)	3887 (19.2)	3062 (20.6)	2230 (18.7)	5543 (23.1)	1657 (19.8)
2	9435 (24.2)	4579 (22.6)	3539 (23.8)	2705 (22.7)	5896 (24.6)	1874 (22.4)
3	8488 (21.9)	4435 (21.9)	3339 (22.4)	2703 (22.7)	5149 (21.5)	1732 (20.7)
4	6905 (17.7)	3913 (19.3)	2758 (18.5)	2377 (19.9)	4147 (17.3)	1536 (18.4)
5 – most deprived	5475 (14.1)	3472 (17.1)	2202 (14.8)	1911 (16.0)	3273 (13.6)	1561 (18.7)
Not recorded	719 (1.8)	489 (2.4)	276 (1.8)	284 (2.3)	443 (1.8)	205 (2.4)
Parity						
Nulliparous	15,176 (38.3)	12,210 (58.8)	–	–	–	–
Multiparous	24,451 (61.7)	8565 (41.2)	–	–	–	–
BMI at booking – mean (SD)	24.3 (3.7)	24.0 (3.8)	24.0 (3.6)	23.8 (3.7)	24.4 (3.8)	24.4 (3.9)
Not recorded, n (%)	4702 (11.9)	1802 (8.7)	1757 (11.6)	1304 (10.7)	2945 (12.0)	768 (10.0)
Gestation at birth (weeks) – mean (SD)	40.1 (1.0)	40.2 (1.0)	40.0 (1.0)	40.1 (1.0)	40.2 (0.9)	40.2 (0.9)
Not recorded, n (%)	135 (0.3)	60 (0.3)	45 (0.3)	26 (0.2)	90 (0.4)	34 (0.4)
Birthweight (g) – mean (SD)	3518 (409)	3511 (421)	3412 (386)	3440 (399)	3584 (409)	3612 (431)
Not recorded, n (%)	71 (0.2)	64 (0.3)	30 (0.2)	38 (0.3)	41 (0.2)	26 (0.3)

TABLE 13 Maternal and infant demographics and characteristics of waterbirths and birth out of water, by parity (*continued*)

Population	All birth records for all low-risk women with no complications arising in labour		Nulliparous women (para = 0)		Multiparous women (parity 1–3)	
	Waterbirth	Birth out of water	Waterbirth	Birth out of water	Waterbirth	Birth out of water
Clinical concern identified prior to birth						
Yes	268 (0.7)	1860 (9.0)	112 (0.7)	1204 (9.9)	156 (0.6)	656 (7.7)
No	39,359 (99.3)	18,915 (91.0)	15,064 (99.3)	11,006 (90.1)	24,295 (99.4)	7909 (92.3)

Note
All data are n (%) unless otherwise stated.

TABLE 14 Non-inferiority analyses of the maternal primary outcome of OASI by parity and for all women

	Waterbirth		Left pool before born		Non-inferiority testing	
Outcome (study population, source)	*N*	*n* (%)	*N*	*n* (%)	UOR (one-sided 95% CI)	aOR[a] (one-sided 95% CI)
Primary maternal outcome: OASI (W, MIS)						
Main analysis						
Nulliparous women (para 0)	15,176	730 (4.8)	12,210	641 (5.3)	0.91 (−∞ to 0.99)	0.97 (−∞ to 1.08)
Multiparous women (para 1–3)[b]	24,451	269 (1.1)	8,565	144 (1.7)	0.65 (−∞ to 0.77)	0.64 (−∞ to 0.78)
All women	39,627	999 (2.5)	20,775	785 (3.8)	0.66 (−∞ to 0.71)	0.89 (−∞ to 0.98)
Sensitivity analysis						
1. Imputation						
Nulliparous women	–		–		–	0.95 (−∞ to 1.05)
Multiparous[b] women	–		–		–	0.68 (−∞ to 0.81)
All women	–		–		–	0.89 (−∞ to 0.97)
2. IPW						
Nulliparous women	–		–		–	0.91 (−∞ to 1.02)
Multiparous[b] women	–		–		–	0.62 (−∞ to 0.77)
All women	–		–		–	0.82 (−∞ to 0.97)
3. IV analysis						
Nulliparous women	–		–		–	0.96 (−∞ to 1.17)
Multiparous[b] women	–		–		–	[d]
All women	–		–		–	0.92 (−∞ to 1.17)
4. No clinical concern[c]						
Nulliparous women	15,064	723 (4.8)	11,006	580 (5.3)	0.91 (−∞ to 1.00)	0.97 (−∞ to 1.08)
Multiparous[b] women	24,295	268 (1.1)	7,909	130 (1.6)	0.67 (−∞ to 0.80)	0.64 (−∞ to 0.78)
All women	39,359	991 (2.5)	18,915	710 (3.8)	0.66 (−∞ to 0.72)	0.89 (−∞ to 0.98)

W, whole study population.
a Adjusted for year and quarter of birth, ethnic group, deprivation quintile, maternal age at birth, parity, gestational age, BMI, birthweight (g), clinical concern at birth. Clustering of women within sites accounted for by fitting a two-level logistic regression model.
b Para 1–3 only. Para 4 and above are in women with recorded risk factors during pregnancy or at the time of pool entry (group 4).
c Excluding births where midwife concerns were identified prior to birth.
d Instrumental variable analysis (IVA) could not be carried out for multiparous women since assumptions regarding an association between IV and exposure were not met.

women, there was no association between the proportion of women using water for labour and exposure. For nulliparous women, the aOR was 0.96 (one-sided 90% CI −∞ to 1.17).

Secondary analyses

The lower rate of OASI in water for multiparous women and all women was sufficient that, when tested in superiority analysis as prespecified in the SAP, it met the thresholds of statistical significance (aOR 0.64, two-sided 95% CI 0.51 to 0.80, *p*-value < 0.001, 0.89, 0.80 to 0.997, 0.045, respectively). For nulliparous women, the lower rate of OASI did not meet the thresholds of statistical significance (aOR 0.97, two-sided 95% CI, 0.86 to 1.11, 0.684).

Subgroup analyses

A planned and powered subgroup of the primary maternal outcome was conducted to compare rates of OASI separately for nulliparous and multiparous women. There was evidence of a differential effect for nulliparous and multiparous women's rates of OASI (interaction *p*-value = 0.001).

Another planned subgroup was that of the relationship between the proportion of women using a pool during labour at individual sites and the incidence of the adverse maternal primary outcome. There was no association between the rate of site pool use and the rate of OASI and neither did it significantly differ by birthing in water or not (interaction *p*-value = 0.205).

Infant outcome: adverse infant outcome or treatment

Main analysis

The primary infant outcome of 'adverse infant outcome or treatment' was captured in prospective maternal and NNRD data. Of the 16,223 infants born after site opening, 14,946 (92%) contributed to the analysis. Data for four sites were excluded as they did not routinely collect postnatal data and could not therefore contribute to the outcome. Fewer infants in the waterbirth group had an adverse infant outcome than in those who left the pool [263 of 9868 infants (2.7%) vs. 224 of 5078 infants, respectively (4.4%); aOR 0.65; one-sided 95% CI, −∞ to 0.79] (*Table 15*). The upper limit of the CI for the difference in infant outcome between the groups was less than the prespecified non-inferiority margin of 1.0% (OR < 1.21), suggesting that non-inferiority can be concluded and birthing in water is no worse than birthing out of water (see *Figure 7*).

Individual components of the infant primary outcome

The individual components of the infant primary outcome are shown in *Table 15*. Of the infants who experienced an adverse infant outcome in waterbirth (*n* = 263) and in those who left the pool (*n* = 224), 3 (1.1%) in the waterbirth group had died, with no deaths in those who left the pool. Fewer infants in the waterbirth group had a NNU admission, requiring respiratory support than in those who left the pool (0.9% vs. 2.0%, aOR 0.44; one-sided 95% CI −∞ to 0.60). All infants were administered with intravenous antibiotics within 48 hours of birth.

Sensitivity analyses

Sensitivity analyses were performed to assess the robustness of the results to factors that may introduce bias. The main findings were consistent in these prespecified sensitivity analyses (*Table 15*). IVA could not be performed since the assumption of the IV (proportion of women who used a pool by site), being associated with exposure, was not met.

Secondary analyses

The lower rate of adverse infant outcomes in water was sufficient that, when tested in superiority analysis as prespecified in the SAP, it met thresholds of statistical significance (aOR 0.65, two-sided 95% CI 0.52 to 0.82, *p*-value < 0.001).

An important secondary analysis of the infant primary composite outcome used NNU admissions requiring respiratory support, intrapartum stillbirth and early neonatal death captured over both periods of data collection in both data sources, thus increasing the sample size and power of the analysis. Administration of intravenous antibiotic within 48 hours of birth among babies not admitted to a NNU was not captured over the retrospective data period. The finding was consistent in this prespecified secondary analysis (aOR 0.69, one-sided 95% CI −∞ to 0.78, *p*-value < 0.001).

Subgroup analyses

A planned (but unpowered) subgroup analysis of the primary infant composite outcome was conducted by parity to compare rates separately for infants born to nulliparous and multiparous women. There was no evidence of a differential effect (of birthing in water compared to out of water) for nulliparous and multiparous women (interaction *p*-value = 0.932).

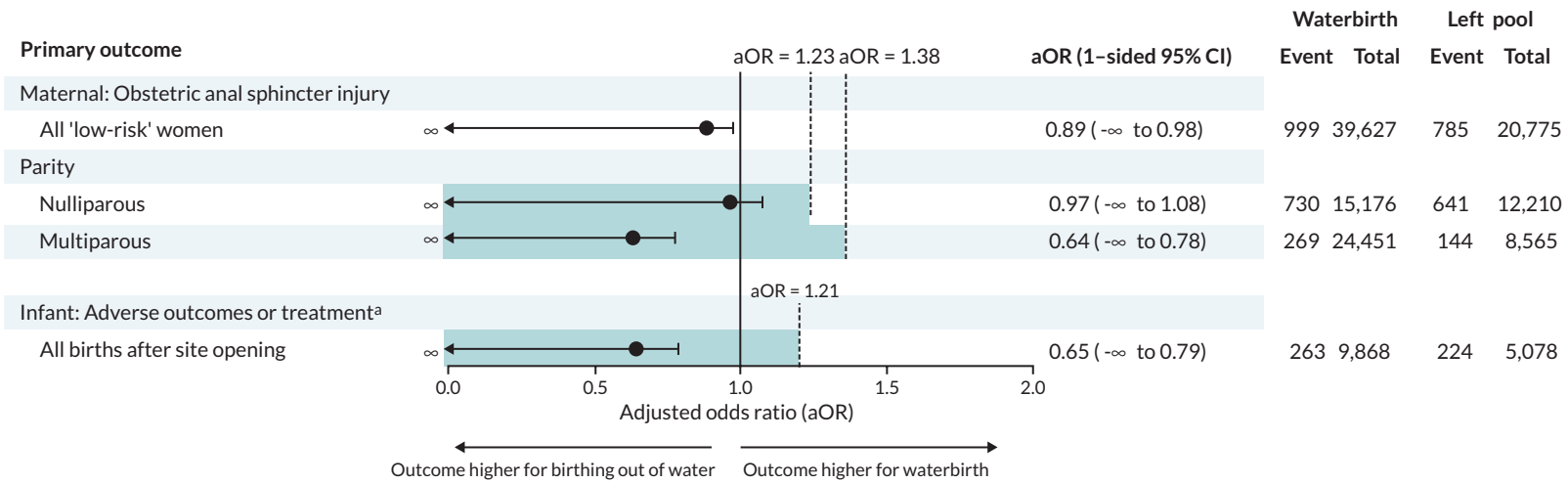

FIGURE 7 Forest plot of maternal and infant primary outcomes. a, The infant primary outcome included: any NNU admission requiring respiratory support, intravenous antibiotic administration within 48 hours of birth (with or without culture proven infection) or intrapartum stillbirth and all deaths prior to NNU/postnatal ward discharge. Note: dashed lines represent the non-inferiority margin for each comparison, and shaded areas represent the equivalence zone.

TABLE 15 Non-inferiority analyses of the infant primary composite outcome of 'adverse infant outcomes or treatment' and its separate components (secondary outcomes)

Outcome (study population, source)	Waterbirth		Left pool before born		Non-inferiority testing	
	N	*n* (%)	*N*	*n* (%)	UOR (one-sided 95% CI)	aOR[a] (one-sided 95% CI)
Infant outcome: adverse infant outcomes or treatment[b] (P, MIS/NNRD)						
Main analysis	9868	263 (2.7)	5078	224 (4.4)	0.59 (−∞ to 0.69)	0.65 (−∞ to 0.79)
Intrapartum or neonatal deaths per 1000 births (MIS/NNRD)	9868	*3 (0.3)*	*5078*	*0 (0.0)*	–	–
NNU admission requiring respiratory support (NNRD)	9868	*91 (0.9)*	*5078*	*104 (2.0)*	*0.45 (−∞ to 0.56)*	*0.44 (−∞ to 0.60)*
Administration of intravenous antibiotics commenced within 48 h of birth (MIS/NNRD)	9868	*263 (2.7)*	*5078*	*224 (4.4)*	–	–
Subgroup analysis: parity						
Nulliparous women	3521	109 (3.1)	2823	147 (5.2)	–	0.69 (−∞ to 0.90)
Multiparous[c] women	6347	154 (2.4)	2255	77 (3.4)	–	0.62 (−∞ to 0.81)
Sensitivity analysis						
1. Imputation						0.65 (−∞ to 0.82)
2. IPW						0.63 (−∞ to 0.80)
3. No clinical concern[d]	9753	253 (2.6)	3865	171 (4.4)	0.57 (−∞ to 0.67)	0.59 (−∞ to 0.72)
Secondary analysis						
Retrospective and prospective[e]	34,223	657 (1.9)	18,302	552 (3.0)	0.61 (−∞ to 0.67)	0.69 (−∞ to 0.78)

P, prospective study population (after site opened to data collection).
a Adjusted for year and quarter of birth, ethnic group, deprivation quintile, maternal age at birth, parity, gestational age, BMI, birthweight (g), clinical concern at birth. Clustering of women within sites accounted for by fitting a two-level logistic regression model.
b The infant primary outcome included: any NNU admission requiring respiratory support, intravenous antibiotic administration within 48 hours of birth (with or without culture proven infection) or intrapartum stillbirth and all deaths prior to NNU/postnatal ward discharge. Excludes data from four sites that did not record any postnatal outcome.
c Para 1–3 only. Para 4 and above are in women with recorded risk factors during pregnancy or at the time of pool entry (group 4).
d Excluding records where midwife concerns were identified prior to birth.
e Uses retrospective and prospective data WS and NNRD data for NNU admissions requiring respiratory support, intrapartum stillbirth and early neonatal death; does not include administration of intravenous antibiotic within 48 hours of birth among babies not admitted to a NNU.

Subgroup analyses

A planned and powered subgroup of the primary maternal outcome was conducted to compare rates of OASI separately for nulliparous and multiparous women. There was evidence of a differential effect (of birthing in water compared to out of water) for nulliparous and multiparous women (interaction *p*-value = 0.001). There was no association between the rate of site pool use and the rate of infant primary outcome and neither did it significantly differ by birthing in water or not (interaction *p*-value = 0.126).

Secondary outcomes

Maternal intrapartum outcomes

Fewer women in the waterbirth group experienced adverse maternal intrapartum outcomes than those leaving the pool to give birth, suggesting that birthing in water is no worse than birthing out of water according to these outcomes (*Table 16*).

TABLE 16 Maternal intrapartum secondary outcomes

Outcome (study population, source)	Waterbirth, *N* = 39,627	Left pool before born, *N* = 20,775	Non-inferiority testing	
			UOR (one-sided 95% CI)	aOR[a] (one-sided 95% CI)
Shoulder dystocia recorded (W, MIS)				
No	39,406 (99.4)	20,124 (96.9)		
Yes	221 (0.6)	651 (3.1)	0.18 (−∞ to 0.20)	0.16 (−∞ to 0.18)
In those with shoulder dystocia recorded:	*N* = 221	*N* = 651		
(a) Head-to-body birth interval (minutes), mean (SD), min to max	3.5 (1.7) 0–12	3.3 (1.8) 0–11		
(b) Management collected at sites (categories not mutually exclusive)	177 (80.1)	526 (80.8)		
McRoberts position	78 (44.1)	452 (85.9)		
Suprapubic pressure	22 (12.4)	187 (35.6)		
Internal manoeuvres	44 (24.9)	146 (27.8)		
Episiotomy	1 (0.6)	32 (6.1)		
Change of position	45 (25.4)	17 (3.2)		
Not recorded	11 (6.2)	13 (2.5)		
(c) Adverse infant outcome or treatment (P)	11/103 (10.7)	18/157 (11.5)		
(d) Receipt of therapeutic hypothermia	4/221 (1.8)	12/651 (1.8)		
(e) Apgar at 5 minutes (score < 7)	16 (7.2)	39 (6.0)		
Management of the third stage of labour: Active vs physiological (W, MIS)				
Physiological management	10,737 (27.1)	2260 (10.9)		
Active management	28,855 (72.9)	18,497 (89.1)	0.33 (−∞ to 0.34)	0.31 (−∞to 0.33)
Oxytocin for third-stage management administered before leaving pool (prospective MIS data)	*N* = 10,760	–		
Receipt of oxytocin	4,034 (37.5)	–		
Management of the third stage of labour: MROP (W, MIS)				
No	38,917 (98.2)	20,257 (97.5)		
Yes	710 (1.8)	518 (2.5)	0.71 (−∞ to 0.79)	0.69 (−∞ to 0.78)

TABLE 16 Maternal intrapartum secondary outcomes (*continued*)

Outcome (study population, source)	Waterbirth, N = 39,627	Left pool before born, N = 20,775	Non-inferiority testing	
			UOR (one-sided 95% CI)	aOR[a] (one-sided 95% CI)
PPH[b] ***(W, MIS)***				
Total blood loss ≥ 500 ml	5199 (13.1)	3329 (16.0)	Descriptive only	
Total blood loss ≥ 1000 ml	1165 (2.9)	797 (3.8)	0.76 (−∞ to 0.82)	0.90 (−∞ to 0.98)
Total blood loss ≥ 1500 ml	445 (1.1)	274 (1.3)	Descriptive only	
Treatment for haemorrhage in women with PPH ≥ 500 ml	*N* = 5199	*N* = 3329		
Any IV therapy (categories not mutually exclusive)	1579 (30.4)	1282 (38.5)	0.70 (−∞ to 0.75)	0.77 (−∞ to 0.85)
IV fluids (including NaCl, Hartmann's, normal saline)	1090 (21.0)	902 (27.1)		
Oxytocin infusion	987 (19.0)	742 (22.3)		
Blood transfusion/products (including RBC)	75 (1.4)	43 (1.3)		
Plasma expanders	240 (4.6)	167 (5.0)		
Obstetric involvement in woman's care following birth (W, MIS)				
No obstetric involvement	37,064 (93.5)	18,777 (90.4)		
Need for obstetric involvement	2564 (6.5)	2000 (9.6)	0.65 (−∞ to 0.68)	0.77 (−∞ to 0.82)
Reason for obstetric involvement following birth (categories not mutually exclusive)				
Treatment for haemorrhage	1591 (4.0)	1289 (6.2)	Descriptive only	
MROP	710 (1.8)	518 (2.5)		
OASI repair	999 (2.5)	785 (3.8)		
Sepsis	2 (0.0)	4 (0.0)		
Incidence of perineal and other genital trauma (W, MIS)				
Perineal trauma (mutually exclusive)				
Perineum intact	14,978 (37.8)	6586 (31.7)		
Any perineal trauma	24,649 (62.2)	14,189 (68.3)	0.76 (−∞ to 0.79)	0.84 (−∞ to 0.88)
First degree	7225 (18.2)	2855 (13.7)		
Second degree	16,400 (41.4)	8755 (42.1)		
Episiotomy	25 (0.1)	1794 (8.6)		

continued

TABLE 16 Maternal intrapartum secondary outcomes (*continued*)

Outcome (study population, source)	Waterbirth, *N* = 39,627	Left pool before born, *N* = 20,775	Non-inferiority testing	
			UOR (one-sided 95% CI)	aOR[a] (one-sided 95% CI)
Third degree	955 (2.4)	739 (3.6)		
3a	478 (47.8)	366 (46.6)		
3b	257 (25.7)	202 (25.7)		
3c	88 (8.9)	76 (9.7)		
Not specified	*132 (13.2)*	*95 (12.1)*		
Fourth degree	44 (0.1)	46 (0.2)		
Other trauma (not mutually exclusive)	39,627	20,775		
Cervical tear	11 (0.0)	14 (0.1)		
Anterior trauma/clitoral/urethral involvement	525 (1.3)	311 (1.5)		
Labial trauma	9330 (23.5)	4981 (24.0)		
Vaginal laceration/tear	1853 (4.7)	1086 (5.2)		
Other trauma, including grazes	1483 (3.7)	628 (3.0)		
Declined examination and other reasons	45 (0.1)	27 (0.1)		
Management of perineal and other genital trauma (W, MIS)				
No record	27,002 (68.1)	11,751 (55.7)		
Record of a perineal repair[c]	12,625 (31.9)	9204 (44.3)	0.59 (−∞ to 0.61)	0.78 (−∞ to 0.81)
Maternal position at birth (W, MIS)				
Semi-recumbent/sitting	15,678 (39.6)	10,141 (48.8)		
Kneeling/leaning forward	9635 (24.3)	1439 (6.9)		
All fours	8322 (21.0)	2537 (12.2)		
Lateral L&R	493 (1.2)	1,623 (7.8)		
Squatting	2034 (5.1)	409 (2.0)		
'Lithotomy-like'	42 (0.1)	1637 (7.9)		
Birthing stool/chair/toilet	174 (0.4)	768 (3.7)		
Standing	462 (1.2)	878 (4.2)		

TABLE 16 Maternal intrapartum secondary outcomes (*continued*)

Outcome (study population, source)	Waterbirth, *N* = 39,627	Left pool before born, *N* = 20,775	Non-inferiority testing	
			UOR (one-sided 95% CI)	aOR[a] (one-sided 95% CI)
Floating/mobile/lying in water	257 (0.6)	1 (0.0)		
McRoberts	60 (0.2)	444 (2.1)		
Supine	103 (0.3)	66 (0.3)		
Unable to determine[d]/other	2,3667(6.0)	832 (4.0)		

L&R, left and right; MROP, manual removal of placenta; P, prospective study population (after site opened to data collection); RBC, red blood cell.
a Adjusting for site, quarter, year, ethnicity, deprivation, maternal age at delivery, parity, gestation at birth, BMI at booking, infant birthweight and clinical concern.
b PPH is determined from the total blood loss at/after delivery.
c Continuous one- or two-layer repair, end-to-end, overlapping, subcuticular, interrupted.
d Mainly emergency and elective caesarean sections where the question of position is not asked.

Note
OR > 1 indicates a higher rate in the waterbirth group, and an OR < 1 indicates a higher rate in those who left the water.

Management of the third stage of labour

Following waterbirth, active management of the third stage of labour was used less frequently than following births out of water (72.8% vs. 89.0%), and physiological management was used more frequently (27.1% vs. 10.9%); both were non-inferior to birthing out of water (aOR 0.31, one-sided 95% CI −∞ to 0.33; 0.69, −∞ to 0.78, respectively). An important subgroup were women who left the pool prior to delivery of the placenta compared with women who remained in the pool.

Of the 10,760 waterbirths recorded after site opening (where the fields on intention/actual delivery of placenta were added), 910 (8.5%) of midwives intended to deliver the placenta in water, whereas 7422 (69%) intended to deliver out of water. Overall, the placenta was delivered in water following 926 (8.6%) of all waterbirths, including on 58.4% of the occasions when it was intended to deliver the placenta in water. Among women who gave birth in water after site opening for whom data were collected, 37.5% (4031/10,760) received oxytocin for third-stage management before leaving the pool.

Rates and management of postpartum haemorrhage

The PPH (defined as the total blood loss at and after delivery of ≥ 500 ml and also ≥ 1 l) was more prevalent in those who left the water than those staying in water to give birth (13.1% vs. 16.0%; 2.9% vs. 3.8%, respectively). Major obstetric haemorrhage (≥ 1500 ml) was recorded in 1.1% of waterbirths compared to 1.3% among births out of water. For PPH ≥ 1 l (the only tested PPH outcome), the aOR was 0.90 (one-sided 95% CI −∞ to 0.98), indicating that birth in water was non-inferior to birth out of water. For women experiencing a PPH ≥ 500 ml, IV therapy was given in 30.4%

TABLE 17 Perineal and other trauma by parity

	Nulliparous		Multiparous	
	Waterbirth *N* = 15,176	Left pool before born *N* = 12,210	Waterbirth *N* = 24,451	Left pool before born *N* = 8565
Perineal trauma (mutually exclusive)				
Perineum intact	4541 (29.9)	2988 (24.5)	10,437 (42.7)	3598 (42.0)
First degree	1923 (12.7)	1256 (10.3)	5302 (21.7)	1599 (18.7)
Second degree	7959 (52.4)	5772 (47.3)	8441 (34.5)	2983 (34.8)
Episiotomy	23 (0.2)	1533 (12.7)	2 (0.0)	241 (2.8)
Third degree	698 (4.6)	607 (5.0)	257 (1.1)	132 (1.5)
3a	*336 (48.1)*	*306 (50.4)*	*142 (55.3)*	*60 (45.5)*
3b	*191 (27.4)*	*161 (26.5)*	*66 (25.6)*	*41 (31.1)*
3c	*69 (9.9)*	*64 (10.5)*	*19 (7.4)*	*12 (9.1)*
Grade not specified	*102 (14.6)*	*76 (12.5)*	*30 (11.7)*	*19 (14.4)*
Fourth degree	32 (0.2)	34 (0.3)	12 (0.0)	12 (0.1)
Other trauma (not mutually exclusive)				
Cervical tear	5 (0.0)	6 (0.0)	6 (0.0)	8 (0.1)
Anterior trauma/clitoral/urethral involvement	232 (1.5)	196 (1.6)	293 (1.2)	115 (1.3)
Labial trauma	5359 (35.3)	3659 (30.0)	3971 (16.2)	1322 (15.4)
Vaginal laceration/tear	1027 (6.8)	788 (6.5)	826 (3.4)	298 (3.5)
Other trauma, including grazes	513 (3.4)	315 (2.6)	970 (4.0)	313 (3.7)
Declined examination and other reasons	17 (0.1)	11 (0.1)	28 (0.1)	16 (0.2)

of all waterbirths compared to 38.5% of those who left the water to birth [IV fluids: 21% vs. 27.1%; Oxytocin infusion: 19.0% vs. 22.3%; plasma expanders: 4.6% vs. 5.0%, blood transfusions: 1.4% vs. 1.3%, respectively].

Need and reason for obstetric involvement in woman's care following birth

Evidence of obstetric involvement in woman's care following birth included a record of obstetric treatment for haemorrhage, manual removal of placenta (MORP) or obstetric repair of a third-/fourth-degree perineal tear or other complex trauma. Obstetric involvement was recorded in fewer mothers in the waterbirth group than those who left the pool (6.5% vs. 9.6%; aOR 0.78, one-sided 95% CI −∞ to 0.82).

Incidence and management of perineal trauma

Perineal trauma was more prevalent in births out of water compared to waterbirths (32% vs. 38%, respectively; aOR 0.84, one-sided 95% CI −∞ to 0.88), specifically for second-, third- and fourth-degree trauma and episiotomies, whereas first-degree traumas were higher in waterbirths (18% vs. 14%). Ordinal regression showed that births out of water have more severe perineal trauma (aOR, 0.72, one-sided 95% CI −∞ to 0.74). The prevalence of genital tears was comparable between the two groups, with the majority (24%) experiencing labial trauma/lacerations. A record of perineal repair was observed in 32% of waterbirths and 44% of births out of water. Perineal trauma was also broken down by parity (*Table 17*).

Maternal position at birth

The most common birthing position in both in and out of water was semi-recumbent/sitting (40% and 49%, respectively). For waterbirth, this was followed by kneeling or leaning forward (24% and then all fours 21%), both of which were more prevalent than those out of water (7% and 12%, respectively). Most of the other positions were more prevalent in birth out of water (e.g. lateral left and right, lithotomy, use of a birthing chair and McRoberts); squatting was more prevalent in waterbirth (5%), accounting for the partial births.

Incidence of shoulder dystocia and required management

When a shoulder dystocia occurred during a waterbirth, if the baby's head had been born into water, they remained in the waterbirth group for analysis (group 1a or 1b, depending on whether prior midwife concerns had been present) even if the birth was completed out of water. Shoulder dystocia was recorded in fewer births in water than among births out of water [221 of 39,627 births (0.6%) vs. 651 of 20,775 births (3.1%); aOR 0.16; one-sided 95% CI, −∞ to 0.18]. As non-inferiority was shown, a superiority analysis was performed; this showed lower rates of shoulder dystocia among births in water (aOR 0.16; −∞ to 0.19, *p*-value < 0.001) compared to births out of water. Information describing the management of shoulder dystocia was not routinely collected for around 20% of events, either due to non-completion, or as these data were not included in the MIS at some sites. For the remainder, there were differences in management between groups (35% of waterbirths with shoulder dystocia used the McRoberts position compared to 69% of shoulder dystocia cases occurring out of water; 10% used suprapubic pressure for waterbirths compared to 29% out of water). In the waterbirth group, 20% of cases of shoulder dystocia were managed by a change of position or exiting the pool only, whereas a change in position was the only management used in 2.6% of case of shoulder dystocia occurring out of water. The head-to-body birth interval was comparable by group (waterbirth 3.5 minutes vs. birth out of water 3.3 minutes).

For the infant primary outcome, a higher rate of adverse infant outcome or treatment was observed following shoulder dystocia than in those without shoulder dystocia (11.2% vs. 3.0%, respectively) (*Table 18*). Cases of shoulder dystocia had a higher prevalence of NNU admissions and required respiratory support when compared to births without shoulder dystocia (12.4% vs. 4.3%, respectively; 4.2% vs. 1.0%, respectively). The prevalence of therapeutic hypothermia and antibiotics administered within 48 hours of birth were also higher (14.8% vs. 2.5%, respectively; 7.6% vs. 2.0%, respectively). No neonatal deaths resulted from shoulder dystocia and brachial plexus injuries were rare (see *Table 18*).

Management of the third stage of labour following waterbirth

Of the 10,760 waterbirths recorded after site opening (where the fields on intentional/actual delivery of placenta were added), 910 (8.5%) of midwives intended to deliver the placenta in water, whereas 7422 (69.0%) intended to deliver out of water (*Table 19*). Overall, the placenta was delivered in water following 926 (8.6%) of all waterbirths, including on 59.5% of the occasions when it was intended to deliver the placenta in water. The prevalence of PPH between waterbirths where the placenta was delivered in water compared to those who left the pool during the third stage

TABLE 18 Outcomes following shoulder dystocia

	Shoulder dystocia, *N* = 60,402 (W, MIS)		
	Yes ***N*** **= 872**	**No** ***N*** **= 59,530**	**Percentage difference (95% CI)**
NNU admissions (NNRD)			
No	764 (87.6)	56,980 (95.7)	
Yes	108 (12.4)	2550 (4.3)	8.1 (6.1 to 10.5)
NNU admission requiring respiratory support (NNRD)			
No	835 (95.8)	58,919 (99.0)	
Yes	37 (4.2)	612 (1.0)	3.2 (2.1 to 4.8)
Brachial plexus injury			
No	870 (99.8)	59,528 (100.0)	
Yes	2 (0.2)	2 (0.0)	0.2 (0.06 to 0.8)
Receipt of therapeutic hypothermia (NNRD)			
No	856 (98.2)	59,466 (99.9)	
Yes	16 (1.8)	64 (0.1)	1.7 (1.0 to 2.9)
Antibiotics administered within 48 hours of birth (NNRD)			
No	806 (92.4)	58,327 (98.0)	
Yes	66 (7.6)	1203 (2.0)	5.6 (4.0 to 7.5)
Intrapartum or neonatal deaths per 1000 births (MIS/NNRD)			
Yes	0 (0.00)	13 (0.22)	−0.02 (−0.04 to 0.4)
	Shoulder dystocia, ***N*** **= 16,223 (prospective data collection only)**		
	Yes ***N*** **= 260**	**No** ***N*** **= 15,963**	
Infant primary outcome			
No adverse infant outcome or treatment	231 (88.8)	15,480 (97.0)	
Adverse infant outcome or treatment	29 (11.2)	483 (3.0)	8.1 (4.8 to 12.5)

W, whole cohort.
Bold indicates that the study population has changed and that these are the total numbers.

is shown in *Table 20*. The rate of PPH was lower for women who had their placenta delivered in water compared to those leaving the pool during the third stage, but when tested (total blood loss ≥ 1000 ml), there was no evidence of a significant difference (aOR 0.70, two-sided 95% CI 0.42 to 1.18, *p*-value = 0.181).

Maternal postnatal outcomes

Table 21 reports the maternal postnatal outcomes.

Duration of postnatal stay (hours)

Women who had waterbirths experienced shorter durations of postnatal stay (hours) than for those who left the pool (11.5 vs. 15.5 hours), indicating that waterbirth was non-inferior to birthing out of water (IRR 0.83, one-sided 95% CI −∞ to 0.85) (see *Table 20*).

TABLE 19 Management of the third stage of labour – waterbirth group

	Placenta actually delivered			
	In water	Out of water	Not recorded	Total
Placenta intended to be delivered				
In water	541 (59.5)	362 (39.8)	7 (0.8)	910 (8.5)
Out of water	143 (1.9)	7200 (97.0)	79 (1.1)	7422 (69.0)
Undecided	242 (17.7)	1117 (81.8)	7 (0.8)	1366 (12.7)
Not recorded	0	0	1062 (100)	1062 (9.9)
Total	926 (8.6)	8679 (80.7)	1155 (10.7)	*N* = 10,760

Note
Prospective study population (after site opened to data collection)/MIS.

TABLE 20 Rate of PPH for 'low-risk' women who, following birth in water, deliver the placenta underwater or leave the water prior to delivery of the placenta

	Placenta delivered in water	Placenta delivered out of water	UOR (one-sided 95% CI)	aOR (one-sided 95% CI)
Number of waterbirths	**926**	**9834**		
PPH				
Total blood loss ≥ 500 ml	109 (11.8)	1343 (13.7)		
Total blood loss ≥ 1000 ml	18 (1.9)	322 (3.3)	0.59 (−∞ to 0.88)	0.70 (−∞ to 1.08)
Total blood loss ≥ 1500 ml	6 (0.6)	115 (1.2)		
Treatment for haemorrhage in women with PPH ≥ 500 ml	109	1343		
Any IV therapy (not mutually exclusive)	22 (20.2)	440 (32.8)		
IV fluids	16 (14.7)	301 (2.4)		
Oxytocin infusion	15 (13.8)	281 (20.9)		
Blood transfusion/products	0 (0.0)	25 (1.9)		
Plasma expanders	2 (1.8)	58 (4.3)		

Breastfeeding initiation and continuation (at community discharge of care)

The rate of not initiating breastfeeding was 16.2% in waterbirths and was 20.2% in those leaving the pool; and it had increased at community discharge of care to 27.9% and 32.2%, respectively (*Table 21*). Waterbirth was non-inferior to birthing out of water at both time points (initiation and community discharge of care) (aOR 0.79, one-sided 95% CI −∞ to 0.83; aOR 0.83, one-sided 95% CI −∞ to 0.88, respectively).

Higher-level care

Less than 0.5% of mothers in groups 1 and 2 were transferred to higher level of care (including transfer to critical care, high-dependency unit) (aOR 0.92, one-sided 95% CI −∞ to 1.21).

TABLE 21 Maternal postnatal secondary outcomes

Outcome (study population, source)	Waterbirth *N* = 39,627	Left pool before baby was born, *N* = 20,775	Non-inferiority testing	
			UOR (one-sided 95% CI)	aOR[a] (one-sided 95% CI)
Breastfeeding initiation (W, MIS)				
Yes – breastfeeding initiated (expressed/maternal milk)	32,293 (83.8)	15,805 (79.8)		
No – breastfeeding initiated (formula/donor milk)	6221 (16.2)	4013 (20.2)	0.76 (−∞ to 0.79)	0.79 (−∞ to 0.83)
Breastfeeding at community discharge of care[b] ***(W, MIS)***				
Yes – breastfeeding and partial breastfeeding	11,897 (72.1)	6058 (67.8)		
No – artificial milk feeding only	4613 (27.9)	2873 (32.2)	0.82 (−∞ to 0.86)	0.83 (−∞ to 0.88)
Need for higher-level care[c,d] ***(W, MIS)***				
No	39,509 (99.7)	20,680 (99.5)		
Yes	118 (0.3)	95 (0.5)	0.65 (−∞ to 0.82)	0.92 (−∞ to 1.21)
Maternal re-admission or hospital assessment[b,d] ***(W, MIS)***				
No	34,783 (98.9)	18,502 (98.6)		
Yes	382 (1.1)	261 (1.4)	0.78 (−∞ to 0.89)	0.92 (−∞ to 1.07)
			UIRR (one-sided 95% CI)	**AIRR (one-sided 95% CI)**
Duration of postnatal stay (hours), Median (IQR)[b] (W, MIS)	*N* = 33,514 11.7 (6.2 to 23.2)	*N* = 17,420 15.5 (7.6 to 27.8)	0.64 (−∞ to 0.65)	0.85 (−∞ to 0.87)
< 6 hours	7989 (23.8)	2894 (16.6)	Descriptive	
7–24 hours	17,586 (52.5)	9129 (52.4)		
25–48 hours	5313 (15.9)	3535 (20.3)		
49–168 hours (7 days)	2292 (6.8)	1630 (9.4)		
> 7 days	334 (1.0)	232 (1.3)		

AIRR, adjusted incidence rate ratio; P, prospective study population (after site opened to data collection); UIRR, unadjusted incidence rate ratio.
a Adjusted for site, quarter, year, ethnicity, deprivation, maternal age at delivery, parity, gestation at birth, BMI at booking, infant birthweight and some clinical concern.
b Excludes data from four sites that did not record any postnatal outcome.
c Includes admission or transfer for assessment to critical care, high-dependency unit.
d Original outcome was re-admission within 7 days of birth; however, timing of the re-admission was not available.

Maternal re-admission to hospital

Maternal re-admission to hospital or a hospital assessment was recorded in around 1% in women (1.1% waterbirth vs. 1.4% left pool to give birth) (aOR 0.92, one-sided 95% CI −∞ to 1.07). Reasons for admission includes breastfeeding problems, secondary PPH, abdominal wound infection, perineal problems, postdural headaches, urinary incontinence or retention, or for evacuation of retained products of conception.

Infant outcomes

Table 22 reports the infant secondary outcomes.

TABLE 22 Infant secondary outcomes

Outcome (study population, source)	Waterbirth *N* = 39,627	Left pool before born *N* = 20,775	Non-inferiority testing	
			UOR (one-sided 95% CI)	aOR[a] (one-sided 95% CI)
Snapped umbilical cord prior to clamping (P, MIS)	*N* = 10,760	*N* = 5,463		
No/not recorded/null	10,654 (99.0)	5447 (99.7)		
Yes	106 (1.0)	16 (0.3)	3.39 (−∞ to 5.27)	3.89 (−∞ to 6.88)
Delayed cord clamping > 60 seconds after birth (W, MIS)				
Delayed cord clamping > 60 seconds	8736 (94.6)	4330 (91.9)		
Cord clamping within 60 seconds	497 (5.4)	380 (8.1)	0.65 (−∞ to 0.73)	0.73 (−∞ to 0.85)
Apgar score at 1 minute (W, MIS)				
7–10	38,095 (96.4)	19,669 (94.9)		
< 7	1425 (3.6)	1054 (5.1)	0.70 (−∞ to 0.75)	0.72 (−∞ to 0.78)
Apgar score at 5 minutes (W,MIS)				
7–10	39,293 (99.5)	20,517 (99.1)		
< 7	189 (0.5)	182 (0.9)	0.54 (−∞ to 0.64)	0.62 (−∞ to 0.77)
Neonatal resuscitation at birth (W, NNRD)				
No evidence of resuscitation	38,008 (95.9)	19,460 (93.7)		
Evidence of resuscitation	1619 (4.1)	1315 (6.3)	0.63 (−∞ to 0.67)	0.61 (−∞ to 0.65)
Basic (stimulation/suction/bag and mask ventilation)	1598 (4.0)	1278 (6.1)		
Advanced (intubation/drug administration/cardiac massage)	21 (0.1)	39 (0.2)		
Intrapartum or neonatal deaths per 1000 births (W, MIS/NNRD)	7 (0.18)	6 (0.29)	0.61 (−∞ to 1.53)	0.22 (−∞ to 0.80)
Cause of death (W, MIS/NNRD)				
Birth asphyxia	1	0		
Did not achieve unsupported respirations	2	0		
Reorientation of care	0	2		
Early neonatal death – cause of death unknown	2	0		
Livebirth – cause of death unknown	2	2		
Stillbirth	0	2		

continued

TABLE 22 Infant secondary outcomes (*continued*)

Outcome (study population, source)	Waterbirth *N* = 39,627	Left pool before born *N* = 20,775	Non-inferiority testing	
			UOR (one-sided 95% CI)	aOR[a] (one-sided 95% CI)
Skin-to-skin contact at birth[b] (W, MIS)				
Yes, skin-to-skin	33,811 (94.5)	17,687 (92.4)		
No evidence of skin-to-skin	1986 (5.6)	1447 (7.6)	0.72 (−∞ to 0.76)	0.74 (−∞ to 0.80)
First breastfeed within first hour[c] (W, MIS)				
Breastfed within first hour	4451 (82.4)	2194 (72.3)		
Not breastfed within first hour	951 (17.6)	840 (27.7)	0.56 (−∞ to 0.61)	0.63 (−∞ to 0.70)
NNU admission[d] (W, NNRD)				
No	38,172 (96.3)	19,572 (94.2)		
Yes	1455 (3.7)	1203 (5.8)	0.62 (−∞ to 0.66)	0.66 (−∞ to 0.71)
NNU admission length of stay (hours) (W, NNRD)	*N* = 1,455	*N* = 1,203		
Median (IQR)	48.0 (23.3–101.4)	50.3 (22–110.8)	IRR: 0.92 (−∞ to 0.98)	IRR: 0.88 (−∞ to 0.94)
NNU admission requiring respiratory support (W, NNRD)				
No	39,298 (99.2)	20,455 (98.5)		
No NNU admission	*38,158 (96.3)*	*19,563 (94.2)*		
NNU admission not respiratory requiring support	*1140 (2.9)*	*892 (4.3)*		
Yes	329 (0.8)	320 (1.5)	0.54 (−∞ to 0.61)	0.58 (−∞ to 0.68)
Receipt of therapeutic hypothermia (W, NNRD)				
No	39,601 (99.93)	20,721 (99.74)		
Yes	26 (0.07)	54 (0.26)	0.25 (−∞ to 0.37)	0.33 (−∞ to 0.53)
Brachial plexus injury[e] (W, NNRD)				
No	35,165 (100.0)	18,763 (100.0)		
Yes	0 (0.0)	4 (0.0)	-	-

TABLE 22 Infant secondary outcomes (*continued*)

Outcome (study population, source)	Waterbirth *N* = 39,627	Left pool before born *N* = 20,775	Non-inferiority testing	
			UOR (one-sided 95% CI)	aOR[a] (one-sided 95% CI)
Treatment for jaundice*[e] *(W, NNRD)				
No/*not recorded*	34,769 (98.9)	18,441 (98.3)		
Yes	396 (1.1)	322 (1.7)	0.65 (−∞ to 0.74)	0.75 (−∞ to 0.86)
Successful/attempted lumbar puncture*[e] *(P, MIS)				
No	9822 (99.5)	5039 (99.2)		
Yes	46 (0.5)	39 (0.8)	0.62 (−∞ to 0.89)	1.00 (−∞ to 1.62)
***IV antibiotic administration within 48 hours of birth (±culture-proven infection) (W, NNRD)*[e]**				
No IV antibiotics administered/IV antibiotics administered after 48 hours/N/A (no NNU admission)	34,461 (98.2)	18,158 (97.1)		
Antibiotic administered within 48 hours	629 (1.8)	535 (2.9)	0.62 (−∞ to 0.68)	0.69 (−∞ to 0.77)
Duration of antibiotics (days) (W, NNRD), median (IQR)	*N* = 629 3 (2–5)	*N* = 535 4 (3–6)	0.94 (−∞ to 0.99)	0.93 (−∞ to 0.99)
Timing of antibiotics				
< 48 hours	34 (5.4)	36 (6.7)	0.80[f] (−∞ to 0.98)	0.70[f] (−∞ to 0.89)
2–5 days	453 (72.0)	343 (64.1)		
6–7 days	101 (16.1)	114 (21.3)		
> 7 days	41 (6.5)	42 (7.9)		
In those administered antibiotics within 48 hours	***N* = 629**	***N* = 535**		
Culture-proven infection*[e] *(W, NNRD)				
Blood culture sent	84 (13.4)	61 (11.4)		
Growth (clear/unclear pathogenicity) recorded	4 (4.8)	2 (3.3)		
No growths recorded	80 (95.2)	59 (96.7)		
Antibiotics administration within 48 hours of birth[e] (P, MIS)	***N* = 9868**	***N* = 5078**		
No/not recorded	9687 (98.2)	4929 (97.1)		
Yes, antibiotics within 48 hours	181 (1.8)	149 (2.9)	0.62 (−∞ to 0.74)	0.74 (−∞ to 0.94)
Culture-proven infection[e] (P, MIS)	***N* = 9868**	***N* = 5078**		

continued

TABLE 22 Infant secondary outcomes (*continued*)

Outcome (study population, source)	Waterbirth *N* = 39,627	Left pool before born *N* = 20,775	Non-inferiority testing	
			UOR (one-sided 95% CI)	aOR[a] (one-sided 95% CI)
Blood culture sent	206 (2.1)	168 (3.3)		
Growth recorded	1 (0.5)	3 (1.8)		
Blood sample sent but awaiting results	7 (3.4)	1 (0.6)		
No growths recorded	198 (96.1)	164 (97.6)		
			UIRR[fg] (one-sided 95% CI)	aIRR[fg] (one-sided 95% CI)
Highest CRP mg/dl (P, MIS) Median (IQR)	*N* = 183 8.6 (3–26)	*N* = 146 8 (3–26.25)	0.99 (−∞ to 1.22)	1.23 (−∞ to 1.57)

AIRR, adjusted incidence rate ratio; N/A, not applicable; UIRR, unadjusted incidence rate ratio.
a Adjusted for site, quarter, year, ethnicity, deprivation, maternal age at delivery, parity, gestation at birth, BMI at booking, infant birthweight and some clinical concern.
b Includes father skin-to-skin and skin-to-skin after recovery or suturing.
c Only includes data from 6 sites; 18 sites remainder had 100% missing, and 2 sites had 100% nonsensical data.
d Excludes length of stay = 0, as these are likely to be from transitional care.
e Excludes data from four sites that did not record any postnatal outcome.
f Ordinal regression.
g Negative binomial regression.

TABLE 23 Outcomes for babies with and without snapped umbilical cord (Waterbirth and birth out of water combined), *N* = 16,223

	Snapped umbilical cord prior to clamping, *N* = 16,223		
	Yes *N* = 122	No *N* = 16,101	Percentage difference (95% CI)
Infant primary outcome (P, MIS/NNRD)			
No adverse infant outcome or treatment	110 (90.2)	15,601 (96.9)	
Adverse infant outcome or treatment	12 (9.8)	500 (3.1)	6.7 (2.6 to 13.3)
NNU admissions (P, NNRD)			
No	106 (86.9)	15,336 (95.2)	
Yes	16 (13.1)	765 (4.8)	8.3 (3.4 to 15.4)
NNU admission requiring respiratory support (P, NNRD)			
No	118 (96.7)	15,900 (98.7)	
Yes	4 (3.3)	201 (1.3)	2.0 (0.03 to 6.9)
Receipt of therapeutic hypothermia (P, NNRD)			
No	122 (100.0)	16,085 (99.9)	
Yes	0 (0.0)	20 (0.1)	−0.001 (−0.002 to 0.03)
Antibiotics administered within 48 hours of birth (P, NNRD)			
No	115 (94.3)	15,684 (97.7)	
Yes	7 (5.7)	370 (2.3)	3.4 (0.4 to 9.0)
Intrapartum or neonatal deaths (P, MIS/NNRD)			
No	122 (100.0)	16,097 (99.98)	
Yes	0 (0.0)	4 (0.02)	−0.0002 (−0.0006 to 0.03)

Snapped umbilical cord prior to clamping

There was a higher rate of snapped umbilical cords prior to clamping in the infants born in water compared to those born out of water (1.0% vs. 0.3%, respectively), with the null hypothesis accepting that waterbirth is inferior to leaving the pool (aOR 3.89, one-sided 95% CI −∞ to 6.88). *Table 23* describes key outcomes for infants with snapped cord (*n* = 122) compared to infants with no record of snapped cord (*n* = 16,101). All outcomes were more prevalent for infants with snapped umbilical cords (including NNU admissions with respiratory support: 13% vs. 5%); antibiotics were administered within 48 hours of birth, 5.7% vs. 2.3%, but there were no deaths among babies with a snapped cord prior to clamping.

Timing of cord clamping

Cord clamping of < 60 seconds after birth was observed in a low proportion of each group (waterbirth: 5.4% vs. birth out of water: 8.1%), demonstrating that waterbirth was non-inferior to birthing out of water after adjusting for confounders (aOR 0.73, one-sided 95% CI −∞ to 0.85).

Apgar scores

Apgar scores at 1 and 5 minutes were dichotomised into 7–10 (normal) vs. 0–7 (low). Apgar score at 10 minutes was not available from the data. A high proportion of both groups had normal Apgar scores at each time point, with 3.6% vs. 5.1% with low scores at 1 minute and 0.5% vs. 0.9 at 5 minutes (waterbirth and out of water, respectively). After adjustment for confounders, there was evidence to show that waterbirth was non-inferior to birthing out of water at 1 and 5 minutes (aOR 0.72, one-sided 95% CI −∞ to 0.78; 0.62, −∞ to 0.77, respectively).

Resuscitation at birth

Evidence of resuscitation was seen in 4.1% of infants born in water and 6.3% born out of the pool, demonstrating that waterbirth was non-inferior to birthing out of water (aOR 0.61, −∞ to 0.65). The most common method of resuscitation was stimulation/suction bag and mask ventilation (basic resuscitation), with the remaining using intubation, drug administration or cardiac massage.

Intrapartum stillbirth or deaths prior to neonatal unit/postnatal ward discharge and cause

Intrapartum or neonatal deaths were reported for 13 infants: 7 following waterbirth (0.18 per 1000 births) and 6 (0.29 per 1000 births) among babies born out of water, with evidence of non-inferiority (aOR 0.22, one-sided 95% CI −∞ to 0.80). There were no records that suggested the babies who died and did so from a congenital anomaly.

Skin-to-skin contact at birth

Skin-to-skin contact between the infant and mother or father was recorded in the majority of births; 5.6% of all waterbirths had no record of skin-to-skin contact compared to 7.6% in those leaving the pool. This suggests that waterbirths are non-inferior to birthing out of water (aOR 0.74, one-sided 95% CI −∞ to 0.80).

First breastfeed within first hour

There were 17.6% of waterbirth babies who were not breastfed within the first hour compared to 27.7% babies born out of water; waterbirths are non-inferior to birthing out of water (aOR 0.63, one-sided 95% CI −∞ to 0.70).

Neonatal unit admissions and respiratory support

The NNU admissions were observed in 3.7% of waterbirths compared to 5.8% of births out of water, with the average length of stay for NNU admissions in the waterbirth group being 48 hours compared to 50.3 hours in births out of water. Respiratory support was provided in 0.8% of waterbirths and in 1.5% of births out of water. For all outcomes, waterbirth was found to be non-inferior to birthing out of water [aOR 0.66, one-sided 95% CI −∞ to 0.71; IRR 0.88, one-sided 95% CI −∞ to 0.94; aOR 0.58, one-sided 95% CI −∞ to 0.68, respectively].

Therapeutic hypothermia, brachial plexus injury, treatment for jaundice, successful/attempted lumbar puncture

Therapeutic hypothermia was recorded in 0.07% of waterbirths and in 0.26% of births out of water (aOR 0.33, one-sided 95% CI −∞ to 0.53). No brachial plexus injuries were recorded in the data for waterbirth and four were recorded in births out of water. Treatment for jaundice was observed in 1.1% of waterbirths and in 1.7% of births out of water (aOR 0.75, one-sided 95% CI −∞ to 0.86). Successful or attempted lumbar punctures were recorded in 0.5% of waterbirths and in 0.8% of births out of water (aOR 1.00, one-sided 95% CI −∞ to 1.62).

Administration of intravenous antibiotics, including timing and duration

From the NNRD records, antibiotics were administered within 48 hours of birth for 1.8% (*n* = 629) of all waterbirths and 2.9% (*n* = 535) for infants born out of water, with similar rates recorded in the MIS data from site opening (*n* = 181, 1.8% and *n* = 149, 2.9%, respectively). Being born into water was found to be non-inferior to being born out of water (aOR 0.69, one-sided 95% CI −∞ to 0.77; aOR 0.74, one-sided 95% CI −∞ to 0.94, respectively). The average duration of antibiotic administration for infants admitted to NNU administered within 48 hours of birth was 3 days (IQR: 2–5) and 4 days (3–6), respectively.

Highest C-reactive protein and blood culture positive with a recognised pathogen

Among the 1164 (waterbirth: *n* = 629; out of water: *n* = 535) babies who had been recorded on the NNRD as those who received IV antibiotics within 48 hours of birth, blood culture results were extracted from the NNRD. Blood cultures were sent for 84 (13.4%) and 61 (11.4%) of waterbirths and births out of water, respectively, of which 4 (4.8%) and 2 (3.3%), respectively, had growth recorded (either clear or unclear pathogenicity).

After site opening, data relating to CRP and blood culture results were also captured in the MIS.

Overall, 2.0% (*n* = 329/16,223) of babies born after site openings received IV antibiotics within 48 hours of birth; the mean highest CRP result was similar among babies born into water and out of water (8.6 mg/dl vs. 8 mg/dl,

respectively). Of the 374 blood cultures recorded as being sent after site opening, four babies had a blood culture performed and had a growth confirmed infection (one baby born in water, and three babies born out of water).

Re-admission to hospital within 7 days of birth

As babies requiring re-admission to hospital are usually admitted to a ward outside of maternity, infant re-admissions to hospital were not reported in the MIS or NNRD data received.

Chapter 6 Factors influencing the use of birth pools for labour and birth in the United Kingdom

Background

Research on use of water immersion during labour and birth in the UK is limited, but international studies have identified several barriers to its widespread adoption. Negative attitudes from medical staff, often stemming from a lack of experience and safety concerns, have been frequently reported,[46–49] along with insufficient knowledge and education among other healthcare professionals.[47,49] Water immersion policies and guidelines have been found to be restrictive,[47] and inadequate staffing levels,[46,48] poor information provision[50] and stigma from friends and family[51] also affect birth pool use.

In the UK, birth options include OUs, alongside midwifery units (AMUs), freestanding midwifery units (FMUs) and home births, although many services do not offer all options. However, women planning to give birth in OUs, even those without risk factors, tend to have significantly lower rates of pool use compared to those in freestanding or AMUs. As found internationally, negative staff attitudes have been identified as a key barrier to water immersion during labour and waterbirths in the UK.[52,53]

To address gaps in understanding the factors influencing birth pool use in the UK, we conducted a two-stage qualitative study. Stage 1 comprised online discussions and interviews with women, midwives, neonatologists and obstetricians to explore their attitudes and experiences related to birth pool use for labour and birth. Stage 2 comprised in-depth case studies of OUs and midwifery units.

Methods and findings are summarised here, but these are described in detail in two publications.[44,45]

Stage 1: online discussion groups and interviews

Methods

Between October and December 2018, separate online discussion groups were set up for midwives, women who were pregnant or had given birth within the previous year, and neonatologists/paediatricians and obstetricians. The aim was to explore experiences, attitudes and beliefs in relation to the use of birth pools during labour and birth. This method was selected to engage geographically diverse participants and to encourage open expression of views via an anonymous forum. The online discussion groups were advertised via professional and parenting networks. Due to the difficulty in recruiting medical staff to participate in online discussions, between December 2018 and February 2019, we offered brief semistructured interviews to capture the views and experiences of this group. All midwives and medical staff worked in NHS settings in the UK.

Findings

The study revealed a range of factors influencing birth pool use in the UK, which were grouped into three main categories: Resources, unit culture and guidelines, and staff endorsement.

Resources

Availability of birth pools was a significant factor affecting pool use. Some women and midwives reported a shortage of pools, leading to limited access; the lack of availability of waterproof CTG equipment also restricted pool use for

women with risk factors. Midwives suggested that a shortage of pools affected their ability to accommodate women's choices in labour and created a reluctance to offer a pool, which in turn impacted on women's awareness and midwives' experience of intrapartum water immersion and waterbirth. Time taken for filling and cleaning pools between uses and inefficient allocation of birthing rooms were also highlighted. In obstetric-led units, where pool availability was particularly scarce, some women, who wanted to use a pool, were unable to.

Women described using strategies to ensure access to a pool, such as selecting a maternity unit with sufficient pools, contacting several units around their due date to assess occupancy, requesting a pool when telephoning the unit in labour or planning a home birth (which as women identified, due to cost, would not be accessible for all).

> *When planning my second delivery, I chose the unit based on how likely I was to get in the pool. The one I chose had the pool in a small internal room with no natural light; they were clear that it was only ever used for pool deliveries. The other potential unit … stated that the pool room was the largest room they had and was a lovely environment, so it often got used for normal deliveries just because it was one of the nicest rooms. I was shocked that they would allow the pool to be blocked in this way.*
>
> *Woman 308*

Unit culture and guidelines

Hospital guidelines were perceived as rigid and arbitrary by participants, making it challenging for women with risk factors to access intrapartum water immersion. Some participants mentioned that birth was often overmedicalised, especially in obstetric-led units, which led to pool use being viewed as unusual, and thus constrained, in contrast to the experience of women labouring in MLUs who generally described pool access as easy.

> *I was blocked (from using a pool) without genuine evidence-based rationale – it was a blanket policy they have of not letting any woman with any level of GD (gestational diabetes) use the birth centre … Postcode lottery comes into play as other areas would let a GD mother use a pool, which tells me that the risk cited by some clinicians is debatable and not evidence based.*
>
> *Woman 202*

Staff endorsement

Women receiving midwifery-led care generally felt supported in their choice to use a pool for labour and birth. Some midwives identified that a lack of confidence due to limited experience may underpin staff resistance to offering water immersion during labour and birth. Lack of support from obstetricians and senior midwives was also cited as a barrier to pool use, particularly in OUs.

Medical staff considered water immersion during the first stage of labour to be generally safe, but they raised concerns about potential risks of waterbirths, such as delayed recognition of complications, meconium aspiration, infection due to unclean water, increased perineal trauma and difficulties with fetal monitoring. Neonatologists, in particular, did not see any benefits of waterbirth for the baby and expressed concerns about potential harm, while obstetricians believed that pools provided effective analgesia for the first stage of labour but were less suitable for birth. It was suggested that some midwives preferred a 'hands-on' approach for the birth due to concerns about perineal tearing and would therefore encourage women to leave the pool before birth. Medical staff highlighted the difficulty of establishing the relative risks (RRs) of waterbirths due to lack of evidence and suggested that their perception of the safety of waterbirth might be biased due to their involvement in complicated births.

> *I do think there is still some resistance to (waterbirth) in the obstetric field. So better information wouldn't be a bad thing … people are worried about infections … aspirations, pneumonia in babies. So yeah there are obstetricians who take a long time to change their views.*
>
> *Obstetrician 1004*

Conclusions from online discussion groups and interviews

This work identified various factors influencing the use of birth pools and rates of waterbirths in the UK and emphasised the need to address issues related to resource availability, including midwives with experience of caring for women in a pool, unit culture and guidelines, and staff endorsement. Demand for intrapartum water immersion and waterbirth was perceived to vary across the UK and across different socioeconomic groups: health professionals suggested that greater promotion of the options by maternity unit staff could increase awareness among women. Proactive support for waterbirth in obstetric-led units was seen as lacking. Obstetricians and neonatologists and some midwives held differing views towards water immersion during the first and second stages of labour. Those expressing concerns about birth in water generally expressed some acceptance of the potential analgesic benefits of water immersion during the first stage of labour, but they had concerns about the safety of birth in water for mothers and their babies. Other midwives, who were experienced and confident with caring for women in water during labour and birth, did not make this separation when talking about pool use.

Stage 2: case studies

Stage 2 of the qualitative work was designed to gain a deeper understanding of the factors influencing water immersion practices in selected maternity units. Data collection took place between July 2019 and March 2020 and included semistructured interviews, collating service documents and public-facing information, and observations of the unit environment.

Sampling and recruitment

Three case study sites were selected from NHS Trusts or Health Boards participating in the wider POOL Study, each with a MLU and an OU and at least one birth pool. The selection of sites aimed to ensure geographical diversity and varying waterbirth rates, as shown in *Table 24*.

Participants

111 interviews were conducted across the six case study units (*Table 25*).

Case study findings

We identified similarities and differences across the case study units that influenced the rates of pool use for labour or birth.

Some of the key similarities were:

- Limited access to training: Most midwives had received no formal training in caring for women during intrapartum water immersion or during waterbirth. Training was considered as a 'luxury' due to time constraints. Student midwives had mixed exposure to intrapartum water immersion and waterbirth during their training, and obstetricians

TABLE 24 Case study site characteristics

	Site A		Site B		Site C	
	MLU	OU	MLU	OU	MLU	OU
Births per year (circa)	400	5000	1000	4000	600	4000
Birth rooms	3	12	4	12	5	12
Pools	2	2	4	1	3	1
Waterbirth rate (circa) (%)	61	5	30	1	28	0.5

TABLE 25 Interview participants

	Site A		Site B		Site C	
	MLU	OU	MLU	OU	MLU	OU
Bands 5–6 midwives	3	6	4	4	3	5
Bands 7–8 (senior) midwives	4	6	2	1	1	2
Student midwives	4	1	2	2	1	2
Maternity care assistants	3	2	1	1	0	0
Postnatal women	1	1	6	4	4	5
Community midwives	6		4	0	6	0
Obstetricians	N/A	4	N/A	0	N/A	4
Neonatologists/paediatricians	N/A	2	N/A	0	N/A	2
Doulas	0	0	2	0	0	0

also had limited knowledge. Midwives felt that greater awareness of the benefits of water immersion among doctors would support their practice.

- Sociodemographic differences in pool use: Midwives observed that 'White, middle-class women' who were well-informed about their options were more likely to use a birth pool. Women from ethnic minority communities, particularly Asian women, were perceived as less likely to use a pool for labour or birth due to unfamiliarity or cultural reasons. Midwives suggested that providing comprehensive information to all women during the antenatal period could help reduce sociodemographic differences in pool use.
- Issues using waterproof fetal monitoring equipment: Units had waterproof equipment for continuous fetal monitoring, but it was not widely used, and some midwives or consultants were unaware of its availability. The equipment was not always charged, was sometimes not working or not synchronised to centralised fetal monitoring systems and was described as awkward to use in the pool. Midwives' reluctance to facilitate continuous fetal monitoring in water meant that women who were recommended to have this were usually prevented from accessing water immersion.

We identified differences in criteria for pool use, equipment and resources, senior staff support and women's awareness and attitudes towards intrapartum water immersion and waterbirth among the case study sites. These differences are summarised in *Table 26*.

Criteria in all units were generally seen as appropriate and supportive of intrapartum water immersion and waterbirth by midwives. However, guidelines were inconsistently applied, depending on individual clinicians' knowledge and attitudes. For instance, some midwives had mixed views on whether women should use a pool in early labour, and cervical dilation requirements sometimes prevented pool use when women declined vaginal examinations.

On OUs, women were found often not to be offered with the option of water immersion even when they met the unit criteria for doing so.

> *I think if people followed the guidelines on who can use the pool a bit more, then they would be helpful. Like … up on the high-risk unit now, if they thought about who could actually labour in the pool … But … it's not really offered, even to the women who can use it.*
>
> *Site B, Midwifery unit, Student Midwife, 109*

Use of equipment and resources varied across the sites. In site A, pool rooms on the OU were allocated efficiently, encouraging maximum pool use; however, this was not the case in sites B and C.

TABLE 26 Differences between case study sites

Categories and themes	Barriers	Facilitators
Criteria for pool use		
Criteria for intrapartum pool use	Women must meet specific criteria to use a pool during labour. Lots of exclusion criteria. *Site C*	Few contraindications to pool use mentioned in guidelines; risk factors assessed on an individual basis. *Site A* Guidelines specifically mention women with risk factors who can use a pool. *Site B*
Staff training requirements	Midwives required to be trained to support women in water for labour/birth; otherwise, they have to approach their manager before undertaking this. *Site C*	No specific training is required (other than emergency evacuation training); midwives are required to have the necessary competences and skills. *Sites A and B*
Cervical dilation criteria for entering the pool	Women should be in established labour (4–5 cm). *Sites B and C*	No fixed cervical dilation required; pool can be used for prolonged latent phase. *Site A*
Use of equipment and resources		
Allocation of pool rooms	Women usually automatically allocated a non-pool room. *Site B, Obstetric unit* General pool room use so is rarely empty. *Site C, Obstetric unit* Women not using the pool would not be moved out of the pool room during labour. *Site C, Obstetric unit*	Low-risk women asked at triage if they would like to use a pool. *Site A, Obstetric unit* Some midwives will ask women to switch rooms to free up the pool room. *Site A, Obstetric unit*
Filling pool	Pool is usually filled after women arrive. *Sites B and C, Midwifery unit*	Pool is automatically run when women are on their way. *Site A, Midwifery unit*
Pool room environment	Pool rooms less popular than other rooms. *Sites B and C, Obstetric unit*	Considered 'nicer' than general birth rooms; one pool room located near midwives' station. *Site A, Obstetric unit*
Emergency procedures	Emergency evacuation not well-practised; some midwives not confident in emergency procedures. *Site C, Obstetric unit*	Midwives confident in ability to cope with emergencies in the pool. *Sites A and B, Obstetric unit*
Home birth pool use	Cost can be a barrier to pool hire. *Sites A and B* Women have to source their own pool. *Sites A and B*	Pools, liners and water pumps provided for women wanting to use a pool at home. *Site C*
Support for 'physiological birth'		
Support for 'physiological birth'	Obstetric consultants sometimes block women from accessing the midwifery unit. *Site C*	Obstetric consultants are supportive of the midwifery unit and facilitate women going there. *Sites A and B* Support for 'physiological birth' at all levels of management. *Site A*
Women's awareness of and attitudes towards pool use		
Tours of the unit	No tours of the midwifery or OU; virtual tour available online. *Site B*	Women are invited to have a tour of the midwifery unit. *Sites A and C*
Antenatal classes	Antenatal classes are oversubscribed, so not all women have the chance to attend. *Sites A and B*	Antenatal classes are available for all women and pool use is discussed at length. *Site C*
Sociodemographic differences	Large Asian population who are perceived as less likely to want to use the pool. *Site C*	Women in the area are well-informed and aware of their options. *Sites A and B*

> *I think there is a culture of it's kind of not the right place for waterbirths … it's not facilitated for that reason so if they've got somebody else in that room who doesn't need (the pool) they wouldn't swap them round for it.*
>
> *Site C, Obstetric unit, Bands 5–6 Midwife, 405*

TABLE 27 Key differences between OUs and midwifery units

Categories and themes	OUs	Midwifery units
Physical environment		
Pool availability	Pool in 7–17% of birth rooms	Pool in 60–100% of birth rooms
Pool room environment	Some pool rooms are disliked by midwives	Described by women/midwives as relaxing/encouraging of pool use
Midwives' intrapersonal factors		
Midwives' attitudes	Some are not keen on pool use during labour and birth, often due to lack of confidence	All are very positive about pool use
Confidence of midwives	Some are not confident – frightened of pool use	All are confident in supporting pool use
Autonomy and support of midwives		
Senior staff support	Some senior staff are unsupportive of pool use	Midwives feel very supported by seniors to support pool use
Midwives' autonomy	There is some autonomy to offer the pool to 'low-risk' women	There is complete autonomy to offer the pool to all women
Information and support for women		
Women's awareness	Women do not necessarily know there is a pool, so they do not ask	Women are very aware of pools on the unit; most ask to use one
Information given to women	Pool use is not fully discussed antenatally	Pool use is discussed and encouraged antenatally
Proactive offering of pool	Pool is not usually offered – women have to be proactive	Pool is offered/promoted to all women
Support for women to use a pool	Pool use is generally discouraged, and in some cases, blocked	Women are supported/actively encouraged to use a pool

Senior staff support for 'physiological birth' played a significant role in influencing pool use during labour and birth. In sites A and B, obstetric consultants supported midwifery-led care, leading to increased access to water immersion and rates of waterbirths. However, in site C, obstetricians tended to discourage women from accessing the midwifery unit, impacting intrapartum pool use.

> *They suspected that I had a blood condition … (but) when the bloods came back, they were … normal … every time and there was no reason for me to be induced (on the OU). But the doctors were adamant. So, they would say like, 'She's at risk of stillbirth' and … things like that….*
>
> *Site C, Midwifery unit, Woman, 434*

Women's awareness and attitudes towards intrapartum pool use were influenced by factors such as unit tours and antenatal classes. In sites A and C, unit tours and pool room visits encouraged the consideration of their use during labour. Antenatal classes were also useful in raising awareness, although the availability was limited in sites A and B.

> *When I fell pregnant I was straight away thinking epidural in hospital, but (after visiting) I thought actually the birth centre was a much calmer, nicer place to give birth if I could.*
>
> *Site A, Midwifery unit, Woman, 319*

Differences between OUs and midwifery units within each site were more substantial than those between the same type of units across the sites. Differences fell into four main categories: physical environment, midwives' intrapersonal factors, autonomy and support of midwives, and information and support for women (*Table 27*).

The physical environment of maternity units, particularly the availability and location of pools, considerably influenced the numbers of women using pools. Some midwives suggested that the low number of pools available in OUs suited the low level of demand from women. However, others proposed that the limited availability itself affected requests to use a pool. Women felt discouraged from requesting to use a pool in OUs due to their perceived scarcity, and the nature of the rooms themselves made them less popular with some midwives (e.g. described as being located at the furthest point from the midwives' station, set up differently to other birth rooms or not connected to the unit's central fetal monitoring systems).

> *There's one pool in the whole (unit) and it is first come first served … I think I had that in my head … just even if I asked for it I probably wouldn't get it.*
>
> *Site B, Obstetric unit, Woman, 117*

Midwives' attitudes and confidence played a crucial role in facilitating water immersion and waterbirths. Midwives in MLUs were more positive and experienced in water immersion and facilitating waterbirth, while those in OUs had varying attitudes and experience, with some expressing fear or reluctance. Midwives proposed that they and their colleagues fitted into one of two categories: 'low-risk' midwives who are confident in low-risk settings, and 'high-risk' midwives who are skilled at supporting higher-risk women but less comfortable with low-risk births.

> *Some midwives don't like working in the midwifery-led unit, they're not midwifery-led midwives, they'll call themselves high risk midwives … they will be then the midwives that are highly skilled in looking after that diabetic mother, or you know, all of those kind of things, and their knowledge in a different area will be absolutely superb and much more superior to somebody else, but switch their roles, and they both feel really uncomfortable and out of their comfort zone.*
>
> *Site B, Bands 7–8 Midwife, 102*

Autonomy and support for midwives were also important factors. Midwives in MLUs felt fully supported and encouraged to offer water immersion and waterbirths to women. By contrast, midwives in OUs often had to seek approval from senior staff, fearing they could be blamed for adverse outcomes if they supported pool use.

> *Everybody's happy if the outcome is good, but if (it's not) … they go back and back and back … and then they'll start looking and saying … her blood pressure was up once, so why did you put her in the pool? So that is sometimes the issue … It's not quite as black and white up here to put somebody in the pool as it is on the midwifery-led unit.*
>
> *Site B, Obstetric unit, Bands 7–8 Midwife, 133*

The information provided to women about intrapartum water immersion and waterbirths during antenatal care appeared to influence their choices. In MLUs, pool use was actively promoted and routinely offered to women. In OUs, pool use was not discussed as frequently, leading to a reliance on women actively requesting the option, resulting in lower utilisation.

> *I think if it's high risk, I don't think (pool use is) discussed … it just gets dropped … and I don't think it is given as a valid, potential option … If your obstetric staff are not keen on it, it won't be promoted via them, they'll actually try and put women off, and if the midwives are not experienced in it, then they won't promote it either.*
>
> *Site C, Obstetric unit, Bands 7–8 Midwife, 402*

Discussion of qualitative work

Stage 1 of the qualitative research identified factors influencing the use of birth pools for labour and birth by exploring the attitudes and experiences of key stakeholders, and it was the first UK study to encompass the perspectives of women, midwives and medical staff. Overarching categories were resources, unit culture and guidelines, and staff

endorsement. Obstetricians and neonatologists generally expressed safety concerns around births in water, which were shared by some midwives. Midwives who were supportive of waterbirths regarded a lack of opportunity for training, experience and confidence of individual midwives as factors limiting pool use, particularly in OUs. Stage 2 of the research provided new insights into the influence of maternity unit culture on pool use through examination of the differences between six UK maternity units with varying waterbirth rates. Consistent with UK pool use statistics, the greatest differences were between OUs and midwifery units within case study sites rather than between the sites themselves. Criteria for intrapartum pool use, equipment and resources, staff attitudes and confidence, senior staff support for colleagues and endorsement of physiological birth were identified as key, alongside information provided to and encouragement for women to use a pool for labour or birth.

In both stages of the research, we found that pool availability had a broad impact, affecting women's choice of maternity unit, requests for water immersion during labour, midwives' ability to offer the pool and confidence in relation to pool use. Although limited pool availability acted to reduce the demand for water immersion and waterbirth, low demand was often cited as a reason for limiting the number of pools available, creating a vicious circle in which pool provision remained low. As found by Russell,[52,53] birth room allocation practices in case study maternity units were a key influence on pool access, and it appeared to reflect the extent to which pool use was supported by the maternity unit. The timing of filling the pool also influenced the extent to which women were encouraged or enabled to use water immersion or have a waterbirth.

Examination of the UK context highlighted the differences between MLUs and obstetric-led maternity units. Women participating in stage 1 of the research generally perceived MLUs as supportive of pool use and waterbirths, but they described obstetric-led units as an overmedicalised environment in which pool use was seen as unusual and therefore restricted. Exploring the perspectives of medical staff facilitated understanding of the reasons behind these differences in culture, building on previous quantitative research.[48] For example, obstetricians and neonatologists, although supportive of water immersion as analgesia during the first stage of labour, acknowledged that there was hypervigilance around birth in water, attributing this to a lack of evidence on the safety of waterbirth for mothers and babies and skewed perceptions of risk due to experiences being confined to complicated births.

The pool room environment was also found to influence the use of water immersion during labour, with midwifery units at case study sites providing welcoming pool rooms, while OU pool rooms had barriers to use, such as poorer monitoring facilities. Although several studies[54–56] show that the birth room environment positively influences labour experience and outcomes, how this occurs, and the implicit messages conveyed by environment, have not been fully explored.

The relationship between midwives' attitudes to water immersion and waterbirths, their confidence in offering the pool to women and the setting is a complex one. In terms of encouraging water immersion, in the midwifery units midwives were confident and experienced, with easier access to facilities and supported by senior staff.. Conversely, in the OUs, midwives were often fearful of facilitating pool use, had fewer opportunities to gain experience and worked with senior staff who themselves did not support water immersion or promote the pool as an option. In stage 2 of this research, midwives highlighted fundamental differences in the beliefs and competences of those working in the different settings. It is not possible to elicit the causal chain in this situation: whether midwives are attracted to a certain type of setting due to previous preference, or whether finding themselves in a particular setting, they develop the beliefs, competences and confidence to match, conforming to the norm for that setting. These differences and this interplay of factors have the potential to impact considerably on the way care is delivered and thus merit further exploration.

Lack of training and unfamiliarity with equipment were both given as reasons for midwives based in OUs being unable or reluctant to care for women in a pool. Such attitudes would not be tolerated towards other equipment on OUs, suggesting an acceptance among all levels of staff that the option for women to use a pool on an OU is an optional luxury rather than an essential midwifery skill.

In stage 1 of the research, strict eligibility criteria for intrapartum pool use (as found by Newnham *et al*. in 2015[57] and 2017[58]) were found to have a clear impact on the accessibility of the option during labour and birth. In line with previous studies,[47] both women and medical staff suggested that eligibility assessment was subjective rather than

evidence-based. The existence of guidelines should have the potential to support midwives' confidence and autonomy. However, we found that inconsistent implementation across case study sites meant that some women were prevented from using a pool when trust/health board policy would have supported them to do so. Pool use guidelines at all three sites had relaxed in recent times, with a general shift towards assessing suitability on an individualised basis; for example, increasing cut-off BMIs, removing cervical dilation requirements for pool entry and supporting women who are carriers of GBS and who require intravenous antibiotic prophylaxis to use a pool. Midwives generally welcomed this increased flexibility; however, not all were aware of the changes.

In support of Russell's findings,[53] participants suggested that water immersion tended not to be actively offered as an option, therefore there was a reliance on women themselves requesting to use a pool. This is contrary to the NICEguidance,[59] which states that women should be offered the opportunity to use a pool during labour. Evidence suggests that antenatal information plays a vital role in enabling women to make an informed choice about water immersion.[50,60,61] This is particularly important in starting to democratise pool use and break down some of the barriers, either real or assumed, faced by women from different backgrounds accessing waterbirth.

Recommendations for practice based on qualitative work

Midwives, doctors and managers working within obstetric-led care need to be aware of the potential barriers to intrapartum water immersion and waterbirth, so they can act to reduce these and support use of pools where appropriate. Increasing exposure to care of women using pools during labour and birth for student midwives and midwives in OUs may enhance confidence and be instrumental in changing unit culture. Strong midwifery leadership, for example through ensuring the presence of a consultant midwife in all settings (as recommended by the Royal College of Obstetricians and Gynaecologists[62]), is also key to ensuring a culture that safely supports uncomplicated labour and births.

Providing obstetricians and neonatologists with information on, and exposure to, waterbirths could increase support for pool use, reduce the risk of adverse events erroneously being attributed to birth in water and increase confidence in responding to emergencies in the pool. Applying local guidelines consistently will help to ensure that women who can safely use a pool are enabled to do so.

Even in areas with perceived low demand for water immersion, increasing the provision of pools in birth rooms can enhance midwives' experience and confidence, enable water immersion to be offered more frequently and encourage women to request to use a pool. Birth room allocation practices should also be considered to facilitate more effective use of unit resources. Thought should be given to the birth room environment to ensure that all birth rooms are attractive to both women and midwives and that the layout of pool rooms encourages use of the pool. Filling the pool ready for a woman's arrival may also facilitate this.

More importantly, it is vital that, in the antenatal period, women are provided with information to enable an informed choice about water immersion during labour and birth. Time constraints may make it difficult to discuss this in routine antenatal appointments, so it is important that antenatal information and/or maternity unit tours are available for all. At an organisational level, support for MLUs and home birth can help to increase access to these settings, and in turn, pool use.

Conclusions from qualitative work

The context of care in maternity units has a substantial influence on pool use during labour and birth. We found considerable differences between OUs and midwifery units in relation to equipment and resources, staff attitudes and confidence, senior staff support and women's awareness of intrapartum water immersion. Findings have several implications for practice: increased exposure to care of women during intrapartum water immersion for labour and birth is vital to improve the confidence of midwives, particularly those working in OUs; sharing of information with for

obstetricians and neonatologists on the practicalities and outcomes of pool use could increase support for waterbirth; and improved access to antenatal information would help increase awareness of the option to use a pool. We recommend that OUs increase pool provision, ensure birth room allocation, maximise the use of unit resources, design pool room environments that encourage use and ensure that all midwives take the responsibility for being familiar with water immersion equipment and unit guidance.

Chapter 7 Discussion and conclusions

The POOL Study was conducted to determine whether, among women without 'risk-factors', who use water immersion during labour, having a waterbirth is as safe for themselves and their babies as leaving the water prior to birth. The POOL Study provides compelling evidence that among women who use water immersion during labour, waterbirth, as practiced by NHS midwives, is as safe for mothers and their babies as birth out of water.

The cohort study had a non-inferior design, that is, the study tested whether the rates of adverse outcomes were higher following waterbirth than among births out of water. Data were extracted from the MIS from 26 NHS maternity services, and for babies admitted to a NNU, date were extracted from the NNRD, relating to births between January 2015 and June 2022.

After data cleaning, including removal of duplicates, 869,744 individual birth records were received over the study period, of which 87,040 (10.0%) related to women who used a pool during labour or birth, and 782,704 (90.0%) records related to women who did not use a pool. The number of births an individual site contributed to the study ranged from 6804 to 65,667. Rates of pool use varied by site between 1.6% and 22.9%, and in the proportion of women using a pool who gave birth in water, it ranged across sites from 32.7% to 82%. Overall, 15.9% of women using a pool had a risk factor recorded in their antenatal record or at the time of pool entry, although this may be an overestimate of the true rate, as it may include some women unnecessarily due to issues with data storage within the MIS.

Key study findings

Rates of pool use and waterbirth

Over the study period, the proportion of women in England going into spontaneous labour declined from 59% in 2015 to 47% in 2022.[63] This decline was reflected as a reduction in the rate of pool use, and of waterbirths, over the latter part of the study period. The proportion of women using a pool during labour was highest in quarter 3, 2016, when 11.9% of women used a pool and 6.0% of woman gave birth in water; by quarter 2, 2022, the proportions were 7.7% and 4%, respectively. Reflecting closure of MLUs and redeployment of staff to centralised services,[64] the beginning of the COVID-19 pandemic in quarter 2, 2021, was associated with a decline in POOL use and rates of waterbirths, but by the autumn quarter of 2021, the rates had returned to pre-pandemic levels.

Transfer to obstetric care

Among women without complicating factors at pool entry, 29% of nulliparous women (*N* = 11,139) and 5% of parous women (*N* = 1688) received additional monitoring, obstetric interventions or regional analgesia before or during birth. Reflecting clinical need, 97.1% of women (*N* = 12,455) receiving additional care prior to or during birth gave birth in an OU, with rates of SVBs, instrumental birth and birth by caesarean section being 27.9%, 52.2% and 19.8%, respectively. The rate of the neonatal primary outcome among babies born to women who received additional monitoring, obstetric interventions or regional analgesia, before or during birth, was 11.7% (*N* = 434), with 13.6% (*N* = 1,744) of babies being admitted to a NNU.

The rates of additional care before or during birth were similar to the rates of transfer to obstetric care found among nulliparous and parous women, without complicating factors at labour onset when commencing labour care in a MLU or at home, in the Birthplace in England study (32.9% and 6.7% respectively).

Mode of birth among women using a pool

Overall, among women who used a pool without risk factors, the rates of SVBs were high (78.0% nulliparous women, 97.6% parous women), with low rates of instrumental births (10.9% nulliparous women, 1.6% parous women) and birth by caesarean section (5.9% nulliparous women, 0.7% parous women). Rates of instrumental and operative births were similar to those found in the Birthplace in England study among women planning birth outside of an OU.

Primary analysis group

The primary analysis excluded women with risk factors recorded in the antenatal notes or at pool entry and those who received additional monitoring, obstetric care or epidural analgesia prior to birth. The primary analysis included 39,627 births in water, and 20,775 births out of water, and compared rates of adverse events among births in water with births out of water.

Maternal primary outcome

The study found no evidence of increased rates of OASI among women who gave birth in water. After adjusting for differences in the characteristics of women who gave birth in, and those who gave birth out of, water, fewer nulliparous women who gave birth in water had a recorded OASI than in those who left the pool [730 of 15,176 women (4.8%) vs. 641 of 12,210 women (5.3%); aOR 0.97, one-sided 95% CI −∞ to 1.08]. Similarly, after adjusting for differences in the characteristics of women who gave birth in, and those who gave birth out of, water, fewer parous women who gave birth in water had a recorded OASI than among those who left the pool before birth [269 of 24,451 women (1.1%) vs. 144 of 8565 women (1.7%); aOR 0.64, one-sided 95% CI −∞ to 0.78].

The upper limit of the CIs for the difference in the proportion of OASI between the groups were less than the prespecified non-inferiority margin, for both nulliparous and parous women, of 1% (OR < 1.23) and 0.6% (OR < 1.38), respectively, indicating that births in water were associated with no increase in OASI compared to births out of water.

When pooled for all women, the rate of OASI in women giving birth in water was lower than that in those who left the pool [999 of 39,627 women (2.5%) vs. 785 of 20,775 women (3.8%); aOR 0.89, one-sided 95% CI −∞ to 0.98]. Preplanned sensitivity analysis, including propensity score analysis, supported the finding of no additional risk of OASI when births occurred in water.

Infant primary outcome

The primary infant outcome for infants was 'adverse infant outcome or treatment' (death, NNU admission with respiratory support or receipt of IV antibiotics within 48 hours of birth) and included births during the period from the first site opening in January 2019 to June 2022. Of the 16,223 infant records, 14,946 (92%) contributed to the analysis. The remaining were excluded due to incomplete recording of some of the outcomes at sites.

The study found no evidence of increased rates of the neonatal primary outcome among babies born in water. After adjusting for differences in the characteristics of women who gave birth in, and those who gave birth out of, water, fewer babies in the waterbirth group met the primary outcome than those born out of water [263 of 9868 infants (2.7%) vs. 224 of 5078 infants (4.4%); aOR 0.65, one-sided 95% CI −∞ to 0.79]. The upper limit of the CI for the difference in infant outcome between the groups was less than the prespecified non-inferiority margin of 1.0% (OR < 1.21), indicating that being born in water was found to be associated with no increase in adverse neonatal outcomes than being born out of water.

Some components of the composite infant outcome are more common than others. In the prospective cohort, which was underpowered to draw conclusion on the important outcome of baby deaths, three babies died following waterbirth (0.3. per 1000 births) and none died following birth out of water. Among the larger cohort of retrospective and prospective births, *N* = 60,402, there were 13 intrapartum or neonatal deaths: 7 following waterbirth (0.18 per 1000 births) and 6 (0.29 per 1000 births) among babies born out of water, with evidence of non-inferiority (aOR 0.22, one-sided 95% CI −∞ to 0.80); 0.8% (*N* = 329) and 1.5% (*N* = 320) received respiratory support on a NNU; and 1.8% (*N* = 629) and 2.9% (*N* = 535) received IV antibiotics within 48 hours of birth. When rates of the individual component outcomes were examined individually, all were lower among births in water than among births out of water; this included the rate of deaths, but due to small numbers, the CIs were wide.

Secondary outcomes

Third-stage management

Lower rates of active management of the third stage of labour occurred among waterbirths compared to births out of water (72.9% vs. 89.1%; aOR 0.31, one-sided 95% CI −∞ to 0.33). For women giving birth in water during the

period of prospective data collection, information was captured on whether it was intended that the placenta would be delivered in or out of water and whether placental delivery occurred as intended. Among the 69% (*N* = 7,422) of waterbirths, where it was intended that the placenta would be delivered once the woman had left the pool, the placenta was delivered out of the pool in 97% (7200) cases, with 1.9% (*N* = 143) of women delivering the placenta in water. Among the 8.5% (*N* = 910) of waterbirths, where it was intended that the placenta would be delivered in water, the placenta was delivered in water in 59.5% (*N* = 541) of cases, with 39.8% (*N* = 362) of women delivering the placenta out of water. Overall, the placenta was delivered in water following 8.6% (*N* = 926) of waterbirths. Among women who gave birth in water, rates of PPH of ≥ 1000 ml were similar among women delivering the placenta in water compared to women delivering the placenta out of the water (1.9% compared to 3.3%; aOR 0.70, one-sided 95% CI −∞ to 1.18, *p* = 0.181).

Childbirth emergencies

Being in a pool during birth may have the potential to delay emergency treatments, such as in the event of shoulder dystocia, or PPH, where the woman needs to leave the pool for treatment.

Shoulder dystocia was recorded as having occurred in 0.6% of waterbirths and in 3.1% of births out of water (aOR 0.16, one-sided 95% CI −∞ to 0.18). There was no evidence that waterbirth increased the chance of shoulder dystocia or extended the head-to-body delivery interval, with a mean head-to-body delivery interval of 3.5 minutes and 3.3 minutes among births in water and out of water.

Among women who gave birth in water, compared to women who gave birth out of water, fewer had a recorded PPH of ≥ 1000 ml (2.9% vs. 3.8%), although differences in measurement techniques mean that direct comparisons should not be made. Among women who gave birth in water, compared to women who gave birth out of water, fewer underwent a MROP (1.8% vs. 2.5%) or received obstetric care following birth (6.5% vs. 9.6%).

Other maternal intrapartum secondary outcomes

Rates of women sustaining any perineal trauma were lower among waterbirths compared to that among women who gave birth out of water (62.2% vs. 68.3%; aOR 0.84, one-sided 95% CI −∞ to 0.88), and similarly, rates of the woman undergoing perineal repair were lower following waterbirths compared to following birth out of water (31.9% vs. 44.3%; aOR 0.78, one-sided 95% CI −∞ to 0.81).

Among women who gave birth in an OU or MLU, the mean duration of postnatal stay was shorter among women who had a waterbirth compared to the duration among women who gave birth out of water [mean 11.7 hours, *N* = 35,514, vs. 15.5 hours, *N* = 17,420; adjusted incidence rate ratio (AIRR) 0.85, one-sided 95% CI −∞ to 0.87]. Rates of women receiving higher levels of care, rates of blood transfusion and rates of women returning to hospital for assessment or admission in the postnatal period were similar among women giving birth in and out of water.

Infant care and feeding

A higher rate of the umbilical cord snapping before it was clamped occurred among births in water compared to births out of water (1.0% vs. 0.3%, aOR 3.89, one-sided 95% CI −∞ to 6.88). Among the 122 babies in both groups, where their cord snapped prior to clamping, compared to babies where the cord was clamped prior to cutting, there were higher rates of: NNU admission (13.1% vs. 4.8%); NNU admission with respiratory support (3.3% vs. 1.3%) and administration of antibiotics with 48 of birth (5.7% vs. 2.3%). No babies with a 'snapped cord' died or received therapeutic hypothermia.

There was no evidence that waterbirth was associated with babies receiving less recommended care at birth. Compared with babies born out of water, waterbirth was associated with lower proportions of babies with cord clamping within a minute of birth (5.4% vs. 8.1%, aOR 0.73, one-sided 95% CI −∞ to 0.85); no record of skin-to-skin contact between mother and her baby at birth (5.6% vs. 7.6%, aOR 0.74, one-sided 95% CI −∞ to 0.80) and babies not breastfed within the first hour of birth (17.6% vs. 27.7%, aOR 0.63, one-sided 95% CI −∞ to 0.70).

Rates of breastfeeding initiation and breastfeeding at the time of discharge from community midwifery care were both higher following births in water compared to births out of water (83.8% vs. 79.8%; 72.1% vs. 67.8%, respectively).

Waterbirth was non-inferior to birthing out of water at both time points (initiation and community discharge of care) (aOR 0.79, one-sided 95% CI −∞ to 0.83; aOR 0.83, one-sided 95% CI −∞ to 0.88, respectively).

Need for additional neonatal care

Rates of babies with an Apgar score of < 7 at 1 and 5 minutes were lower among babies born in water than among babies born out of water (3.6% vs. 5.1%; aOR 0.72, one-sided 95% CI −∞ to 0.78) and (0.5% vs. 0.9%, aOR 0.54, one-sided 95% CI −∞ to 0.62). Reflecting this, the rates of resuscitation were also lower among babies born in water than among babies born out of water (4.1% vs. 6.3%; aOR 0.61, one-sided 95% CI −∞ to 0.65).

Access to pools and waterbirth

The site case studies explored the context of care in maternity units, and this was found to have a substantial influence on pool use. Considerable differences were found between OUs and midwifery units in relation to equipment and resources, staff attitudes and confidence, senior staff support and women's awareness of water immersion.

The online discussion groups and individual interviews, with women, midwives, obstetricians, neonatologists and doulas, identified various factors influencing the use of birth pools in the UK, including resource availability (including midwives with experience of waterbirth), unit culture and guidelines and staff endorsement. Demand for waterbirth was perceived to vary across the UK and across different socioeconomic groups: health professionals suggested that greater promotion of pool use by maternity unit staff could increase awareness of this option among women. Proactive support for waterbirth in obstetric-led units was seen as lacking.

Women with risk factors using a pool

When restricted to risk factors present at the time of pool entry, as recorded by the midwife following birth among records completed after sites opened to the study, 11.4% (*N* = 2725) records were flagged as the mother having at least one risk factor at pool entry. The most common risk factors reported were: induction of labour 2.3% (*N* = 583); GBS carrier 1.9%, 475; gestational diabetes/diabetes 0.8% (*N* = 188); vaginal birth after caesarean (VBAC) 0.7% (*N* = 83); and BMI > 35 kg/m^2, 0.6% (*N* = 152).

There was some indication that, compared to women who did not use a pool in labour, women who used a pool without risk factors and women with identified risk factors who used a pool in labour, there were differences in the proportions of woman of (1) White ethnicity (70.1%, 81.0%, 83.3%, respectively); (2) women who were fluent in English (79.9%, 85.0% and 90.4%, respectively) and (3) women living in least deprived areas (15.2%, 20.7% and 20.5%, respectively).

Interpretation of results

It is important that the results of the study are interpreted as reflecting outcomes observed in the NHS clinical practice rather than evidence of a causal relationship between birth in water and lower risk of OASI, NNU admission or treatment for potential early onset neonatal infection.

The most plausible explanation of the differences found in outcomes between groups is that some women who gave birth out of water did so when those women or midwives had unrecorded concerns, or when there were other reasons to recommend birth was out of water.

When a woman is in a pool and abnormalities occur during labour, providing there is time for her to do so safely, the woman should be advised to leave the pool for care and to give birth out of water.[65] Indications for advising a woman to leave the pool, for example, concerns in the fetal HR or slow advancement of the fetal head, are also associated with the primary maternal and neonatal outcomes. A higher proportion of births with a midwife concern were reported in the out-of-water group (*N* = 1862, 9.0%) compared to the waterbirth group (*N* = 273, 0.7%). This reflects that there is usually sufficient time between a concern becoming evident for a woman to leave the pool and give birth out of water and that most women are willing, and able, to follow such advice. Some midwife concerns, or considerations, which led to women giving birth out of water may not have been documented in the MIS following birth, concealing unidentified differences between women who gave birth in and out of water.

Although the study was designed to reduce bias, its observational design means that the potential remains for unknown or incompletely measured confounders to exist between women giving birth in and out of the water, which have not been controlled for; for example, a woman's individual determination to give birth in water, or the experience of the midwife caring for her. While this is a limitation of observational studies, it reflects 'real-life' choices of women and NHS practice, and their associated outcomes, and should be interpreted as such.

For some outcomes, particularly involving blood loss measurement, direct comparisons between groups should be interpreted with caution. Estimation of blood loss while a woman remains in the water is mostly based on visualisation which is known to be inaccurate,[66] as more accurate blood loss measurement techniques suitable for pool use are yet to be developed.

POOL Study findings in context

The POOL Study provides new knowledge about outcomes for women and their babies following pool use in labour. The findings of the POOL Study add to previous large observational and small randomised studies, conducted in the UK,[18] USA[17] and Australia,[16,67] in finding waterbirth to be associated with no additional morbidity for mothers or their babies.

Perineal trauma

In the mid-1990s, the rate of OASI among women experiencing a SVB in the UK and participating in a randomised trial of perineal care was 1.3%.[68] Low rates of OASI were also reported in out-of-hospital births in the USA between 2012 and 2018 among a cohort of 17,530 women who had a waterbirth propensity matched to 17,530 land births.[17] After matching, the cohort included 26.5% nulliparous women, with rates of OASI of 0.75% and 0.84%, respectively, among births in and out of water.

Over recent years, rates of detected OASI following vaginal birth in the UK have increased.[28] The increasing rates have been attributed to improved detection, women being at greater risk due to the increasing age and BMI of women and potentially other undetermined factors.[30]

The POOL Study was designed to be sufficiently powered to be able to conduct an analysis of OASI rates by parity subgroups, and it found no evidence to indicate that birth in water is associated with increased rates of OASI in either group. The rates of OASI in the POOL Study cohort were 4.6% and 5.0%, respectively, among nulliparous women giving birth in and out of water and were 1.1% and 1.5%, respectively, for parous women giving birth in and out of water.

Rates of OASI found in the POOL Study were higher than those reported in a hospital-based cohort study of 1007 waterbirths at a hospital in England over the 10-year period from 2007 to 2017, which compared outcomes with 36,924 similar 'low-risk' women experiencing a SVB over the same period.[69] The rates of OASI in the period 2007–17 were 4.3% and 4.0%, respectively, among nulliparous women giving birth in and out of the water, and these were 0.9% and 0.9%, respectively, for parous women giving birth in and out of the water.

A UK-based cluster randomised trial explored the impact of a care bundle on rates of OASI between 2016 and 2018. The care bundle included antenatal information for women on OASI, recommending an episiotomy when clinically indicated, perineal protection during all vaginal births and systematic perineal examination following birth. Overall OASI rates among SVBs were 2.6% before and 2.2% after the implementation of the care bundle (aOR 0.75, 95% CI 0.60 to 0.93); rates among nulliparous women were 5.2% before and 4.9% after implementation of the care bundle (aOR 0.81, 95% CI 0.65 to 1.00); and among parous women, the rates were 1.7% before and 1.5% after the implementation of the care bundle (aOR 0.78, 95% CI 0.61 to 1.01).[70] Subsequently, uptake of the care bundle was encouraged across all UK maternity units. Where perineal protection cannot be implemented, such as during waterbirth, midwives are required by the care bundle to document their non-compliance and are encouraged to document the reason for their non-compliance for this aspect of the bundle.

In the UK, two midwives are usually expected to be present at waterbirths but not during SVBs occurring out of water. Evidence from a randomised trial in Sweden, including women experiencing their first vaginal birth (*N* = 3776), found that the presence of a second midwife during SVBs reduced the rate of OASI from 5.7% to 3.9% (aOR 0.69, 95% CI 0.49 to 0.97).[71] A second midwife as standard at SVBs out of water is not currently a component of the RCOG OASI care bundle, but such an addition may have the potential to reduce OASI rates if implemented in the UK.

Rates of OASI found in the POOL Study were similar to those in other studies from the UK, where rates have been reported by parity. This indicates that around 1 in 20 women experiencing a SVB of their first baby will sustain identified damage to their anal sphincter regardless of whether birth is in or out of water. Although the OASI care bundle has shown some effectiveness, further research is required to reduce such trauma.

Neonatal primary outcome

The composite neonatal primary outcome was selected to reflect adverse neonatal outcomes of concern to neonatal and paediatric practitioners, as reported in case series and in previous neonatal studies.[26] After adjusting for differences in the characteristics of women who gave birth in, and those who gave birth out of, water, fewer infants born in water met the primary outcome (2.7% vs. 4.4%, aOR 0.65, one-sided 95% CI −∞ to 0.79). This finding will form important evidence on which professionals can base informed opinions on neonatal outcomes associated with waterbirth.

The use of composite primary outcomes for neonatal studies has been criticised on several grounds,[72] including uncertain relevance of composite outcomes that combine events of different importance and severity and composites combining outcomes where effects of the intervention might be in different directions for different components. Composite outcomes can also be driven by individual components that are more common than other components. The infant composite outcome for the POOL Study combined events with very different levels severity and importance, including death and receipt of antibiotics which occurred at very different rates in the low-risk population of interest. It is therefore important to examine the analyses by individual components of the composite outcome. It is reassuring to see that, among the larger cohort of retrospective and prospective births, the POOL Study findings are consistent across all components, with no excess of stillbirth and neonatal death before discharge, admission to a NNU for respiratory support or receipt of antibiotics in the first 48 hours, among babies born in water.

Shoulder dystocia

The first-line management of shoulder dystocia in water is to stand the woman up or encourage her to leave the water. By contrast, first-line recommended management of shoulder dystocia when the woman is out of water is to use the McRoberts position.[73] Among cases of shoulder dystocia occurring in water, 25.4% (*N* = 45) were resolved by change of the woman's position alone, including exiting the pool, compared to 3.2% (*N* = 17) of cases occurring out of water. McRoberts position and suprapubic pressure were used less frequently among cases of shoulder dystocia in water compared to cases occurring out of water (78/177, 44.1% vs. 452/526 85.9% for McRoberts position) (22/177, 12.4% vs. 187/526 35.6% for suprapubic pressure). There was similar use of internal manoeuvres (44/177, 24.9% vs. 146/526, 27.8%).

The finding that 25.4% of cases of shoulder dystocia occurring in water were resolved by a change of maternal position alone suggests that a diagnosis of shoulder dystocia, on occasions, may be made at a lower threshold in births in water, compared to births out of water. In the out of water situation, a diagnosis of shoulder dystocia is made only after axial traction on the fetal head has failed to facilitate birth of the fetal shoulders.[73] During births in water, midwives are discouraged from applying axial traction due to concern that this may trigger fetal water inhalation,[65] and it appears shoulder dystocia may be diagnosed following failure of the fetal shoulders to be delivered through maternal effort alone.

With NICE recommending that women with a history of shoulder dystocia should be advised to plan birth in an OU,[31] it is important that shoulder dystocia is not overdiagnosed, as this can limit the birth choices of women in future pregnancies. Midwives should be aware that during waterbirths, a change of maternal position with birth, facilitated by axial traction, does meet the current criteria for the diagnosis of shoulder dystocia.[73] The evidence base on which discouragement of the use of axial traction in water warrants further investigation as does the threshold at which a diagnosis of shoulder dystocia is made during births in water.

Management of the third stage of labour

For women giving birth in water during the period of prospective data collection, information was captured on whether it was intended that the placenta would be delivered in or out of water and whether placental delivery occurred as intended. Among the 69% (*N* = 7422) of waterbirths, where it was intended that the placenta would be delivered once the woman had left the pool, the placenta was delivered out of the pool in 97% (7200) of cases.

Among the 8.5% (*N* = 910) of waterbirths, where it was intended that the placenta would be delivered in water, the placenta was delivered in water in 59.5% (541) of cases. Rates of PPH of ≥ 1000 ml among women delivering the placenta in water following waterbirth, compared to women delivering the placenta out of the water following waterbirth, were not increased (18/926, 1.9% compared to 322/9834, 3.3%; aOR 0.70, one-sided 95% CI −∞ to 1.08).

Neonatal secondary outcomes

Apart from cord snapping, where birth in water was associated with an increased rate, the POOL Study found no evidence that birth in water was associated with an increased rate of any of the other secondary neonatal outcomes.

Of particular concern, due for the potential for long-term hypoxic brain injury, are babies who have an Apgar score of < 7 at 5 minutes of age or require therapeutic hypothermia. Therapeutic hypothermia was recorded as having been received in 0.07% of babies born in water and 0.26% of babies born out of water (aOR 0.33, one-sided 95% CI −∞ to 0.53). Although previous large observational studies in the USA[17] and England[19] found no increase in the rates of NNU admission following waterbirth, neither reported on the important outcome of treatment with therapeutic hypothermia.

A large cohort study published in 2021[19] used NHS routine data relating to births during the financial year 2015–6 to compare outcomes between 6284 waterbirths and 39,824 SVBs to women without medical complications regardless of water immersion use during labour. The POOL Study found that rates of Apgar score of < 7 at 5 minutes among babies born in water were very similar to those previously reported: POOL Study rate 0.5%, previously reported rate 0.57%.[19] Among babies born out of water, the POOL Study found higher rates of babies with an Apgar score of < 7 at 5 minutes (0.9%) than those reported as associated with SVBs out of water (0.57%).[19]

The rates of Apgar score < 7 at 5 minutes and of therapeutic hypothermia among babies born out of water following water immersion support the fact that women who use water immersion during labour, but who leave the pool before birth, have higher rates of complications occurring during labour than women who remain in the pool for birth, or among the whole population of women having a SVB out of water.

Cord snapping

Consistent with previous studies, a higher rate of cord snapping prior to clamping occurred during births in water compared to births out of water. The rate of umbilical cord snapping prior to clamping in the POOL Study prospective cohort was 1.0% among births in water and was 0.4% out of water. This rate compares to 0.35% among 5192 waterbirths in an observational study, including sites across England, Scotland and Northern Ireland at different time periods between 2000 and 2008;[18] and compares to 0.57% among 17,530 among waterbirths included in a large cohort study of births outside of hospital conducted in the USA.[17] The largest previous cohort study of waterbirths in England (*N* = 6264) was unable to report rates of cord snapping, as this outcome is not captured routinely in all MISs or exported to centralised NHS data.

The complication of cords snapping before being clamped is uncommon but potentially serious for the baby. Among the 122 cases of cord snapping prior to clamping in the POOL Study occurring in births in and out of water, there were increased rates of NNU admission, respiratory support and antibiotic administration within 48 hours of birth. There were no cases of death or treatment for hypoxic ischaemic encephalopathy. We did not have data relating to neonatal blood transfusion, and neonatal anaemia needs to be considered as a potential consequence when the cord snaps prior to clamping. The mechanism behind cord snapping in water warrants further investigation as does the increased rates of respiratory support and antibiotic administration. The importance of having an awareness of tension in the cord when births occur rapidly in water, and when lifting the baby following birth, should be included in midwifery and obstetric training and parental preparation, particularly when waterbirth is planned or being considered.

Study strengths and limitations

The POOL Study is the largest global study of waterbirths conducted to date and provides the best available evidence in relation to outcomes associated with waterbirths conducted by NHS-employed midwives.

The gold standard of study designs is the randomised controlled trial (RCT). Previous studies have concluded that a trial of waterbirth of sufficient size is not feasible;[15,71] therefore, a well-designed observational study using routinely collected data was needed. However, all study designs have inherent strengths and weaknesses and to interpret the POOL Study results, it is necessary to explore the potential biases and what impact these may have on the findings.

Non-inferiority margins were predefined with a difference of ≤ 1%, and ≤ 0.6%, for OASI taken as clinically non-significant among nulliparous and parous women without antenatal complexities, respectively. Similarly for the infant outcome, a non-inferiority margin of ≤ 1.0% was taken as clinically non-significant. These margins were informed by patient and public involvement (PPI) input and clinical judgement. Estimates of the background rates of the maternal and infant primary outcomes were based on a robust and timely source, and these were close to the rates found in the study.

Another key strength of the study was, although observational, methods followed recommendations and reporting guidelines for non-inferiority RCTs.[43,74] Non-inferiority margins were justified in advance; for transparency, presentation of the CI was consistent with the type I error rate used in sample size calculations, missing data were handled appropriately in sensitivity analyses, and for transparency, the protocol and analysis plan were published in advance of use.

Obtaining pilot data in advance enabled a prior understanding of the robustness of the fields to be used for the outcomes and the extent of missing data. This meant that the proposed outcomes were, overall, measured robustly. However, some outcomes on inspection did not have the granularity of data required (e.g. re-admissions to hospital for infants).

The strengths of the study include identification of women who did not receive additional monitoring, obstetric or anaesthetic interventions before birth. This was important to answer the specific study objective of assessing whether there are differences in birth outcomes among women who used a pool during labour and remained in the water for birth and those who used a pool and gave birth out of water but had no contraindications to remaining in the pool. A previous large study conducted in England exploring maternal and neonatal outcomes associated with waterbirths, occurring between April 2015 and March 2016, used centralised maternity audit data to compare outcomes for women who gave birth in, or out of, water.[19] The study included all women without labour complexities who gave birth out of water as the control group, as the study team, using centralised records, were unable to identify women who used a pool during labour but left the water prior to birth.

The POOL Study was required to be specifically designed to compare outcomes between women who gave birth in water and those who gave birth out of water following water immersion. An important bias to overcome when designing the study was the potential for women and babies to be overexcluded from the primary analysis where concerns were recognised, or complications occurred prior to or during birth. To overcome this, women and babes were only excluded from the primary analysis, where there was a record of additional monitoring, obstetric or anaesthetic care prior to birth. To reflect clinical practice and reduce the potential influence of retrospective reporting bias in the event of adverse outcomes, where midwives recorded that concerns had been present prior to birth, but without recorded obstetric involvement in the woman's care, women and their babies remained in the primary analysis.

A separate important question was whether birth in water, in the absence of any midwife concerns, impacts on maternal and neonatal outcomes. Sensitivity analysis restricted to women in whom there had been no midwife concerns prior to birth was performed. This also found waterbirth to be associated with no increase in the primary maternal or neonatal outcomes.

The use of routine data facilitated generating a large data set with required power to answer the study objectives of exploring relationships between uncommon but important adverse maternal and neonatal morbidity and birth in water. Limitations exist around the nature of routine data captured primarily for clinical purposes. High levels of missing data were seen for some fields, with some units not entering any data into specific fields, and some data fields being not as specific or detailed as if designed specifically for research use. Examples in the POOL Study included that some study sites did not enter data relating to postnatal care, and maternal assessment in the hospital could not be distinguished from postnatal re-admission.

The POOL Study was the first to adapt electronic MISs at individual NHS site level for the purpose of collecting research data. Using and adapting existing data systems in this way created an efficient and novel data collection system that maximised the use of existing routinely collected data fields while minimising additional or repetitive data collection for NHS staff.[32] Furthermore, the study matched data held in electronic maternity records with that captured in the NNRD to enable an analysis of outcomes for babies admitted to a NNU following pool use in labour, without the need for any additional data entry or collection by NHS staff.

The study has a low level of inclusion bias. The study included multiple study sites across varied geographical locations, had a prolonged recruitment period and the model of opt-out resulted in the exclusion of few eligible births. Despite these strengths, there remains the possibility that unidentified confounders may exist between groups, which could not be adjusted for, including reason for getting out of pool, which were associated with rates of the primary and secondary outcomes.

Using routine National Health Service data for research

While using routine NHS data for research has advantages, it continues to hold limitations. Accessing NHS data on scale, was possible, but this was a time-consuming and a technically challenging exercise associated with potential methodological limitations.

The study experienced a protracted set-up duration and had to overcome considerable governance and technical hurdles to obtain data from 26 NHS organisations. Timely approvals were granted by the Health Technology Assessment and CAG with minimal changes to the proposed opt-out model. These approvals did not delay study progress. Site set-up incurred many, and for some sites, lengthy delays due to the series of steps required for approval and amendment of individual site systems. The first contract with study sites was signed in January 2019, and the last was signed in August 2020. The complexity of data extraction from NHS sites reduced the number of data extractions possible and limited the opportunity to review data quality, including completeness, and to provide timely feedback to study sites. Routine NHS MISs hold enormous research potential. Governance processes that span multiple organisations, and MISs designed for research as well as clinical use, would be required if their potential is to be realised.

The use of pseudonymised routine data meant that data captured in maternity records could not be verified by the research team. On occasions, data were clinically implausible, for example, placental delivery was described as ‘removed at caesarean section’ following a spontaneous vaginal waterbirth. In such a situation, where evidently incorrect, data were omitted or corrected, but in such a data set with many records and fields, it cannot be assumed that all such inconsistencies were identified. In other situations, data were accepted as provided, for example, where waterbirth position was ‘lithotomy’. This was not excluded as some free text comments described a ‘lithotomy-like’ position in the pool, suggesting midwives to use the description for women other than those with their legs elevated in supports, and it could not be determined how frequently such descriptions also applied to births out of water. While for most fields, data entry options were restricted to tick-box, some included an option for free text comments. Where these were provided, they were coded, but the amount and quality of information provided in open text varied, and some inconsistencies in the interpretation of comments may have also occurred.

Another limitation of the use of routine data was the chance that when midwives were entering data following a birth, they may not have recalled pool use some time previously, or in the event of transfer to an OU, prior to transfer. This

may have led to water immersion not being included in the records of some women and to an underestimate of the proportions of women who used a pool and received obstetric or anaesthetic care prior or during birth.

Study generalisability

Twenty-six NHS study sites were eligible for study participation, and all agreed to participate. The partnered MIS provider was, at the time of study set-up, the most used in the UK. Records were received from all 26 sites relating to births that had occurred over a period of 8 years, from January 2015 to the end of June 2022.

Study sites covered a large geographic spread across England, with one site in Wales, and ranged in size from < 1000 to 15,000+ births annually. All sites provided care in obstetric-led units; 23 had an alongside MLU and 6 had a freestanding MLU. Eleven sites provided level 3 (intensive) neonatal care.

The mean age of women giving birth, in 2019, and, in 2020, in England and Wales was 30.7 years[75] compared to the study population of 29.7 years among women who used a pool, and it was 30.3 years among women who did not use a pool. In 2017, in England and Wales, 2.1% of women gave birth at home,[76] a figure that has remained relatively stable over several years. Among the POOL Study populations, the highest rates of home birth were 5.0% among women without complications in pregnancy or labour who gave birth in water and were 5.4% among women with risk factors at the time of pool entry.

The generalisability of the POOL Study findings to settings outside of the UK, or outside of NHS practice, is not known. In England and Wales, waterbirth is a commonly provided midwifery service. Within our study, care during water immersion analgesia and at waterbirths was provided by NHS-employed midwives. Although they have varying levels of experience of waterbirth, all are required to adhere to national[18] and locally approved guidance. There are clear criteria for pool use and preagreed referral pathways to obstetric and neonatal care in the event of complications or should a woman desire analgesia requiring anaesthetic care. Our findings may be less applicable to countries where care is provided differently, to births unattended by a midwife outside of hospital, including freebirths and BBAs, or to births in the UK but outside of the NHS maternity system.

Equality, diversity and inclusion

The 26 eligible sites in England and Wales using the partnered MIS participated, representing a wide geographical spread. Selection bias in participation was reduced through the inclusion of all births, where care had been provided by the participating NHS organisation regardless of place of birth, the age, ethnicity or any other characteristic of the mother.

Although it was intended that all women using a pool during labour should be informed of the study and their right not to have their data included, it is not possible to determine the proportion of women who received the information as intended, or the extent to which information about the study was translated into another language when required.

Patient and public involvement

The aim of PPI in the study was to provide public and patient involvement during every stage of the research from development of the funding application to report writing and dissemination.

Two PPI coinvestigators have been involved throughout the study as equal members of the SMG and the SSC. One represented the National Childbirth Trust (NCT), the largest parent and childbirth organisation in the UK, and one had expertise in the public communication of health messaging. The NCT representative lives, works and volunteers in a deprived local authority in West Yorkshire, where a significant proportion of families are of South Asian descent. She has also worked as a trainer for a major supermarket chain and was a HR director in a haulage company, giving

her extensive experience in listening to and communicating with a variety of audiences. The SSC was chaired by a PPI representative in the latter stages of the study. Our approach to PPI involvement was aligned with the six UK Standards for Public Involvement: communications, impact, governance, working together, inclusive opportunities, and support and learning.[77]

Changes from published protocol

The main change to the published protocol was the inability to use data held in the 'medical and surgical' history of electronic maternity records to identify women with risk factors to inform analysis of the characteristics and outcomes of women with complicating conditions using a pool during labour. In the protocol and SAP, it was intended to identify women with complicating factors at pool entry from two sources: from data held in the medical and surgical menu of electronic records, and, among women giving birth after site opening, from the additional fields of 'risk factors at pool entry', which was completed by midwives providing intrapartum care. The latter of these fields were unaffected. Prior to awareness of the unreliability of data held in the 'medical and surgical' menu, 13,811 (15.9%) of the cohort had been identified as having a risk factor. Once the identification of women with risk factors at pool entry was reduced to those in the prospective cohort with data captured in the new fields completed during intrapartum care, this figure was reduced to 2725. The necessity to restrict analysis to women with identified risk factors to those identified within the prospective cohort seriously impacted the study's ability to meet an important objective.

Other analyses were not performed

Several planned analyses could not be performed. Apgar scores recorded at 10 minutes of birth were not routinely collected by sites. It was not possible to determine if the records within the data set relating to women returning to hospital following birth related to assessment only or resulted in an admission. It was also not possible to determine the duration between birth and postnatal return to hospital. All records of maternal return to hospital, including assessment or admission, were therefore included in this outcome. It was not possible to identify babies re-admitted following discharge, as many will be admitted to paediatric wards. Whether or not the baby was breastfed within an hour of birth was poorly captured, and this was done only in a small number of sites.

Implications for policy and practice

The POOL Study's results support a policy of offering healthy nulliparous and multiparous women with uncomplicated pregnancies the option for using water immersion during labour and birth.

Among nulliparous women without complicating conditions at pool entry, 29% received care prior to birth, which mostly would have necessitated transfer to an obstetric care if birth had been planned at home or in MLU settings. Rates of caesarean section and instrumental births were low and similar to those observed in a cohort of women planning birth in MLU settings in 2008–10.[8]

Rates of instrumental and operative births were low among women in spontaneous labour. It is important that these findings are shared with women when they are making decisions around planned place and mode of birth, use of water immersion for labour and birth or method of preferred labour onset.

There remains widespread scepticism among neonatal and paediatric healthcare professionals in the UK and internationally about the safety to babies of birth in water.[26] This has been reinforced by case reports of adverse neonatal outcomes, following and often attributed to birth in water,[26] and the absence of more robust recent evidence describing neonatal outcomes in this group.[78] The POOL Study was designed specifically to address these neonatal concerns by including neonatal outcomes, such as any treatment for suspected early onset infection (even in the absence of confirmatory blood culture or other laboratory evidence of infection), which are potentially subjective but remain important to women and families and have important health economic implications. It is very reassuring,

therefore, to see that in this large, appropriately powered, cohort of babies born to women deemed to be low risk at onset of labour, birth in water was not associated with a higher risk of NNU admission for respiratory support or of treatment for suspected early onset neonatal infection when compared to pool use in labour with birth out of water.

Obstetric anal sphincter injury was detected no more frequently for primiparous or parous women who used water immersion when they remained in the water to give birth. This finding will form important evidence on which professionals can base informed opinions on maternal outcomes associated with waterbirth. Antenatal information should be specific to women's parity, given the different rates of obstetric intervention, regional analgesia, modes of birth and OASI.

Healthcare professionals should support women to make evidence-based decision when planning the place and mode of birth, or method of preferred labour onset.

Findings of the qualitative work have several implications for practice: increased exposure to waterbirth is vital to improve the confidence of midwives working in OUs; awareness among obstetricians and neonatologists on the practicalities of pool use, and associated outcomes, could increase the support for water immersion; and improved access to antenatal information would help increase awareness of the option to use a pool. We recommend that OUs increase pool provision, ensure birth room allocation, maximise the use of unit resources, design pool room environments that encourage use and ensure that all midwives take responsibility for being familiar with water immersion equipment and unit guidance.

For policy-makers, the results are important to inform recommended care, decisions about facilities and information provided to prospective families. It is important that the results of the study are interpreted and presented as representing outcomes observed, where care was provided by NHS-employed midwives.

Implications for future studies using an opt-out model

During the period of prospective data collection, the intention was for all women giving birth at study sites to be informed about the study through methods selected by individual sites. At the study end, sites were requested to provide the number of women who had opted out, and 24 sites were able to provide these data. A total of 65 women (range 0–16 women per site) opted out of the study after site opening, with 11 (42%) sites having recorded no opt-outs. It cannot be determined if the low level of opt-out reflected women's willingness to be included, that some women did not receive the information as intended or that the methods used did not facilitate informed choice. With increasing use of routine data and opt-out models, where identifiable information from individual NHS sites is used in research, research is required to better understand how such systems are utilised in practice, understanding by potential participants and how best to facilitate informed choice around inclusion.

Research priorities

Further studies are recommended into the following:

1. interventions to reduce rates of OASI during SVBs
2. women's experiences of use of water during labour and birth, including impact on potential short-term and longer-term impacts, for example, maternal–infant attachment, postnatal depression, sense of control and self-efficacy
3. impact of waterbirth on neonatal physiology and transition to extrauterine environment
4. blood loss measurement in water
5. midwifery care during waterbirth, including in the event of non-spontaneous birth of the fetal shoulders
6. care of babies following cord snapping
7. teaching of waterbirth skills to student midwives and midwives.

Conclusion

The POOL Study established that among nulliparous and parous women, without antenatal complicating conditions, who used water immersion during labour, and who did not receive additional monitoring or interventions prior to birth, remaining in the water to give birth was not associated with an increase in the incidence of OASI, adverse neonatal outcomes or other measured morbidity.

Current NHS midwifery practice relating to labour and birth in water is safe for women and their babies. Women, parents, families, practitioners and policy-makers should be reassured that birth in water, in the context of NHS care, is not associated with increased risks for mothers or their babies. Women considering or using water immersion during an uncomplicated labour should be informed that remaining in the water to give birth is not associated with an increased risk to themselves or their baby, and they should be supported to make evidence-based individualised decisions on their care choices.

Additional information

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Study Steering Committee

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Study sites

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University Hospital of Wales, Cardiff and Vale University Health Board: Judith Cutter (PI), Consultant Midwife for Public Health and Vulnerable Families.

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The Royal Oldham Hospital, The Pennine Acute Hospitals NHS Trust, Northern Care Alliance NHS Group: Chloe Rishton (PI), Research Nurse; Rachel Newport and Zainab Sarwar, Research Midwives; and Grainne O'Connor, Research Nurse.

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St George's Hospital, St George's University Hospitals NHS Foundation Trust: Emily Marler (PI), Senior Research Midwife; and Temitope Bankole, Research Project Manager.

Norfolk and Norwich University Hospital, Norfolk and Norwich University Hospitals NHS Foundation Trust: Laura Harris (PI), Research Midwife.

Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it is important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation

Data-sharing statement

Applicants interested in requesting data for non-commercial purposes should apply via the data application form available on the Centre for Trials Research website (www.cardiff.ac.uk/centre-for-trials-research/collaborate-with-us/data-requests). Following an internal and peer review of the application and subject to approval, data may be released under a data transfer agreement. In the first instance, enquiries about access to the data should be addressed to Professor Julia Sanders, School of Healthcare Sciences, Cardiff University.

Ethics statement

The protocol was approved by NHS Wales Research Ethics Committee on 18 September 2018 (18/WA/0291) and the transfer of identifiable data was approved by HRA CAG on 2 November 2018 (18CAG0153).

Information governance statement

Cardiff University and the Centre for Trials Research are committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, Cardiff University is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection.

Data storage

All POOL Study data are held on the Research Data Storage (RDS) space on Cardiff University; the data will remain on the RDS Space until it is destroyed at the end of the archive retention period. The space cannot be accessed without express permission and data will be archived in accordance with CTR and Cardiff University processes.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/GGHD6684

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Milosevic S, Channon S, Hunter B, Nolan M, Hughes J, Barlow C, *et al.* Factors influencing the use of birth pools in the United Kingdom: perspectives of women, midwives and medical staff. *Midwifery* 2019:**79**:102554. https://doi.org/10.1016/j.midw.2019.102554

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Appendix 1 Selection of information provided to women

Opt-out card

The POOL Study is answering questions about outcomes of waterbirth for mothers and babies. The study is collecting anonymised data on all births in this maternity unit until summer 2022.

If you do not want your information to be included please inform your midwife or email the research midwife: **** or telephone: **********

For more information about the study please search POOL Study Cardiff.

Leaflet

USE OF MEDICAL RECORDS FOR THE POOL STUDY

This study plans to answer the question about the safety of waterbirths. The study is collecting data on the births of all women in around 30 maternity units across the UK until summer 2022.

The study will determine

- how many women are using birth pools
- how many women give birth in water
- whether mothers or their babies come to any extra harm as a result of waterbirth

The study will include women giving birth to their first baby and women giving birth to a subsequent child.

For babies that need specialist care after birth, the study will also use data held by the National Neonatal Research Database (NNRD). This will mean securely sending their NHS number and other identifiers to the NNRD so that we can find them in their database.

All of the information will then be securely sent to the Cardiff University research team. This will be anonymised and we will not be able to identify any mother or child.

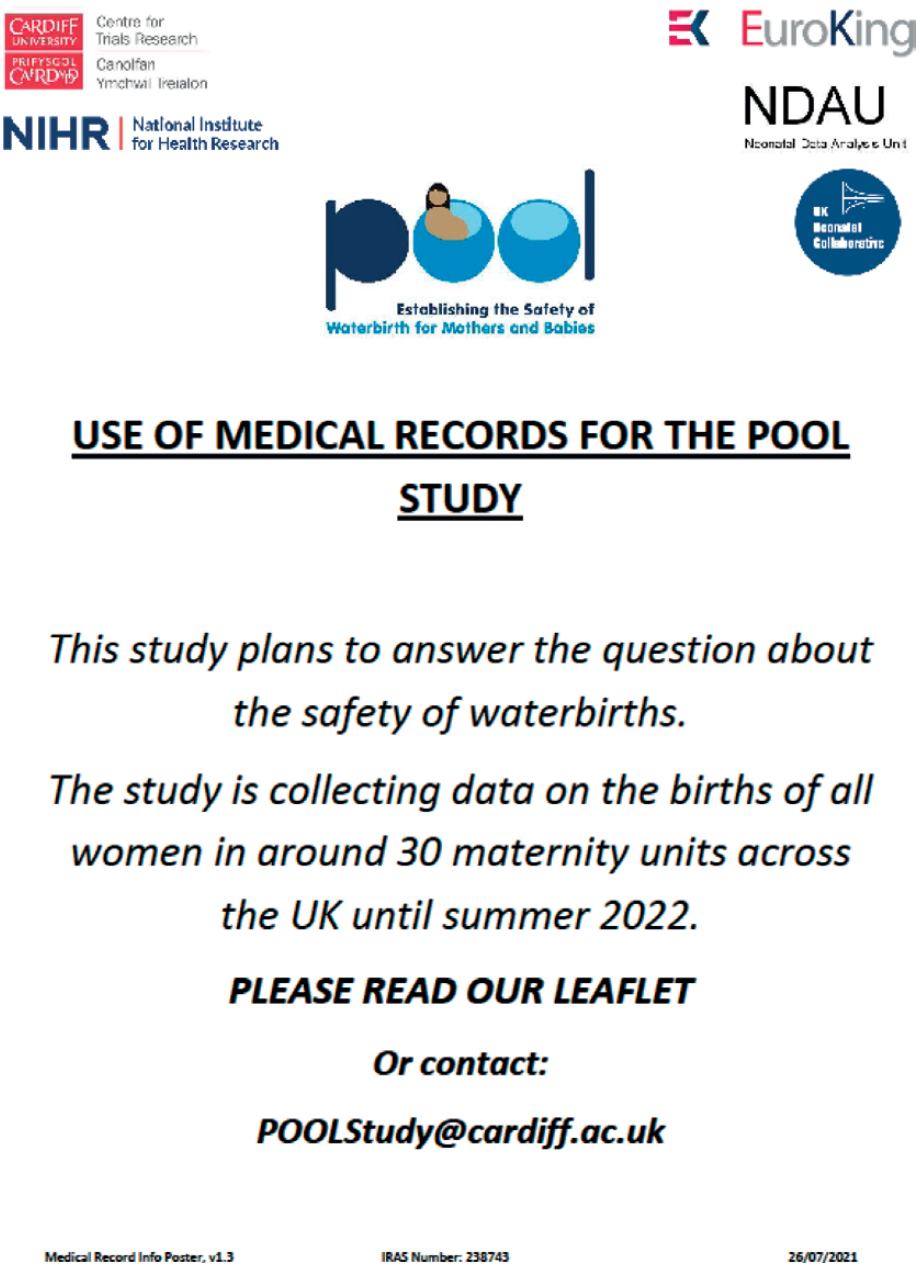
If you do not wish for the research team to have any access to your or your child's medical records for the purpose of the POOL study, please inform your midwife. If you would prefer to contact the research midwife please telephone: **** or email: **********

For more information about the study please search POOL Study Cardiff.
For more information about the research project:
Web page: www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/pool
Email: POOLStudy@cardiff.ac.uk

NDAU Neonatal Data Analysis Unit EuroKing NIHR | National Institute for Health Research

Medical Record Info leaflet, v1.4 IRAS Number: 238743 26/07/2021

Poster



Appendix 2 Ethical amendments

TABLE 28 Ethical amendments

Date	Amendment type	Amendment number	Details
14 November 2018	Non-substantial	1	Online discussion groups to be extended from 1 month in duration (as initially planned) to up to 5 months due to low initial response rate
13 December 2018	Substantial	1	Protocol updated to V2.0 Qualitative approach updated
17 January 2019	Substantial	2	Protocol updated to V3.0 Qualitative approach updated
26 February 2019	Non-substantial	2	Minor amendment to 'USE OF MEDICAL RECORDS FOR THE POOL STUDY' leaflet POOL leaflet – medical records v1.1
20 March 2019	Non-substantial	3	To add four new NHS sites: Norfolk and Norwich University Hospitals NHS Foundation Trust (Norfolk and Norwich University Hospital), Medway NHS Foundation Trust (Medway Maritime Hospital), the Pennine Acute Hospitals NHS (The Royal Oldham Hospital) and Barking, Havering and Redbridge (Queens Hospital) to the POOL Study
29 March 2019	Non-substantial	4	To add five new NHS sites: North Bristol NHS Trust (Southmead), Bolton NHS Foundation Trust (Royal Bolton Hospital), Royal Cornwall Hospital Trust (Royal Cornwall Hospital), the Hillingdon Hospitals NHS Foundation Trust (Hillingdon Hospital) and Newcastle Upon Tyne NHS Trust Foundation (Royal Victoria Infirmary) to the POOL Study
9 April 2019	Non-substantial	5	To add five new NHS sites: Wrightington, Wigan and Leigh Foundation Trust (Royal Albert Edward Infirmary), West Suffolk NHS Foundation Trust (West Suffolk Hospital), South Tees Hospitals NHS Foundation Trust (the James Cook University Hospital and the Friarage Hospital), Maidstone and Tunbridge Wells NHS Trust (Tunbridge Wells Hospital, Maidstone Birth Centre and Crowborough Birth Centre), Manchester University NHS Trust (Wytheshawe Hospital) to the POOL Study
1 May 2019	Non-substantial	6	To add two new sites: University Hospitals of Leicester NHS Trust (Leicester Royal Infirmary) and Stockport NHS Foundation Trust (Stepping Hill Hospital) to the POOL Study
3 May 2019	Non-substantial	7	Amendment of NIHR logo and addition of IRAS number on patient leaflet and medical poster. Versions: 1.2 (leaflet) and 1.1 (poster)
14 April 2019	Non-substantial	8	To add two new sites: East Kent Hospitals University NHS Foundation Trust (the William Harvey Hospital and Queen Elizabeth The Queen Mother Hospital) and Frimley Health NHS Foundation Trust (Frimley Park Hospital) to the POOL Study
14 June 2019	Non-substantial	9	To add four new sites: Blackpool Teaching Hospitals NHS Foundation Trust (Blackpool Victoria Hospital), Isle of Wight NHS Trust (St Mary's Hospital), Northumbria Healthcare Trust (Northumbria Specialist Emergency Care Hospital) and Dartford and Gravesham NHs Trust (Darent Valley Hospital) to the POOL Study

TABLE 28 Ethical amendments (*continued*)

Date	Amendment type	Amendment number	Details
2 August 2019	Substantial	3	Protocol updated to V4.0 Stage 2 of the qualitative component of the research comprises in-depth organisational case studies of sites taking part in the main study. We wish to increase the potential number of sites to be included in the case study research, and to widen the recruitment criteria, in order to ensure that we are able to collect sufficient data. We would also like to include a pilot case study site to enable us to review and refine data collection procedures. Data collected from the pilot case study site will be included in the report of case study findings
11 September 2019	Non-substantial	10	To add one new site: St George's University Hospitals NHS Foundation Trust (St George's Hospital) to the POOL Study
15 October 2019	Non-substantial	11	To add one new site: the James Paget University Hospitals NHS Foundation Trust
8 November 2019	Non-substantial	12	To add one new site: Salisbury NHS Foundation Trust (Salisbury District Hospital)
19 February 2020	Non-substantial	13	Change of PI at three sites: Barking Havering and Redbridge, Norfolk and Norwich and Medway
2 March 2020	Substantial	4	Protocol updated to V5.0 Protocol date updated from 13 August 2019 to 28 February 2020 Typo identified and amended on page 2 Wording of primary and secondary outcomes edited: pages 9, 10, 15, 16; when regarding neonatal outcome, we felt infant death was too broad, therefore this has been edited to be more specific Wording of primary analysis has been edited on page 25 to be more descriptive Further information has been added to sensitivity analysis on page 28
1 July 2020	Non-substantial	14	Change of PI at two sites: Maidstone and Tunbridge Wells and Medway
10 November 2020	Non-substantial	15	Change of PI at three sites: University Hospitals of Leicester NHS Trust, Stockport NHS Foundation Trust and Cardiff and Vale University Health Board
18 November 2020	Non-substantial	16	Protocol amendments: removed administrator details Edited Professor Shantini Paranjothy's new employment details. Edited Dr Chris Gale's job title Amended data collection dates Opt out options further detailed Updated EuroKing to WS as per company update Milestones updated Typo resolved on page 2 Updated flow chart as per correct company terminology. Protocol version number updated to v6.0
5 February 2021	Non-substantial	17	Edited Peter Brocklehurst's job title Added Judith Cutter and take off Abigail Holmes as Co-App Edit Rachel Plachcinski e-mail and job title In planned sample size, rearranged text to be clearer (page 9) Protocol version number updated to v7.0
5 May 2021	Non-substantial	18	Change of PI at one site: Medway
19 July 2021	Non-substantial	19	Change of PI at one site: Barking Havering and Redbridge

continued

TABLE 28 Ethical amendments (*continued*)

Date	Amendment type	Amendment number	Details
9 August 2021	Non-substantial	20	An extension of the funding period for the POOL Study to the end of March 2023. Data collection will continue until summer 2022. The participant information documentation has been updated to reflect these changes and a change in PI at Northern Care Alliance/Pennine
13 August 2021	Non-substantial	21	Update POOL Study Protocol to v8.0 due to project dates
20 October 201	Non-substantial	22	Update POOL Study Protocol from v8.0 to v8.1 due to incorrect date on title page
4 April 2022	Non-substantial	23	Change of PI at one site: Barking Havering and Redbridge
21 April 2022	Non-substantial	24	Change of PI: James Paget University Hospital
23 May 2022	Non-substantial	25	Change in PI at Medway
1 July 2022	Non-substantial	26	Restructuring and reformatting of section 2. Added detail to 'secondary objectives'; removal of 'mode of birth as an outcome' due to this only being relevant to those with birthing complications. Restructured and reformatted section 3 to keep up with section 2. Enhanced the level of detail in section 5. Updated study objectives to match section 2. Updated contents. Typo in section 7. Small edits made to section 9. No amendments have been made to the overall objectives or outcomes (aside from the removal of 'mode of birth'); the protocol has been reformatted to improve understanding and readability of the SAP. Protocol V9.0

IRAS, Integrated Research Application System, PI, principal investigator.

Appendix 3 Data cleaning plan

Data cleaning plan

POOL Study

Development lead			
Name	Position		
Christian Barlow	DM	Signature	Date
			
Approved by			**23 September 2020**
Rebecca Cannings-John	Trial statistician	Signature	
Rebecca Milton	Trial manager	Signature	
Fiona Lugg-Widger	Routine data lead	Signature	1 October 2020
			

Background

The POOL Study is a cohort study with a nested qualitative component. The primary study aim is to establish whether, in the case of 'low-risk' women who use a pool during labour, waterbirth, compared to birth out of water, is as safe for mothers and babies.

Primary study objectives are to:

1. evaluate if waterbirth is associated with an increase in adverse neonatal outcomes or treatment, including asphyxia, infection, respiratory difficulties and mortality; or maternal morbidity, particularly complex perineal trauma (OASIS) and haemorrhage
2. assess the primary safety outcomes among the subgroups of nulliparous and parous women who were low risk at labour onset
3. describe outcomes, including the rates and required management of haemorrhage, among women who following birth in water, deliver the placenta underwater.

To set pool use and waterbirth in the context of NHS care, we will describe the overall proportion of women who use a pool for labour or birth and describe the characteristics of, and outcomes for, women, with identified risk factors, who use a pool during labour.

Secondary study objectives are to:

1. describe the rates, indications and outcomes of women requiring obstetric care during or following pool use during labour
2. explore factors associated with the high and low rates of pool use in individual maternity units
3. describe the demographic and obstetric characteristics of low-risk and high-risk women using a birth pool for labour and birth.

Purpose

This is a working document to ensure that all decisions regarding data cleaning are documented and approved. The purpose of this document is to:

- outline the process that will be used in cleaning the POOL Study data
- to provide a clear audit trail of the decisions made regarding data cleaning of the POOL Study data.

A flow diagram of the data cleaning process is shown in *Figure 8*.

Cleaning and querying during data collection

No checks can be performed on data during data collection, as these were entered by clinical staff as part of usual care directly into maternity MIS and neonatal Badger.net systems at study sites.

Post data entry check of database

This is not possible as data will not be kept in a database by CU; all data entries and checks are the responsibility of sites.

Importing data into an appropriate statistical package, cleaning and conversion to coded data

Data will be deposited by WS and the NNRD into the RDS space, CU, in a folder, with access restricted to the DM, chief investigator and statistician.

Retrospective data

Data will come to CU in .csv format; it will be separated by pipes (|) rather than commas to ensure that all free texts are contained within the correct questions. The .csv files will then be imported into SPSS for cleaning; these will be imported in the order received in the extract. The retrospective data checks spreadsheet will also show when each data set was received, the name of the SPSS file and the stage of cleaning.

Data files received will contain 3 months of data (quarterly data). Once each file has been imported into SPSS, data fields will have the variable length changed to 1000 characters for string variables (almost all variables), and for numeric variables, this will be changed to 12 characters. This will mean that the quarters can be merged together without incident.

Frequencies will then be run on all variables and visually checked for any outlying data or identifiable information within the free text fields. Any identifiable information will be deleted immediately by the DM; this will be completed quarterly and a list of fields with identifiable data will be kept.

Frequency tables will also be used to check for any data that were potentially used for workarounds for mandatory questions, for example staff entering full stops, rather than the required data. If workarounds are being used, this can then be flagged to WS so that they cannot be used in future.

The study IDs (linking field) will be visually checked to ensure that they are in the correct format and that the mother and baby IDs are identical bar the final number so that they can be matched correctly.

Records will be checked for duplicate mother or baby records within and across quarters.

Data sets will then be checked to ensure that all requested variables have been sent. This will be done every quarter to ensure that all variables have been received. This will be done to each data set before merging. The variables received

will be cross-checked against a master list of variables saved in the electronic trial master file (eTMF). A check will be made to ensure that all required derived variables have been received:

- maternal age at delivery
- gestational age at birth
- parity (taken from the standard Euroking variable)
- lower-layer super output area
- duration of rupture of the fetal membranes to birth
- duration from head delivered to birth (only applies to babies with shoulder dystocia)
- duration of postnatal stay.

Once the quarters for each year have had the variable lengths standardised and it is confirmed that all variables have been received, the four quarters of each year will be merged together, and this file will then be saved as 'SITE NAME YEAR'.

The SPSS syntax will be used to convert fields that are extracted in string format into numeric format (e.g. *Livebirth/Stillbirth* to 1 = *Livebirth; 2 = Stillbirth 3 = site specific option*) and frequencies will be run to ensure consistency in coding between sites and for new codes.

These checks will be recorded on the Retrospective Data Checks spreadsheet, which is stored in the eTMF.

Data completeness for key variables needed for the maternal primary outcome will be recorded on the Retrospective Data Matching and Data Completeness spreadsheet by quarter.

The number and proportion of birth in different settings will then be recorded; they will be categorised as OU/home births (both planned and unplanned) MLU and BBAs. A CONSORT flow chart will be populated to include the total numbers of births, the number of women who used a pool and the number of waterbirths. All elective caesareans will be excluded from the 'did not use a pool' numbers. This will be recorded on the retrospective data consort.

Prospective data

All the data checks for the retrospective data (prior to site opening) will be completed on the prospective data (after site opening) as well as additional checks will be performed on the additional variables added at the time of site opening. Quarterly data sets will be merged before the coding and data completeness takes place.

- POOLConditionsPrimary
- POOLConditionsSecondary
- POOLCTGPool
- POOLObstetricCare
- POOLLeftPoolNoReturn
- POOLLabourComplications
- CordClamping
- CordSnap
- POOLThirdStageMgt
- POOLPlacentaIntended
- POOLPlacentaDelivered
- POOLAntibioticsCommenced
- POOLAntibioticsDuration
- POOLBabyLumbarPunc
- POOLBloodCulture
- POOLCRPResult
- POOLData (this is the opt-out variable, it will be checked that no have been received if this variable has been ticked).

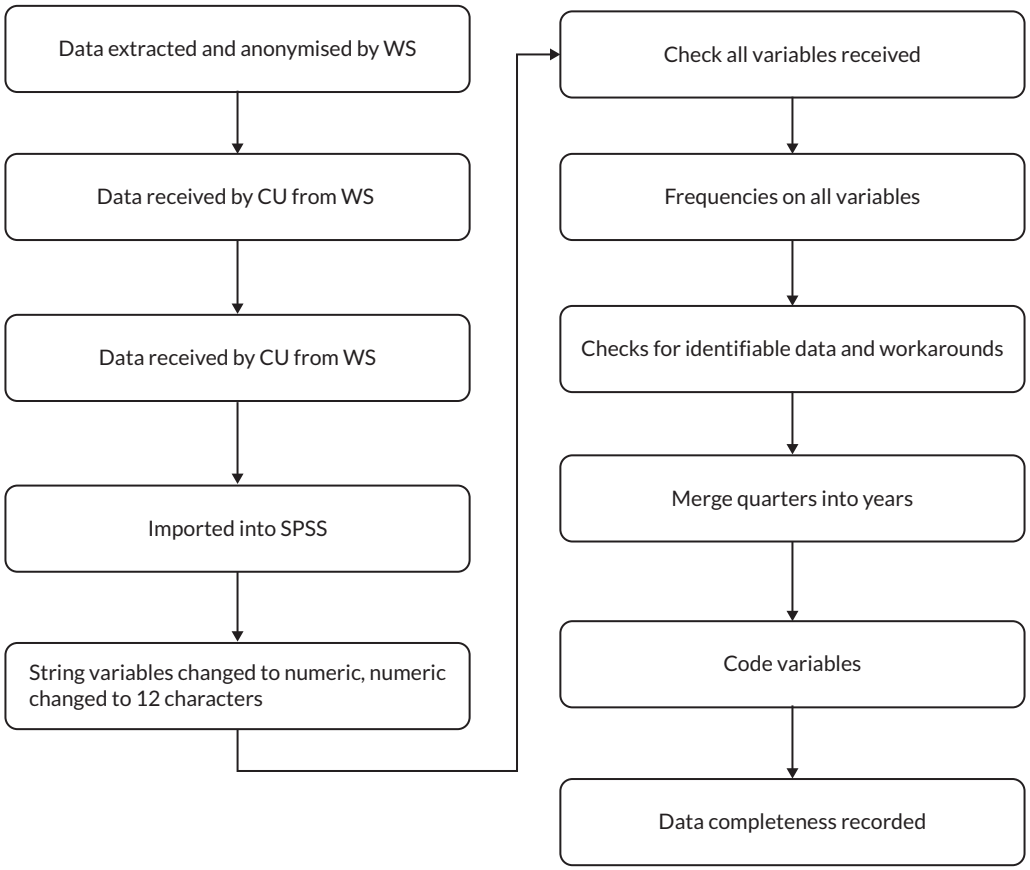


FIGURE 8 Data cleaning diagram.

The additional variables will be checked for data completeness and expectedness, and a table will be populated to show the completeness of each of the individual new variables.

Other variables that will be recorded (the data will only show those who used a pool) in the Data Matching and Data Completeness Spreadsheet will not go in the consort due to small numbers (< 5) being likely:

- number of Stillbirths/neonatal deaths
- total babies to NNU, by site
- total pool use babies to NNU
- waterbirths to NNU
- water use and shoulder dystocia
- water use and breech
- parity percentages.

A record of which sites admit all babies on their transitional care area through Badgernet (® System C, Oxford) will also be kept, as these will all appear in the NNRD data.

National Neonatal Research Database data

Data from the NNRD will be sent at three time points. All variables will have frequencies run to make sure all data are of an expected range; and then these will be checked for identifiable data, which if present will be deleted. NNRD data will then be merged with the EuroKing data via syntax.

All decisions regarding the data will be stored in the Data Decision Log.

Data cleaning will take place continuously as data are sent into the Centre for Trials Research.

TABLE 29 Data cleaning action/decision log

Date	Data item	Issue	Action/decision made
17 May 2019	Prospective data	Making sure all records relating to each birth remain in the quarter of the date of the birth, e.g. if a baby was born on the 31st of the month	Each month data will be extracted 2 weeks after the last day, e.g. data in April will be extracted in mid-May
10 May 2019	Delivery of data	To deliver in quarters or years	To keep delivering data in quarters as that was how the data delivery system was tested
28 August 2019	Used a pool for water or labour	Query as to whether using a bath was considered using a pool	Yes, a bath, or any other water immersion is considered a pool
8 August 2019	Waterbirth	Some women had waterbirth ticked yes, but the midwife had not ticked for using a pool as pain relief	If waterbirth or pool/water for pain relief was ticked yes, then it counts as using a pool
24 July 2019	Risk	A system needs to be developed in order that women in the prospective data set can be classified as low/high risk	Births in midwifery-led care would be classed as low risk, births in obstetric-led care would be classed as high risk and any BBAs will be excluded but any unattended birth in the hospital will be included
	Risk	Risk factors for prospective data	It was decided that the presence of non-significant, meconium-stained liquor would be classed as low risk
9 July 2019	Identifiers	During the pilot, a number of identifiers (baby NHS number, date of birth, maternal postcode) were sent to NNRD for matching	Baby NHS number was found to be sufficient to match the MIS to NNRD records, so only the NHS number will be sent in future
17 May 2019	Prospective data	Making sure all records relating to each birth remain in the quarter of the date of the birth, e.g. if a baby was born on the 31st of the month	Each month data will be extracted 2 weeks after the last day, e.g. data in April will be extracted in mid-May
10 May 2019	Delivery of data	To deliver in quarters or years	To keep delivering data in quarters, as that was how the data delivery system was tested
28 August 2019	Used a pool for water or labour	Query as to whether using a bath was considered as using a pool	Yes, a bath, or any other water immersion is considered as a pool
8 August 2019	Waterbirth	Some women had waterbirth ticked yes, but the midwife had not ticked for using a pool as pain relief	If waterbirth or pool/water for pain relief was ticked yes, it counts as using a pool
24 July 2019	Risk	A system needs to be developed in order that women in the prospective data set can be classified as low/high risk	Births in midwifery-led care would be classed as low risk, births in obstetric-led care would be classed as high risk and any BBA will be excluded, but any unattended birth in the hospital will be included
	Risk	Risk factors for prospective data	It was decided that the presence of non-significant, meconium-stained liquor would be classed as low risk
9 July 2019	Identifiers	During the pilot, a number of identifiers (baby NHS number, date of birth, maternal postcode) were sent to NNRD for matching	Baby NHS number was found to be sufficient to match the MIS to NNRD records, so only NHS number will be sent in future

Appendix 4 Pilot study

The first study site opened in January 2019. In June 2019, a pilot data extraction was undertaken from this single site to test the planned methods of data extraction. Data relating to 24,416 babies born during 24,068 births from the period January 2015 to March 2019 were extracted. The objectives of the pilot were to:

- ensure that the required data fields could be extracted, linked to the NNRD data and were in the expected format
- test and refine the planned steps for data management and cleaning
- assess data completeness for key outcomes and the new data fields
- validate the plan for risk status classification for women.

On receipt of data, the study-generated linking numbers were found to have been successfully separately attached to each mother's and baby's records, which helped to identify them individually and as dyads/triads. The NHS number, date of birth, gender, postcode and study ID of babies born to the 2860 women who used a pool during labour between 1 January 2015 and 31 March 2019 were securely transferred to the NNRD.

The NNRD identified the records of 48 babies (48/2860, 1.6%) born to women who used a pool during labour and matched all 48 records using the baby's NHS number alone. No additional babies were identified from the other identifiers. Following linkage, the NNRD data were transferred to CU, with records identified only by the baby's study ID. Data held by the NNRD, relating to those 48 babies, were subsequently successfully linked to the respective EuroKing mother and infant maternity data that had previously been sent directly to CU.

A detailed data cleaning and management plan was developed for the pilot which outlined required steps prior to analysis. Data quality was explored with particular focus on the new and derived fields as well as an assessment of detailed data quality for the data fields required for the primary outcomes.

Extracts were checked for: (1) receipt of the correct variables, (2) duplicate records and (3) identifiable data. Data sets were then merged and prepared in the agreed format for analysis. Each step completed by the DM was logged on a data processing document so that the status of each data set could be identified. Syntax was written to clean each data set and to make checks on the data; these included checking derived data fields to ensure they were within feasible ranges. Although no fields with known identifiable data were requested, some fields had a free text option box into which NHS staff, on occasions, had typed identifiable information. This led to the development of a process through which the DM was provided with permission to redact identifiable data in free text fields.

Maternal demographic characteristics were found to have been well completed. The data field relating to the maternal primary outcome (severe perineal trauma) was available in the records for the full period of data extraction (1 January 2015–31 March 2019) and were 99.9% complete (24,044/24,068).

The components which would comprise the primary neonatal outcome were explored for completeness. Data relating to stillbirths or neonatal deaths occurring without NNU admission were 99.9% complete, with outcomes provided on 24,415 of the 24,416 babies born during the pilot period.

Data relating to neonatal deaths, respiratory support or antibiotic administration in a NNU were available for all the 48 babies born between 1 January 2015 and 1 January 2019, who had been admitted to a NNU following pool use in labour. These data were ≥ 99.0% complete. Antibiotic usage on the postnatal ward, without NNU admission, was only available for the period from 2 January 2019 to 31 March 2019, and this included all babies regardless of pool use.

Data relating to the use and duration of administration of antibiotics were provided on 87 babies. Completion rates for the new data items relating to markers for neonatal sepsis ranged from 24% to 100%. Reporting of the attempting or performing of a lumbar puncture was well completed (100% of babies receiving antibiotics); blood results, including CRP levels and blood culture results, were poorly completed [21/87 (24.1%)]. Blood loss at birth was well completed [24,046/24,068 (99.9%)], enabling identification of women who had experienced a PPH. One requested field, known to be usually completed in clinical records relating to the timing of the first infant feed, was empty, indicating the failure to identify or transfer this field.

The pilot demonstrated that the planned methods for the amending and use of data held in clinical information systems in multiple NHS sites were feasible, but this highlighted the need to check for data completeness within extractions and ensure that staff were reminded during training to complete the new fields.

The pilot highlighted that the planned methods for data transfer were time-consuming and inefficient and therefore several changes were made. One of the key changes related to how the data were to be transferred. The CU FastFile system involved a member of WS answering a **Completely Automated Public Turing test to tell Computers and Humans Apart** (CAPTCHA). To ensure that data could be sent securely and efficiently between WS and CU, direct access was granted to two members of the WS team. This enabled them to connect securely via a SSH file system and automate the upload of the data extracts between their servers and the CU's shared drive folder. Strict access rights were observed, with access to this space being limited to the named WS employees and the DM. When data were transferred by WS, the DM could then move those across to another secure shared drive which the statistician could also access. Once the pilot data extraction had confirmed feasibility of the planned methods, other sites were opened.

Appendix 5 National Institute for Health and Care Excellence intrapartum care guidelines

Appendix 5, *Tables 30* and *Table 31* show extracts from NICE Guidance[2] providing medical conditions or situations in which there is an increased risk for the woman or baby during or shortly after labour, where care in an OU would be expected to reduce this risk. The factors listed in *Appendix 5*, *Tables 32* and *Table 33* are not reasons in themselves for advising birth within an OU, but they indicate that further consideration of birth setting may be required.

TABLE 30 Medical conditions indicating increased risk suggesting planned birth at an OU

Disease area	Medical condition
Cardiovascular	• Confirmed cardiac disease
	• Hypertensive disorders
Respiratory	• Asthma requiring an increase in treatment or hospital treatment
	• Cystic fibrosis
Haematological	• Haemoglobinopathies – sickle cell disease, beta-thalassaemia major
	• History of thromboembolic disorders
	• Immune thrombocytopenia purpura or other platelet disorder or platelet count < 100 × 10^9/l
	• Von Willebrand's disease
	• Bleeding disorder in the woman or unborn baby
	• Atypical antibodies which carry a risk of haemolytic disease of the newborn
Endocrine	• Hyperthyroidism
	• Diabetes
Infective	• Risk factors associated with GBS whereby antibiotics in labour would be recommended
	• HBV/HCV with abnormal liver function tests
	• Carrier of/infected with HIV
	• Toxoplasmosis – women receiving treatment
	• Current active infection of chicken pox/rubella/genital herpes in the woman or baby
	• Tuberculosis under treatment
Immune	• Systemic lupus erythematosus
	• Scleroderma
Renal	• Abnormal renal function
	• Renal disease requiring supervision by a renal specialist
Neurological	• Epilepsy
	• Myasthenia gravis
	• Previous cerebrovascular accident
Gastrointestinal	• Liver disease associated with current abnormal liver function tests
Psychiatric	• Psychiatric disorder requiring current inpatient care

TABLE 31 Other factors indicating increased risk suggesting planned birth at an OU

Factor	Additional information
Previous complications	• Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty
	• Previous baby with neonatal encephalopathy
	• Pre-eclampsia requiring preterm birth
	• Placental abruption with adverse outcome
	• Eclampsia
	• Uterine rupture
	• Primary PPH requiring additional treatment or blood transfusion
	• Retained placenta requiring manual removal in theatre
	• Caesarean section
	• Shoulder dystocia
Current pregnancy	• Multiple birth
	• Placenta praevia
	• Pre-eclampsia or pregnancy-induced hypertension
	• Preterm labour or preterm prelabour rupture of membranes
	• Placental abruption
	• Anaemia – haemoglobin < 85 g/l at onset of labour
	• Confirmed intrauterine death
	• Induction of labour
	• Substance misuse
	• Alcohol dependency requiring assessment or treatment
	• Onset of gestational diabetes
	• Malpresentation – breech or transverse lie
	• BMI at booking of > 35 kg/m^2
	• Recurrent antepartum haemorrhage
	• SGA in this pregnancy (less than fifth centile or reduced growth velocity on ultrasound)
	• Abnormal fetal HR/Doppler studies
	• Ultrasound diagnosis of oligo-/polyhydramnios
	• Cholestasis[a]
	• Labour outside of 37 + 0 and 41 + 6[a]
Previous gynaecological history	• Myomectomy
	• Hysterotomy

SGA, small for gestational age.
a Some additional conditions, not included in the NICE guidelines, have been identified that, if present, would be also regarded as contraindications to pool use in labour and therefore, if present, would classify the woman as 'high risk'.

TABLE 32 Medical conditions indicating individual assessment when planning place of birth

Disease area	Medical condition
Cardiovascular	• Cardiac disease without intrapartum implications
Haematological	• Atypical antibodies not putting the baby at risk of haemolytic disease
	• Sickle cell trait
	• Thalassaemia trait
	• Anaemia – haemoglobin = 85–105 g/l at onset of labour
Infective	• HBV/HCV with normal liver function tests
Immune	• Non-specific connective tissue disorders
Endocrine	• Unstable hypothyroidism such that a change in treatment is required
Skeletal/neurological	• Spinal abnormalities
	• Previous fractured pelvis
	• Neurological deficits

TABLE 33 Other factors indicating individual assessment when planning place of birth

Factor	Additional information
Previous complications	• Stillbirth/neonatal death with a known non-recurrent cause
	• Pre-eclampsia developing at term
	• Placental abruption with good outcome
	• History of previous baby weighing > 4.5 kg
	• Extensive vaginal, cervical or third- or fourth-degree perineal trauma
	• Previous term baby with jaundice, requiring exchange transfusion
Current pregnancy	• Antepartum bleeding of unknown origin (single episode after 24 weeks of gestation)
	• BMI at booking of 30–35 kg/m^2
	• Blood pressure of 140 mmHg systolic or 90 mmHg diastolic or more on two occasions
	• Clinical or ultrasound suspicion of macrosomia
	• Para 4 or more
	• Recreational drug use
	• Under current outpatient psychiatric care
	• Age over 35 years at booking
Fetal indications	• Fetal abnormality
Previous gynaecological history	• Major gynaecological surgery
	• Cone biopsy or large loop excision of the transformation zone
	• Fibroids

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Appendix 6 Study populations, fields and analysis model for primary and secondary outcomes

TABLE 34 Study populations, fields and analysis model for primary and secondary maternal outcomes

Outcomes	Study population	Fields used	Outcome definition	Original analysis	Change from protocol/SAP?
Primary: OASI	W	PerineumVaginalTears	Presence/absence	LO	No
		PerinealRepair			
Secondary – intrapartum					
Shoulder dystocia	W	ShoulderDystocia	Presence/absence	LO	No
		ShoulderDystociaHelp			
		ProblemsIntrapartum			
		ProblemsMaternal			
Head-to-body birth interval (minutes)	W – shoulder dystocia only	HeadDeliveriedToBirthDuration	Minutes between head and body birth	–	Post hoc analysis – descriptive analysis only
Required management of shoulder dystocia	W	ManoeuvresPerformed	McRoberts position (yes/no)	ORD	Was planned as an ordinal regression, but as categories were not mutually exclusive (women could have more than one management), the outcome is descriptive
		McRoberts	Suprapubic pressure (yes/no)		
		SuprapubicPressure	Internal manoeuvres (yes/no)		
		EpisiotomyPerformed	Episiotomy (yes/no)		
		PosteriorArm	Change of position (yes/no)		
		WoodScrewManoeuvre	Not recorded		
		AllFoursPosition			
		OtherManoeuvres			
Management of the third stage of labour	P (waterbirth group only)	POOLThirdStageMgt/ POOLPlacentaDelivered/ Intended	Placenta delivered into water; placenta delivered out of water	LO	Descriptive in waterbirth group only
	W	PlacentadeliveredHow	1. Active vs. physiological management		No
		OxytocinDrug3rd Stage	2. MROP vs. no MROP		

continued

TABLE 34 Study populations, fields and analysis model for primary and secondary maternal outcomes (*continued*)

Outcomes	Study population	Fields used	Outcome definition	Original analysis	Change from protocol/SAP?
PPH	W	BloodlossAtdelivery BloodLossAfterDelivery	Total blood loss (at and after delivery)	LO ≥ 1 l only	Not in protocol paper but added to SAP
		Combined to make TOTAL_BLOOD_LOSS	≥500 ml or < 500 ml		500 ml and 1.5 l descriptive
			≥1 l or < 1 l		
			≥1.5 l or < 1.5 l		
Treatment for haemorrhage	W for women with PPH ≥ 500 ml	IVTherapyPostDelivery	Categorical: Blood transfusion	ORD	Not in protocol paper but added to SAP
			Oxytocin infusion		Was planned as an ordinal regression, but as categories were not mutually exclusive (women could have more than one management), the outcome is descriptive
			Plasma expanders (Plasma-Lyte, Gelofune, colloids)		
			IV fluids (including NaCl, Hartmann's, normal saline)		
Need for obstetric involvement in woman's care, including sepsis	W	Presence of any of: MROP	Yes, need for obstetric involvement vs. no need	LO	No
		Treatment for haemorrhage OASI defined previously			
Reason for obstetric involvement in woman's care	W	Presence of MROP, treatment for haemorrhage, OASI defined previously	Categorical:	ORD	Not in protocol paper but added to SAP
			Sepsis		Was planned as an ordinal regression, but as categories were not mutually exclusive (women could have more than one management), the outcome is descriptive
			MROP		
			Treatment for haemorrhage		
			OASI		
Incidence of perineal and other genital trauma	W	PerineumVaginalTears	Presence/absence	LO	No
		PerinealRepair			

TABLE 34 Study populations, fields and analysis model for primary and secondary maternal outcomes (*continued*)

Outcomes	Study population	Fields used	Outcome definition	Original analysis	Change from protocol/SAP?
Management of perineal and other genital trauma	W	PerinealRepair	Record of a perineal repair	ORD	Yes –binary outcome LO
Maternal position at birth	W	DeliveryPosition	See categories in *Appendix 2*	ORD	Changed to descriptive
Secondary – postnatal					
Duration of postnatal stay (hours)	W	PN_StayDuration	Count of days	PO/NBM	No
Breastfeeding initiation	W	FeedingMethodDelivery	Yes – breast (expressed/maternal milk/few breastfeeding attempts/colostrum given) No – artificial/breast (donor)	ORD	Changed to LO as outcome binary
Breastfeeding at community discharge of care	W	FDFeeding	Yes – exclusively and partial Breast No – artificial milk feeding	ORD	Changed to LO as outcome binary
Need for higher-level care	W	Transferred	Yes/no	LO	No
Maternal re-admission to hospital (within 7 days of birth)	W	PNT_Reason	Yes/no	LO	All records of maternal returned to hospital, including assessment or admission (rather than within 7 days)

LO, Logistic regression; ORD, ordinal regression; P, prospective data only collected after site opening; PO/NBM, Poisson or negative binomial regression; W, whole population.

TABLE 35 Study populations, fields and analysis model for primary and secondary infant outcomes

Outcomes	Study population	Fields used	Outcome definition	Analysis	Change from protocol/SAP?
Infant primary outcomes					
Adverse infant outcomes or treatment	P/NNRD	respsupportGiven anti48Given Death POOLAntibioticsCommenced Outcome PbRComplication	Presence/absence	LO	No
Secondary					
Snapped umbilical cord prior to clamping	P	POOLcordsnap	Yes/no	LO	No
Timing of cord clamping	W	cordclamping	Delayed cord clamping > 60 seconds after birth or not	LO	No
Apgar scores @ 1, 5 and 10 minutes	W NNRD	Apgar1MinuteNN4B_Value Apgar5MinuteNN4B_Value Apgar_1 minute Apgar_5 minutes	Low score ≤ 7 Healthy score = 7+	LO	Data for Apgar at 10 minutes were not available
Neonatal resuscitation	W	DrugsOtherProcedures IntermitPosPresVentil DurationBirthToIntubation DurationO2Intubation	Yes/No	LO	No
Intrapartum stillbirth or neonatal death prior to NNU/postnatal ward discharge occurring within 7 days of birth	W	Death (NNRD) Outcome, PbRComplications (MIS)	Neonatal death/stillbirth (antepartum/intrapartum resuscitation attempted/not attempted)	ORD	Binary outcome so logistic regression carried out as 'Death recorded or not'
Cause of intrapartum stillbirth or death prior to NNU/postnatal ward discharge	W	Cause (NNRD)		Descriptive	Description in the data was not sufficient for reporting
Skin-to-skin contact at birth	W	SkinToSkinContact	Yes/no	LO	No
Was the baby breastfed within 1 hour of delivery?	W	Fed1Hour	Yes/no	LO	No
NNU admissions	W (NNRD only)	Derived flag for NNRD data excluding where LOS = 0 (as indicative of transitional care)	Count of admissions	PO/NBM	Changed to logistic as outcome was binary – admitted to NNU or not
NNU admission length of stay (days)	W	TotalLOS	Count of days	PO/NBM	No
NNU admission requiring respiratory support	W (NNRD data)	respsupportGiven	Yes/no	LO	No
Receipt of therapeutic hypothermia	W (NNRD only)	thGiven	Yes/no	LO	No
Brachial plexus injury	W	BirthInjurySuspected brachialplexus_injury	Yes/no	LO	No
Treatment for jaundice	W	BNT_JaundiceTreatment	Yes/no	LO	No
Successful/attempted lumbar puncture	P	POOLBabyLumbarPunc	Presence/absence	LO	No

TABLE 35 Study populations, fields and analysis model for primary and secondary infant outcomes (*continued*)

Outcomes	Study population	Fields used	Outcome definition	Analysis	Change from protocol/SAP?
IV antibiotic administration commenced within 48 hours of birth (with/without culture proven infection)	W (among babies admitted to NNU) P	antiGiven anti48Given POOLAntibioticsCommenced	Yes/no/attempted but unsuccessful	ORD	Binary outcome, so logistic regression was carried out
Duration of antibiotics for babies receiving IV antibiotics as mentioned above	W (among babies admitted to a NNU) P	numberofantidays	< 48 hours, 5 days, 6–7 days, > 7 days, other	ORD	Outcome not specified in protocol paper but in SAP Examined as count of days also (NBM)
Highest CRP results	P	POOLCRPResult	Continuous CRP result	LIN	No
Culture-proven infection	W (among babies admitted to a NNU) P	AnyGrowth PathogenicGrowth POOLBloodCulture	Yes/no	LO	No analysis performed –sparse data
Re-admission to hospital within 7 days of birth	W	NA	Yes/no	LO	Outcome could not be reported

LIN, linear regression; LO, logistic regression; ORD, ordinal regression; P, prospective data only collected after site opening; PO/NBM, Poisson or negative binomial regression; W, whole population.

Appendix 7 RECORD checklist

The RECORD statement – checklist of items, extended from the STROBE statement, that should be reported in observational studies using routinely collected health data

	Item no.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
Title and abstract					
	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	NA – NIHR study name given	RECORD 1.1: the type of data used should be specified in the title or abstract. When possible, the name of the databases used should be included	Study strengths and limitations and Using routine National Health Service data for research
				RECORD 1.2: if applicable, the geographic region and time frame within which the study took place should be reported in the title or abstract	
				RECORD 1.3: if linkage between databases was conducted for the study, this should be clearly stated in the title or abstract	
Introduction					
Background rationale	2	Explain the scientific background and rationale for the investigation being reported	Background and waterbirth in the National Health Service and Justification for the study		
Objectives	3	State-specific objectives, including any prespecified hypotheses	Study objectives		
Methods					
Study design	4	Present key elements of study design early in the paper	Cohort study design		

	Item no.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
Setting	5	Describe the setting, locations and relevant dates, including periods of recruitment, exposure, follow-up and data collection	Study participants: Study participants: inclusion and exclusion criteria Exposure: Identification of women in group 1 Follow-up period: Data collection period and Follow-up period		
Participants	6	*(a) Cohort study* – give the eligibility criteria and the sources and methods of selection of participants Describe methods of follow-up		RECORD 6.1: the methods of study population selection (such as codes or algorithms used to identify subjects) should be listed in detail. If this is not possible, an explanation should be provided	N/AN/A*Data management*, *Figure 2*
		Case-control study – give the eligibility criteria and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls		RECORD 6.2: any validation studies of the codes or algorithms used to select the population should be referenced. If validation was conducted for this study and not published elsewhere, detailed methods and results should be provided	
		Cross-sectional study – give the eligibility criteria and the sources and methods of selection of participants		RECORD 6.3: if the study involved linkage of databases, consider use of a flow diagram or other graphical display to demonstrate the data linkage process, including the number of individuals with linked data at each stage	
		(b) Cohort study – for matched studies, give matching criteria and number of exposed and unexposed			
		Case-control study – for matched studies, give matching criteria and the number of controls per case			
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders and effect modifiers. Give diagnostic criteria, if applicable	Outcomes: Outcomes Exposure: Identification of women in group 1 Confounders: Descriptive analysis	RECORD 7.1: a complete list of codes and algorithms used to classify exposures, outcomes, confounders and effect modifiers should be provided. If these cannot be reported, an explanation should be provided	Fields used for outcomes are in *Appendix 6*
Data sources/ measurement	8	For each variable of interest, give sources of data and details of methods of assessment (measurement)	Data sources: Data sources		
		Describe comparability of assessment methods if there is more than one group			

	Item no.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
Bias	9	Describe any efforts to address potential sources of bias			
Study size	10	Explain how the study size was arrived at	Sample size		
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Descriptive analysis		
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	(a) Primary analysis, secondary analyses and secondary outcomes		
		(b) Describe any methods used to examine subgroups and interactions	(b) Subgroup: Subgroup analysis		
		(c) Explain how missing data were addressed	(c) Missing data		
		(d) *Cohort study* – if applicable, explain how loss to follow-up was addressed	(d) NA		
		Case-control study – if applicable, explain how matching of cases and controls was addressed	(e) Sensitivity analysis: Sensitivity analyses		
		Cross-sectional study – if applicable, describe analytical methods, taking account of sampling strategy			
		(e) Describe any sensitivity analyses			
Data access and cleaning methods				RECORD 12.1: authors should describe the extent to which the investigators had access to the database population used to create the study population	Data access, storage and cleaning
				RECORD 12.2: authors should provide information on the data cleaning methods used in the study	
Linkage				RECORD 12.3: state whether the study included person-level, institutional-level or other data linkage across two or more databases. The methods of linkage and methods of linkage quality evaluation should be provided	Data management

	Item no.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
Results					
Participants	13	(a) Report the numbers of individuals at each stage of the study (e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up and analysed)	Descriptives by parity	RECORD 13.1: describe in detail the selection of the persons included in the study (i.e. study population selection), including filtering based on data quality, data availability and linkage. The selection of included persons can be described in the text and/or by means of the study flow diagram	N/A – no measure of quality of linkage is available
		(b) Give reasons for non-participation at each stage			
		(c) Consider use of a flow diagram			
Descriptive data	14	(a) Give characteristics of study participants (e.g. demographic, clinical and social) and information on exposures and potential confounders	Demographics and confounders: Descriptives by parity		
		(b) Indicate the number of participants with missing data for each variable of interest	Exposure: Groups 1 and 2: Intervention– women giving birth in water and comparator – leaving the pool to give birth		
		(c) *Cohort study* – summarise follow-up time (e.g. average and total amount)			
Outcome data	15	*Cohort study* – report numbers of outcome events or summary measures over time	Chapter 5		
		Case-control study – report numbers in each exposure category, or summary measures of exposure			
		Cross-sectional study – report numbers of outcome events or summary measures			
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g. 95% CI). Make clear which confounders were adjusted for and why they were included	Chapter 5		
		(b) Report category boundaries when continuous variables were categorised			

	Item no.	STROBE items	Location in manuscript where items are reported	RECORD items	Location in manuscript where items are reported
		(c) If relevant, consider translating estimates of RR into absolute risk for a meaningful time period			
Other analyses	17	Report other analyses done – e.g. analyses of subgroups and interactions and sensitivity analyses	Chapter 5		
Discussion					
Key results	18	Summarise key results with reference to study objectives	Key study findings		
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Study strengths *and* limitations	RECORD 19.1: discuss the implications of using data that were not created or collected to answer the specific research question(s). Include discussion of misclassification bias, unmeasured confounding, missing data and changing eligibility over time, as they pertain to the study being reported	Interpretation of results
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies and other relevant evidence	Interpretation of results		
Generalisability	21	Discuss the generalisability (external validity) of the study results	Study generalisability		
Other information					
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Funding		
Accessibility of protocol, raw data and programming code				RECORD 22.1: authors should provide information on how to access any supplemental information such as the study protocol, raw data or programming code	Funding

STROBE, Strengthening the Reporting of Observational Studies in Epidemiology.

Notes
Source: Benchimol *et al.*[79]

Appendix 8 Changes from the statistical analysis plan and protocol paper

Omission from the statistical analysis plan

The following changes were omitted from the SAP following publication of the protocol paper:

Section 5.5.2 Exclusion criteria

- Data from women who opt out from the study will not be received.
- Women and infants recorded in MIS as being BBA or recorded as freebirths (unattended) or birth in transit.
- Women and infants recorded in MIS as a birth in transit.
- Births before 24 weeks of gestation.
- Stillbirths or terminations before labour onset.

Section 5.5.5 Defining women who leave, or do not return to the pool due to a clinical need (a complication developed during labour with interventions that could not have been provided in the pool) – group 3

Women with a breech identified during labour or were recorded as transferred to OU during labour would also be included in group 3.

Analyses not completed

Due to issues with the MIS data, we were unable to carry out the following planned descriptives:

- Group 4 – characteristics of, and outcomes among, women with risk factors who used a pool (based on original MIS data).
- Group 5 – characteristics of, and outcomes among, women with risk factors who did not use a pool (based on original MIS data).

The following planned analyses were carried out.

Statistical analysis plan sampling and recruitment risk categorisation

To identify women with risk factors at the commencement of labour, we will use both definitions of low-risk using (1) a combination of risk factors described in the existing MIS fields and the midwives' assessment at pool entry and (2) using the midwives' assessment at the time of pool entry alone. We will quantify agreement in risk categorisation by source.

Statistical analysis plan discussion of qualitative work bias

There is a potential for reporting bias of the risk categorisation at pool entry collected by midwives after site opening, as this will usually be recorded after the outcome of the baby/mother was known. To examine this bias, we will examine trends in the incidence of overall risk and by categories over the study period and by the data sources (MIS existing fields and midwives' entry) to detect any increases caused my 'diagnostic drift'.

In addition, we could not analyse (or were limited) the following outcomes:

- Apgar scores recorded at 10 minutes of birth: this information was not routinely collected by sites.
- Maternal admission to hospital within 7 days of birth: it was not possible to determine if records within the data set relating to women returning to hospital following birth followed assessment only or resulted in an admission. It was

also not possible to determine the duration between birth and postnatal return to hospital outcome indicated within 7 days. All records of maternal return to hospital, including assessment or admission, were therefore included in this outcome.

- Infant re-admission to hospital within 7 days of birth: it was not possible to identify babies re-admitted following discharge as many will be admitted to paediatric wards.
- Whether or not the baby was breastfed within an hour of birth was poorly captured and could be done only in a small number of sites.

Analyses where the approach was modified are detailed in *Appendix 6*.

Appendix 9 Breakdown of high-risk conditions recorded in antenatal notes

TABLE 36 Breakdown of high-risk conditions recorded in antenatal histories

Conditions		Based on all women who used a pool, *N* = 87,040
Primary		***N* (%)[a]**
1	ROMs > 24 hours	841 (1.0%) > 36 hours at birth
3	Meconium-stained liquor – significant	Field cannot be reliably measured at pool entry – unlikely to be able to assess until at time of birth
4	Abnormal fetal HR	Condition cannot be reliably measured in MIS
5	Hypertensive	Condition varies over time – cannot reliably be measured at pool entry
6	Clinical or ultrasound suspicion of macrosomia	Condition varies over time – cannot reliably be measured at pool entry
7	IUGR/SGA – confirmed on ultrasound	79 (0.1)
8	Para 4 or more	716 (0.8) of all data | (1.3) of all valid data (*n* = 54,895)
9	Breech presentation before onset of labour	10 (0.0)
10	Labour outside of 37^{+0} and 41^{+6}	594 (0.7)
11	Induction of labour	5,192 (6.0)
12	GBS carrier (including any history of GBS positive testing)	2744 (3.2)
13/15	Twins/triplets/multiple birth	20 (0.0) (10 twins)
14	Fetal abnormality	38 (0.0)
16	Placenta praevia	Condition cannot be reliably measured in MIS
17	Haemoglobin < 85 g/l	Condition cannot be reliably measured in MIS
18	Confirmed intrauterine death	4 (0.0)
19	Gestational diabetes/diabetes	611 (0.7)
20	BMI at booking of > 35 kg/m^2	1265 (1.5)
21/34	Thrombocytopenia platelet count < 100 × 10^9/l	Condition cannot be reliably measured in MIS
22	VBAC	605 (0.7)
23	Previous PPH with blood transfusion	Condition cannot be reliably measured in MIS
24	Previous baby weight > 4.5 kg	3 (0.0)
26	Major gynaecological/uterine surgery	21 (0.0) (myomectomy)
27	Cone biopsy or large loop excision of the transformation zoon	Condition cannot be reliably measured in MIS
28	Fibroids	Condition varies over time – cannot reliably be measured at pool entry
29	Substance misuse	Condition varies over time – cannot reliably be measured at pool entry
30	Asthma requiring an increase in treatment or hospital treatment	85 (0.1)
31	Cystic fibrosis	15 (0.0)

continued

TABLE 36 Breakdown of high-risk conditions recorded in antenatal histories (*continued*)

Conditions		Based on all women who used a pool, *N* = 87,040
Primary		***N* (%)[a]**
32/56/57	Haemoglobinopathies – sickle cell disease, beta-thalassaemia major	56 (0.1)
33	History of thromboembolic disorders	360 (0.4)
35	Von Willebrand's disease	
36	Bleeding disorder in the woman or unborn baby	
37	Atypical antibodies with risk of HDN	63 (0.1)
38	Hyperthyroidism	25 (0.0)
39	Diabetes	30 (0.0)
40	HIV	7 (0.0)
41	Toxoplasmosis – women receiving treatment	5 (0.0)
42	Current active infection of chicken pox/rubella/genital herpes	37 (0.0) (primary genital herpes only)
43	Tuberculosis under treatment	3 (0.0)
44	Systemic lupus erythematosus	Condition cannot be reliably measured in MIS
45	Abnormal renal function	Condition cannot be reliably measured in MIS
46	Epilepsy	Condition cannot be reliably measured in MIS
47	Myasthenia gravis	Condition cannot be reliably measured in MIS
48	Previous cerebrovascular accident	1 (0.0)
49/58	Liver disease and HBV/HCV	68 (0.1)
50	Psychiatric disorder requiring current inpatient care	20 (0.0)
51	Previous stillbirth/neonatal death	243 (0.3)
52	Previous baby with neonatal encephalopathy	8 (0.0)
53	Previous uterine rupture	0 (0.0)
54	Previous shoulder dystocia	144 (0.2)
55	Previous 3rd/4th degree or other complex tear	674 (0.8)
56	Sickle cell trait	See 32
57	Thalassaemia trait	See 32
58	HBV/HCV	See 49
59	Non-specific connective tissue disorders	26 (0.0)
60	Spinal abnormalities	2 (0.0)
61	Previous fractured pelvis	75 (0.1)
62	Neurological deficits	Condition cannot be reliably measured in MIS
63	Crohn's disease	Condition cannot be reliably measured in MIS
64	Ulcerative colitis	Condition cannot be reliably measured in MIS
	Other conditions noted by midwife	8 (0.0)

IUGR, intrauterine growth restriction; ROM, rupture of membranes; SGA, small for gestational age.

Note
Individuals could have more than one condition recorded, so conditions are not mutually exclusive.

EME
HSDR
HTA
PGfAR
PHR

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