External assurance review of Neonatal losses for Gloucester Hospitals NHS Foundation Trust, during the period 2020-2023, undertaken at the request of the trust board.

Gloucestershire Hospitals NHS Foundation Trust - External Review Neonatal Loss 2020-2023

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1. Summary of review

Between 2020 and 2023 forty-four babies sadly died during labour or after birth at Gloucester Hospitals NHS Trust, or after having care there. All babies who die after 24 weeks of pregnancy have their care reviewed at a local level and those who die after 37 weeks of pregnancy, or in labour or after birth are also reviewed by a national team, at that time known as the Healthcare Safety Investigation Branch (or HSIB, now called Maternity and Neonatal Safety Investigations, or MNSI). Each of these babies had the appropriate investigations, but a further independent review of the births was requested by the trust, following national media reporting, to provide further assurances that maternity services in Gloucester were safe.

A team, consisting of a consultant obstetrician Specialised in care of high risk mothers and babies, a consultant midwife specialised in care of mothers and babies during birth and after birth and a midwife with expertise in reviewing care of mothers and babies who died, independently reviewed the forty-one sets of notes that were available. These were either paper notes, electronic notes (Badgernet) or a combination of both, as the trust were moving over to electronic notes at the time of the births being reviewed. Findings from this review may not align with previous investigations as the team only had access to the maternity notes provided, did not receive local trust guidelines to review from the period, or interview the staff or grieved parents.

The review compared the care recorded in the notes against national standards of best maternity practice. The following are just some of the areas that were included:

- Antenatal care from booking to birth – e.g., whether mothers had the recommended number of visits, if correct referrals to specialists were made, whether risks for preterm birth were identified and followed up and whether stop smoking support was given.
- Birth – e.g., was the baby born in the safest place, were preterm labours managed correctly, was the baby's heartbeat monitoring done correctly and were there any delays in emergency care.
- After birth – e.g., was the correct newborn life support process followed.
- Was there evidence that the local reviews carried out by Gloucester were thorough and that learning had been put into place to prevent future avoidable harm.

2. Positive Findings and Areas of Good Practice

This review identified areas of excellent clinical care, which followed national maternity standards:

- All women who were known to the trust had their first midwife booking appointment before 12 weeks, allowing early referrals to other specialists to be made.
- Women with pregnancies at high risk of complications were overseen by specialist consultant doctors, often working closely alongside a team of other professionals.
- Women in preterm labour were routinely given treatments recommended to improve baby outcomes (including steroids (to help mature babies lungs) and magnesium sulphate (to protect babies from brain damage).
- Where documentation was available, resuscitation of babies at birth appeared to be performed well and transfer to the neonatal unit was rapid, and in line with best practice guidelines.
- Excellent examples of compassionate debriefing were seen, with emotional support provided to bereaved families by specialist teams.

Despite these strengths, gaps in documentation, escalation processes, and adherence to national guidelines were identified, leading to missed opportunities for optimising care in some cases which potentially could have made a difference in the outcome of small number of babies.

3. Key Findings

Ten babies died before 28 weeks of pregnancy and thirty one after 28 weeks. Of all the reviews 9 deaths were felt to warrant further investigation by the trust as missed opportunities in their care were identified that could have potentially changed the outcome of the babies.

- **Health Inequalities**
  The ethnicities of the mothers reviewed appeared to be in line with the local population. Some mothers were seen to have a range of vulnerabilities (such as involvement social care, drug use and homelessness) and they were not usually provided with continuity of care from a named midwife, which is a national recommendation, to improve coordination of care and build a trusting relationship, which has been shown to reduce the numbers of babies who die.

- **Smoking**
  Smoking remains a known significant risk for babies dying in pregnancy and after birth. Monitoring of carbon monoxide (CO) levels could not be performed for all women during 2020-23 due to safety concerns in the COVID-19 pandemic. However, in general CO monitoring was inconsistent for all women and documented discussions of conversations about smoking and referral to 'stop smoking' services were inadequate for the 10 women who smoked during pregnancy.

3.1 Babies that died at less than 28 weeks

- None of the babies who died at less than 28 weeks were felt to have died avoidably. Babies mainly died due to genetic conditions that affected their survival or severe and unpredictable complications of pregnancy, including waters breaking at a very early stage of pregnancy.
- A mother's risk of having a preterm birth was correctly assessed in most cases, but it was unclear whether a specialist pre-term birth clinic provided care to these women.
- Gloucester neonatal unit has facilities to care for babies born after 28 weeks of pregnancy. Babies born before this time have a much higher chance of survival when born in a specialist unit with resources for caring for the earliest preterm babies. Timing of transfer is often challenging to assess, and mothers are not always stable enough to transfer, or birth appears to be too imminent. However, for at least half of the babies who died there was a lack of clear decision making and documentation around transfer in labour to a more appropriate unit, despite appearing to be opportunities to do so.
- Newborn care notes were often not included in the records provided. Where it could be reviewed, resuscitation appeared to be performed appropriately.

3.2 Babies that died after 28 weeks

- 9 baby deaths were felt to warrant further investigation by the trust as elements of care raised concern. Concerns that were highlighted included:
- During pregnancy: Incomplete risk assessments particularly around reduced fetal movements, safeguarding referrals, and fetal growth monitoring.
- During labour: Misinterpreting or delaying calling for senior review where fetal heart rate monitoring suggested a baby needed urgent intervention.

In general, the external investigators believe that the above challenges were in line with challenges that any other maternity units with the same size could face.

3.3 Internal reviews of care

- The quality of the internal investigations using the Perinatal Mortality Review Tool (or PMRT – a national tool to review the care of mothers and babies where a baby dies during pregnancy or following birth) did not meet the best practice standards including:
  - Majority of the reviews did not involve professionals from outside to the trust, to provide external scrutiny. In some cases, clinicians involved in the incident were actively participating in the review.
  - Care grading often appeared to underestimate the missed opportunities and failings in care.
  - Action plans inadequately responded to the issues in care and rarely had time frames and feedback mechanisms to ensure they had been completed.

4. Recommendations

The following recommendations were made based on the findings of this review.

- **Documentation**
  Enhance record keeping with electronic patient records to allow a thorough PMRT review of all baby deaths. Provide ongoing up-to-date assurances that key safety actions are being performed routinely and accurately, including fetal monitoring, risk assessments and CO monitoring.
- **Preterm birth care**
  Establish a dedicated preterm birth clinic with clear referral criteria. Make counselling about baby care and outcomes standard for all women at risk of having a preterm baby. Create a decision-making framework to improve care planning when considering transfer for a mother in possible preterm labour to a unit with more specialist neonatal facilities.
- **Labour care**
  Ensure baby heartrate monitoring training and practice, is done according to national recommendations. Review processes for requesting senior support when babies need to be born urgently that reduces delays in caesarean births being performed.
- **Postnatal care**
  Develop a clear pathway for newborn babies who are at home, to be urgently reviewed when there are any parental or midwifery concerns.
- **PMRT**
  Strengthen action plans that come from the learning when baby's die to ensure they are appropriate, completed and their effectiveness reviewed. Make sure that the group providing review for the PMRT are appropriate and include external reviewers as standard and specialists where appropriate.

5. Conclusion

The issues identified in this review, and the recommendations made, are consistent with those raised in national reviews of maternity care over many years and highlight the complexity of birth. Many areas of good care were identified and there were no concerns over recurrent poor practice from any members of staff. Since these babies died Gloucester Hospitals NHS Foundation Trust have taken steps to address the previous failings in care and some of these recommendations may already have been addressed.

The review group would like to extend our sincere condolences to the families that have been the subject of this review for the loss of their babies.

Executive Summary: Neonatal Loss Review 2020-2023

Maternity services have faced sustained scrutiny following high-profile inquiries into maternity and neonatal care, including the Francis Report (2013), Kirkup Review (2015), and the Ockenden Reports (2020, 2022). These reviews consistently highlight themes of poor escalation, inadequate fetal surveillance, failures in multidisciplinary working, and delays in emergency obstetric intervention.

Gloucestershire Hospitals NHS Foundation Trust has undergone multiple CQC inspections, with an inadequate rating in 2022 and a Section 29a Notice relating to clinical governance concerns. The Trust has since entered the NHS England Maternity Safety Support Programme (MSSP), requiring significant improvements to meet national maternity safety standards.

The Chief Executive commissioned a review of neonatal Loss between 2020-2023. The Trust Board wished to have an external review of the data relating to neonatal death rates and the review processes relating to oversight of the neonatal losses with the intention to demonstrate transparency and openness, to ensure that the reporting processes were in line with national reporting requirements and that all possible learning from the neonatal losses had been identified.

The Trust outlined a series of questions to be considered as part of the external review, in relation to babies born at less than 28 weeks' gestation, with additional considerations being required for babies born at more than 28 weeks' gestation. The review was designed to identify whether themes emerged when reviewing the cases as a group, rather than individually. The Terms of Reference were supplied by the Trust ahead of the review and had been agreed through governance processes, these can be found in full in Appendix 1. This review therefore aims to:

✓ Assess compliance with national maternity and neonatal standards.
✓ Identify systemic failings and missed opportunities.
✓ Generate recommendations for clinical improvement.

1. Background and Methodology

This Perinatal Mortality Review (PMRT) benchmarked care against national guidelines including:

- NICE Antenatal Care Guidelines (NG201)
- Saving Babies' Lives Care Bundle (SBL V3)
- Royal College of Obstetricians and Gynaecologists (RCOG) Preterm Birth Toolkit
- MBRRACE-UK Perinatal Mortality Reports
- NHS Perinatal Surveillance Framework
- PERI Prem preterm birth toolkit

A total of 44 neonatal losses meeting the review criteria, were identified that occurred between 2020 and 2023 at Gloucestershire Hospitals NHS Foundation Trust and neighbouring tertiary centres, 41 sets of case notes were reviewed. The review group were unable to view the records for three cases which raised concerns regarding the completeness of local mortality reviews and record-keeping standards. Additionally, immediate neonatal care documentation was largely absent, limiting the ability to assess neonatal stabilisation and resuscitation. The reviewer learnt that in the trust these records could have been documented in other sets of neonatal notes, rather than maternity records but were not provided for the purposes of the review as per the terms of reference.

The review was conducted by an independent multidisciplinary panel, assessing:

- Antenatal care compliance with national guidelines
- Risk stratification and escalation pathways
- Fetal surveillance and intrapartum care
- Adherence to neonatal resuscitation and stabilisation protocols
- Governance and learning from previous internal reviews
- Systemic gaps

2. Positive Findings and Areas of Good Practice

This review identified several areas of strong clinical practice in line with national maternity standards.

- Timely Booking and Risk Stratification: 100% of women were booked before 12 weeks, ensuring early risk assessment and access to appropriate care pathways.
- Effective Multidisciplinary Team (MDT) Collaboration: High-risk pregnancies, including cases of PPROM and congenital abnormalities, demonstrated well-coordinated MDT planning, involving fetal medicine specialists and genetic teams.
- Preterm Birth Management:
    - Antenatal corticosteroids were administered in all eligible cases, optimising neonatal lung development.
    - Magnesium Sulphate for neuroprotection was given in the majority of preterm births, demonstrating compliance with national standards.
- Appropriate Neonatal Resuscitation and Stabilisation: Where documentation was available, neonatal resuscitation appeared to be performed in line with Newborn Life Support (NLS) guidelines, with timely transfer to the neonatal unit (NNU).
- Compassionate Postnatal Debriefing: Regular postnatal debriefing was observed, providing emotional support and clear communication to bereaved families.

Despite these strengths, gaps in documentation, escalation processes, and adherence to national guidelines were identified, leading to missed opportunities for optimising care in some cases.

3. Key Findings

- 10 Neonatal Losses occurred before 28 weeks' gestation.
- 31 Neonatal Losses occurred after 28 weeks' gestation.
- 9 Neonatal Losses were classified as having missed opportunities/care issues that may have/likely have made a difference to the outcome.
- Some concerns regarding CTG interpretation, escalation delays, and inaccessible immediate neonatal resuscitation documentation.

3.1 Equity and Health Inequalities

- 88% of women were of White ethnicity, aligning with the local demographic profile. However, the review lacked ethnicity-specific mortality data to assess disparities.
- 5/41 cases involved social vulnerability factors, including homelessness, financial hardship, and safeguarding concerns, but these women did not receive continuity of midwifery care, as recommended in NICE CG110, particularly when under obstetric-led management.
- Ethnicity-specific neonatal mortality data was unavailable, preventing evaluation of disparities in perinatal outcomes.

3.2 Smoking and Perinatal Risk Management

- Inconsistent application of smoking cessation interventions, with failure to comply with Saving Babies Lives (SBL) guidance on CO monitoring and referrals.
- 10 women were identified as smokers at booking, but only 4 were referred to smoking cessation services, contrary to Saving Babies' Lives (SBL V3) guidelines, and documentation on patient education regarding smoking risks was inadequate.
- CO monitoring was inconsistently documented, and no evidence was found of repeat testing at 36 weeks' gestation.
- COVID-19-related restrictions impacted CO monitoring for 7 cases, but failures in compliance persisted beyond this period.

3.3 Neonatal Losses <28 Weeks

3.3.1 Preterm birth

- Preterm birth risk assessments were performed for 9 of 10 cases, yet referral to a dedicated preterm birth clinic was not documented clearly.
- One case specifically lacked risk assessment despite a prior intrauterine fetal demise (IUFD) at 25 weeks.

3.3.2 Intrauterine transfer and escalation

- Intrauterine transfer (IUT) considerations were inconsistently documented, with 5 cases showing no evidence of IUT discussions, despite potential transfer windows of >12–24 hours.
- IUT was not considered or documented in 5/10 cases, despite tertiary transfer being feasible in at least two cases.
- One twin pregnancy with extreme prematurity was managed in a non-tertiary unit, potentially impacting neonatal outcomes.
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3.3.3 Neonatal resuscitation and stabilisation

- Neonatal counselling was missing in 3 of 7 cases, and neonatal resuscitation documentation was incomplete, limiting the ability to assess stabilisation efforts.
- Where recorded, resuscitation appeared to follow NLS protocols.

3.4 Neonatal Deaths >28 Weeks

- 9 of 31 Neonatal Losses were classified as having missed opportunities/care issues that may have/likely have made a difference to the outcome.

3.4.1 Antenatal care

- Antenatally issues identified included:

🚨 Incomplete risk assessments for fetal wellbeing, particularly in reduced fetal movements (RFM) documentation, safeguarding referrals, and fetal growth monitoring.

3.4.2 Intrapartum care

- Intrapartum care issues identified included:
  - 🚨 CTG misinterpretation and delayed escalation
  - 🚨 Inappropriate use of Dawes-Redman criteria in early labour, inadequate hourly CTG reviews, and inappropriate corrective measures such as IV fluids for abnormal CTGs in the absence of maternal hypotension.
  - 🚨 Lack of senior obstetric involvement in complex cases
  - 🚨 Delays in category 1 and category 2 caesarean section decision-making
  - 🚨 Poor documentation of neonatal resuscitation and stabilisation

3.4.3 Fetal Surveillance & Labour Management

Care Issues identified

✓ Antenatal corticosteroids and Magnesium Sulphate were administered in eligible cases

✓ Safeguarding and mental health concerns were addressed in some cases

❌ CTG fresh eyes reviews were missing in 5 cases

❌ Suboptimal fetal monitoring, including inappropriate intrapartum auscultation

❌ Inadequate escalation of abnormal CTGs in at least 6 cases.

❌ Consultant Decision-Making challenges

- One case involved consultant-led decision reversal delaying a Category 1 caesarean section, with no retrospective documentation explaining the rationale.
- Senior obstetric oversight in high-risk labours was inconsistently documented.

3.5 Transfer Systems and Internal Review Quality

- No formal IUT guidelines or escalation policies were provided, and missed IUT opportunities were identified, particularly in cases of extreme prematurity.
- Deficiencies in PMRT Review Quality
  - ❌ 13 cases were still listed as "in progress" after 2-5 years
  - ❌ PMRT grading did not always reflect identified care failings
  - ❌ Action plans lacked clear interventions, timelines, and audit mechanisms
  - ❌ No external reviewers were present in several of the PMRTs assessed, raising concerns about internal review independence and learning from adverse outcomes.

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4. Strategic Recommendations

4.1 Enhancing Clinical Governance and Documentation

- 📌 **Standardise electronic record integration (Badgernet) across all care settings**:
  Mandate full integration of electronic patient records (Badgernet EPR) across all maternity services to eliminate documentation gaps in antenatal, intrapartum, and neonatal care.
- 📌 **Implement real-time audit dashboards.**
  Introduce real-time audit dashboards to flag incomplete records for fetal monitoring, risk assessments, and smoking cessation compliance.
- 📌 **Mandate external oversight in PMRT reviews where care failings are identified.**
  Require external oversight in PMRT reviews to improve the quality and objectivity of internal mortality investigations (see PMRT recommended team in Appendix 3).

4.2 Optimising Antenatal Risk Assessment and Preterm Birth Pathways

- 📌 **Establish a dedicated Preterm Birth Clinic**
  Establish a dedicated Preterm Birth Clinic, with clear referral criteria, ensuring systematic referrals for women at risk and integrating preterm birth risk assessment into badger notes .
- 📌 **Require structured neonatal counselling for all women at risk of preterm birth.**
  Implement mandatory preterm birth counselling protocols, with structured documentation of neonatal survival discussions in MDT setting with most senior obstetrician and neonatologist and early decision-making on escalation of care.
- 📌 **Develop a formalised IUT decision-making protocol.**
  Enhance IUT decision-making frameworks, ensuring all cases are assessed for transfer feasibility, with structured escalation policies and predefined triggers for consultant/ senior obstetrician early review as well as consultant to consultant hand over.

4.3 Strengthening Intrapartum and Neonatal Care Compliance

- 📌 **Mandate annual multidisciplinary CTG training and competency assessments**
  Implement a multidisciplinary CTG training program, incorporating case-based reviews and annual competency assessments for all obstetric and midwifery staff.
- 📌 **Enhance decision-support tools for category 1 & 2 caesarean sections.**
  Develop an escalation protocol for fetal distress, with real-time decision-support tools to prevent delays in obstetric intervention and category 1 caesarean birth decision-making.

- **Require fresh eyes reviews and real-time documentation in all intrapartum cases**
- **Standardise neonatal resuscitation documentation with structured templates** Standardise neonatal resuscitation documentation, ensuring all records capture cord management, thermoregulation, and immediate neonatal interventions.

4.4 Improving Postnatal Safety Netting and Neonatal Follow-Up

- **Develop a referral pathway for unwell neonates in the community** Develop a structured escalation pathway for neonates found unwell in the community, ensuring early access to hospital-based review for high-risk newborns.

4.5 Strengthening Learning from Mortality Reviews and External Benchmarking

- **Ensure all PMRT action plans are time-bound, measurable, and externally reviewed** Ensure action plans from internal mortality reviews include measurable interventions, defined timelines, and audit mechanisms to track implementation effectiveness.
- **Implement benchmarking against national MBRRACE data to drive perinatal safety improvements.**
  Benchmark local perinatal outcomes against national MBRRACE and Saving Babies Lives data, developing a targeted perinatal quality improvement strategy.
- **External scrutiny.**
  Introduce mandatory external review participation for all PMRT cases and ensure appropriate speciality attendance for complex cases, ensuring independent scrutiny of care quality and escalation decisions.

5. Conclusion

This review has identified gaps in fetal surveillance, intrapartum decision-making, transfer planning, and internal mortality review processes. However, areas of good practice, including timely antenatal booking, effective use of corticosteroids and Magnesium Sulphate, and high-quality MDT collaboration, demonstrate a strong foundation for improvement.

By implementing standardised governance frameworks, enhanced clinical pathways, and strengthened review mechanisms, maternal and neonatal outcomes can be optimised, ensuring full alignment with national maternity care standards, and reducing preventable neonatal deaths by ensuring that systems are in place to optimise compliance with the Health Innovation West – PERIPrem care bundle alongside the Saving Babies Lives care bundle (see Appendix 2).

However, it is acknowledged that since these deaths occurred, it is anticipated that Gloucester Hospitals NHS Foundation Trust would have taken steps to address the previous failings in care and this review may not be reflective of current practice but should provide the trust board with guidance to improve outcomes, through audit and quality improvement programmes.

The review group would like to extend our sincere condolences to the families that have been subject to this review for the loss of their babies.

1. Background

Maternity services nationally have experienced significant scrutiny since 2006 when an initial maternity services review was carried out at Northwick Park, followed by a second review of the Trust's Maternity Service in 2008 due to several maternal deaths which had occurred in the Trust.

The Francis Report was published in 2013, following an inquiry into adult services in Mid-Staffordshire NHS Foundation Trust, which although it did not directly relate to Maternity services, it highlighted implications for patient safety, duty of candour and consent, which are applicable to maternity and neonatal services.

In 2015 Kirkup conducted an inquiry into maternity services at Morecombe Bay and subsequently the Shrewsbury and Telford Inquiry was published as the Ockendon Report in 2020. The themes from these reports are recurrent and following the publication of the Ockenden Report, there was a national drive for changes to the provision of maternity services.

Beyond the impact of the various inquiries, the establishment of the Care Quality Commission (CQC), in 2009 has led to a programme of independent inspections of hospitals in England to ensure that they provide, safe, high quality and effective care. Further, the publication of the Saving Babies Lives Care Bundles in 2016 provides maternity services with evidence-based policy recommendations to support the national ambition to reduce the rates of stillbirths and neonatal deaths in the UK. The care bundle is regularly reviewed and updated to ensure that it is reflective of current evidence.

The Maternity and Newborn Safety Investigations (MNSI) programme is part of the national strategy to improve maternity safety across the NHS in England, by undertaking an independent review of care, following defined patient safety incidents and making safety recommendations to improve services at both a local and national level and is hosted by the CQC.

Despite the numerous public inquiries, there remains significant improvements to be made. The Health and Social Care Committee's inquiry into the safety of maternity services in England (July 2021) identified that whilst there has been a drive to improve the safety of maternity services in England, there remains ongoing concerns and "there can be no complacency when it comes to improving the safety of maternity services and it is imperative that lessons are learnt from patient safety incidents."

"Throughout our inquiry we have considered a range of issues related to the safety of maternity services in England. This report focuses on the need to address several issues, including:

- Supporting maternity services and staff to deliver safe maternity care
- Learning from patient safety incidents
- Providing safe and personalised care for all mothers and babies"

1.1 Providing Safe Maternity Care for Mothers and Babies

Whilst the progress in reduction of stillbirths and neonatal deaths as a marker of improved maternity safety was good, when comparing the NHS to Maternity Care in the rest of the world, there remained concerns regarding the variation in quality of maternity care, indicating that key lessons had not being learned, despite a range of public inquiries and the same mistakes were being made. Professor Ted Baker, Chief Inspector of Hospitals, Care Quality Commission (CQC), reflected in July 2021 that elements from Morecambe Bay were still to be found in maternity services today, including a defensive culture, dysfunctional teams, and poor-quality investigations without learning taking place.

The importance of the Ockenden review was evident when in December 2020, Donna Ockenden highlighted that the Immediate and Essential Actions directed at all trusts were not new and built on recommendations in previous reports. In 2022, Donna Ockenden, highlighted that further action was required to fund a safe and sustainable maternity is required attrition of maternity staff and providing the required funding for a sustainable, safe multidisciplinary workforce to ensure the safety of mothers and their babies, if we are to meet the Government's ambition to halve the 2010 rates of stillbirths, neonatal deaths and brain injuries in babies occurring soon or after birth by 2025.

The State of the Nation report compiled by the MBRRACE-UK Collaboration, jointly led by Oxford Population Health's National Perinatal Epidemiology Unit (NPEU) and the University Of Leicester's The Infant Mortality and Morbidity Studies (TIMMS) research group found that whilst the extended perinatal mortality rates decreased in 2022 to 5.04 deaths per 1,000 total births, following an increase in 2021, this rate remains higher than it was in 2019 and 2020. This demonstrates that increased action is required if maternity and neonatal services in the UK are to meet the Government's ambition to halve stillbirths and neonatal deaths.

Whilst there are national programmes to support measures to reduce health inequalities and adverse outcomes, such as the Saving Babies Lives and Periprem care bundles, it is imperative that maternity and neonatal services undertake timely and independent reviews following serious maternity incidents, this independent external review will support learning from events and enable the trusts to develop and undertake appropriate change.

1.2 Patient Safety Culture

In relation to patient safety, the committee emphasised the importance of developing a positive safety culture (supporting psychological safety in speaking up after mistakes have been made), across the maternity systems, recognising this to be of benefit to clinicians, mothers, and families. The process for reviewing patient safety incidents has evolved and in 2022, NHS England produced guidance for the Patient Safety Incident Response Framework, which uses a system-based approach for learning from patient safety incidents to explore the contributory factors to a patient safety incident or cluster of incidents, to inform improvements to clinical practice.

1.3 Perinatal Mortality Review Tool (PMRT)

MBRRACE and UKOSS remain important National reporting systems, which all Maternity Units are expected to report to. Their reports influence the conduct of maternity services and has contributed to the reduction of maternal deaths from certain conditions.

The Perinatal Mortality Review Tool (PMRT) was developed with clinicians and families in 2017 and launched

in early 2018. This is a national tool designed to support objective, robust and standardised reviews of the deaths of babies from 22 weeks gestation up to 28 days post birth. This reporting process incorporates a systematic process for including families within the review of care, enabling them to provide their perspective of care and raise any questions or concerns, which can be incorporated into the review process from the outset.

The process should facilitate a multidisciplinary, high-quality reviews of the circumstances and care leading up to and surrounding each stillbirth and neonatal death, and the deaths of babies who die in the post-neonatal period having received neonatal care. The review process seeks to clearly understand of why each baby died, accepting that this may not always be possible even when full clinical investigations have been undertaken. During the review process, learning should be clearly identified and actions developed to improve future care.

There should be active communication with parents to ensure they are told that a review of their care and that of their baby will be carried out and how they can contribute to the process, so that the voice of the family is central to the review process.

On completion of the review, a technical clinical report should be produced, and this should be used for discussion with parents from which a meaningful, plain language explanation of why their baby died and whether, with different actions, the death of their baby might have been prevented. Further, families should be counselled regarding any implications for future pregnancies and how any increased risk factors and associated anxieties can be effectively managed.

Other reports can be generated from the tool, which will enable organisations providing and commissioning care to identify emerging themes across several deaths to support learning and changes in the delivery and commissioning of care to improve future care and prevent the future deaths which are avoidable.

MBRRACE produce national reports of the themes and trends associated with perinatal deaths to enable national lessons to be learned from the nation-wide system of reviews.

Parents whose baby has died have the greatest interest of all in the review of their baby's death. Alongside the national annual reports an infographic of the main technical report is written specifically for families and the wider public. This will help local NHS services and baby loss charities to help parents engage with the local review process and improvements in care.

However, despite this standardised review process, the quality of the reviews and the subsequent reports varies across trusts and the reviews may not always be subject to independent scrutiny. It is recommended that external maternity, obstetric and/or neonatal panel members are engaged in the review process. Trusts should constantly evaluate the learning identified from the review process to ensure that systemic changes are implemented into practice and further they should develop strategies to improve the review process and quality of the reports provided.

2. Context for review

Gloucester Hospitals NHS Foundation Trust has been subject to a CQC inspection and received an inadequate rating following an inspection in 2022. The Trust has received a Section 29a Notice from the CQC, relating to clinical incidence closure and level 3 Safeguarding Training. As a result of the CQC rating, the Trust entered the NHS England (NHSE) Maternity Safety Support Programme (MSSP), and an exit criterion has been developed and agreed. The CQC rating led to national media interest, including a BBC Panorama investigative programme, aired in January 2024, focused on Gloucestershire Maternity Service with a focus on maternal deaths.

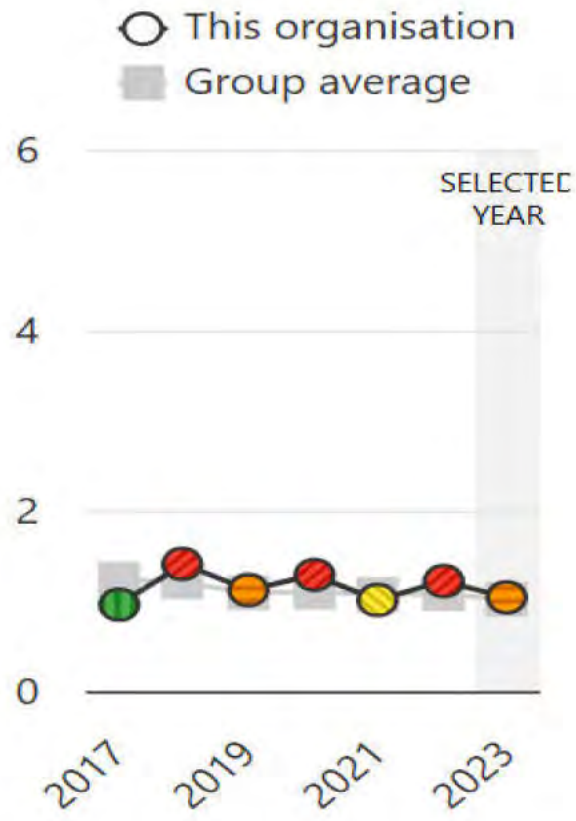
In May 2024, the Trust received a warning notice under Section 31 of the Health and Social Care Act 2008. This required the Trust to make improvements to ensure the safe treatment of women and people using the maternity services and to improve how it was being led and managed. The service continues to have an inadequate rating, although the CQC in January noted some positive changes, but there remain concerns regarding Trust managed systems to identify risks to mothers, babies and people using the service.

MBRRACE data demonstrates that between 2020-2021 and 2022-2023, Gloucester Hospitals NHS Foundation Trust had an increased rate of neonatal deaths, compared to similar units, and the rates of neonatal deaths was higher than the average rate of deaths per 1000 infants in England.

	Gloucester Hospitals NHS Foundation Trust	Gloucester Hospitals NHS Foundation Trust	England
Year	**Neonatal Deaths**	**Rate Per 1000 Infants**	**Rate Per 1000 Infants**
2019-2020	10	1.7	2.5
2020-2021	16	2.7	2.4
2021-2022	11	1.9	2.5
2022-2023	22	3.8	2.7
TOTAL	59	2.5	2.5

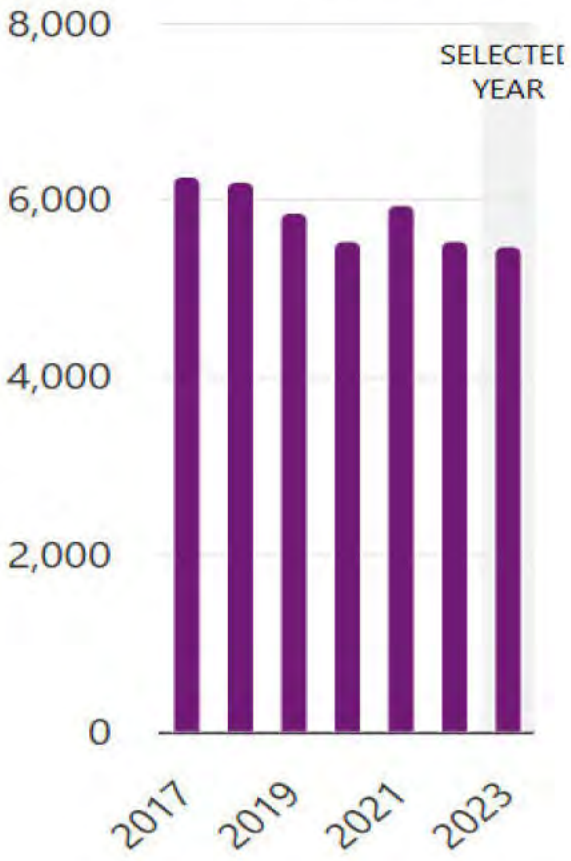
Mortality rates, by year

Stabilised & adjusted neonatal mortality rate per 1,000 live births



Births, by year

Total number of births



3. Methodology

Gloucester Hospitals provided the review group with a list of 44 cases for neonatal deaths occurring between 2020 and 2023. This included 10 deaths in the period occurring more than 28 days after birth but under 1 year. The neonatal deaths occurred at either Gloucester Hospitals, or within neighbouring units at University Hospitals Bristol and Weston NHS Foundation Trust, where the tertiary neonatal intensive care unit is located and provides care for extremely premature babies and unwell babies with a wide variety of medical and surgical conditions. The unit also provides the Newborn Emergency Stabilisation & Transport Team for the region's hospitals.

During the period under review, Gloucester Hospital moved from paper maternity records to the electronic Badgernet maternity system. The review group received copies of the paper maternity records via email as a scanned document or copies of the notes were sent to the team by courier. Electronic records were accessed via the Badgernet maternity system, and all members of the review group were able to independently access and review these records. It was noted that some of the deaths had met the criteria for an external review by the Healthcare Safety Investigation Branch (HSIB), who provided a report to the trust, outlining care provided and making specific safety prompts and/or safety recommendations for cases, where the care provided did not meet the expected standards. The review group were not provided with copies of these reports and therefore cannot comment on any recommendations or make any comparison with the findings of this systematic review.

A total of 41 records were received, the records for 3 mothers and babies were not received, and therefore the deaths were excluded from the review. However the reviewer were reassured by the trust that these three notes were critically assessed and the learning points were implemented by the maternity and neonatal services. A spreadsheet was developed to ensure consistency of review and to reflect the national standards for antenatal care, as outlined by the National Institute for Clinical Excellence, Saving Babies Lives and the Royal College of Obstetricians and Gynaecologists. In respect of pre-term birth optimisation, the review incorporated all elements of the peri Prem care bundle. As patient records were received, the review group would agree on the number of cases to be reviewed, and each record was independently reviewed. The reviewers then met on a weekly basis, to jointly discuss the cases and to complete the spreadsheet to assess compliance with national standards and to identify any additional learning for each death reviewed. When a PMRT report was made available, this was scrutinised for robustness of review and to determine whether all identifiable learning had been reflected in the review discussions.

The review was impacted by the quality of the records received and at times the records provided, did not include the period of care for the baby's death being reviewed. The lead reviewer maintained ongoing dialogue with Gloucestershire Hospitals NHS Foundation Trust to obtain the appropriate records. There were delays in records being provided, which resulted in an extension to the review period. Further, minimal information was provided in respect of neonatal care and therefore, the review group were unable to comment on the neonatal care provided, as this was outside of the remit of this review.

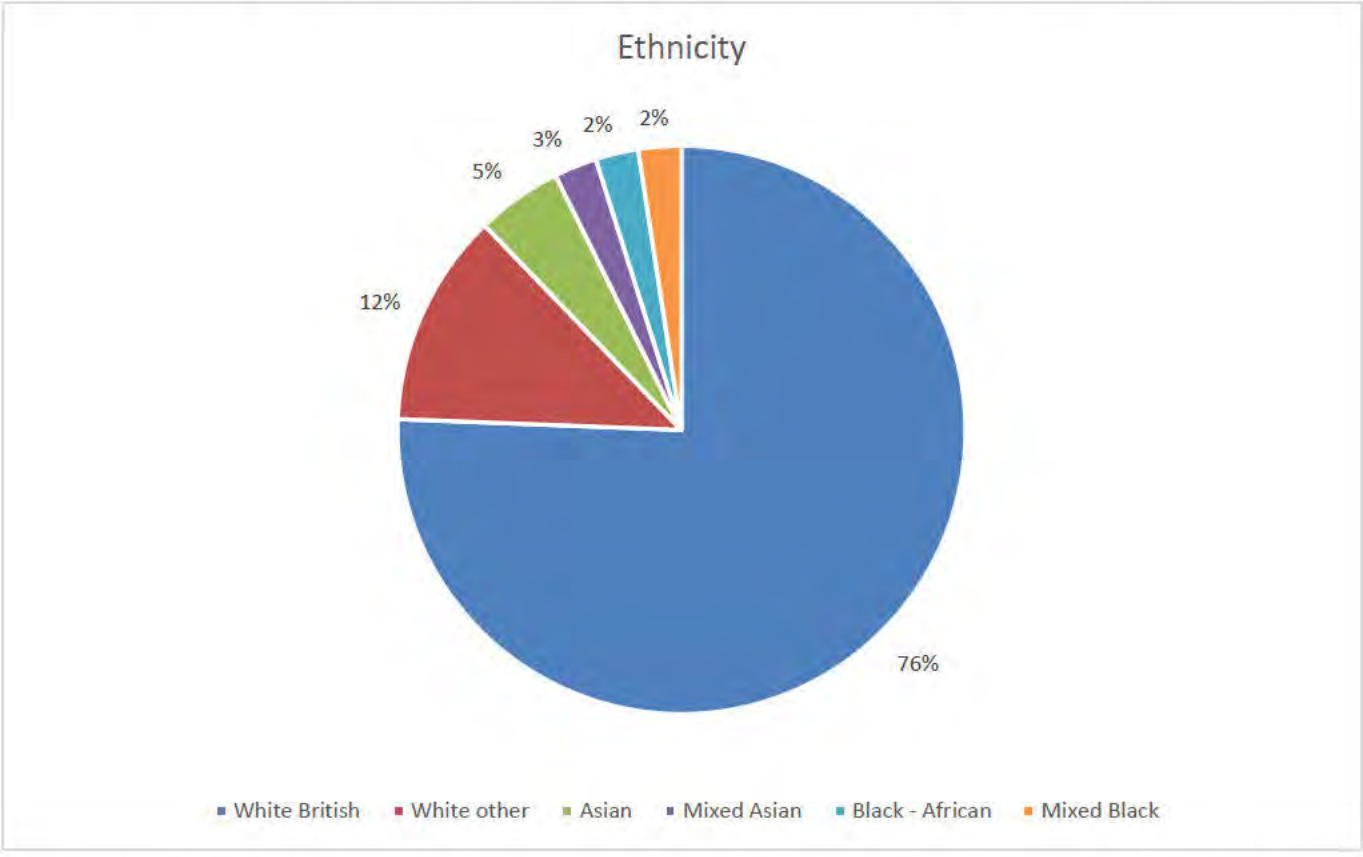
Once all 41 cases had been independently and collectively reviewed with all data captured within a main spreadsheet, the review group began to analyse the findings to identify common themes and learning. To answer specific questions, outlined within the terms of reference, a further spreadsheet was developed to clearly identify the neonatal deaths at <28 weeks and >28 weeks gestation. whose babies died between 2020 and 2023. A thematic analysis can provide enriched data when compared to a single case review, as the reviewers look for recurring patterns and themes, enabling them to respond to the brief provided by Gloucester Hospitals NHS Foundation Trust and to make recommendations to support improvements in care.

Following completion of the analysis of data, the review group meet to discuss the findings from the review and to compile recommendations, for consideration by Gloucester Hospitals NHS Foundation Trust.

4. General findings

4.1 Equity

National reports published by MBRRACE continue to highlight the health inequalities associated with levels of deprivation and for ethnicity. MBRRACE reports that 'stillbirth rates for babies born to mothers living in the most deprived areas decreased to 4.60 per 1,000 total births, but this rate remains much higher than that for babies born to women living in the least deprived areas (2.61 per 1,000 total births). Neonatal mortality rates for babies born to mothers from the most deprived areas increased for the second year and are now twice that of babies born to mothers from the least deprived areas (2.38 per 1,000 live births compared with 1.18 per 1,000 live births)'. Similar ethnic disparities remain with babies of Asian and Black ethnicity continuing to have much higher mortality rates than babies of White ethnicity.



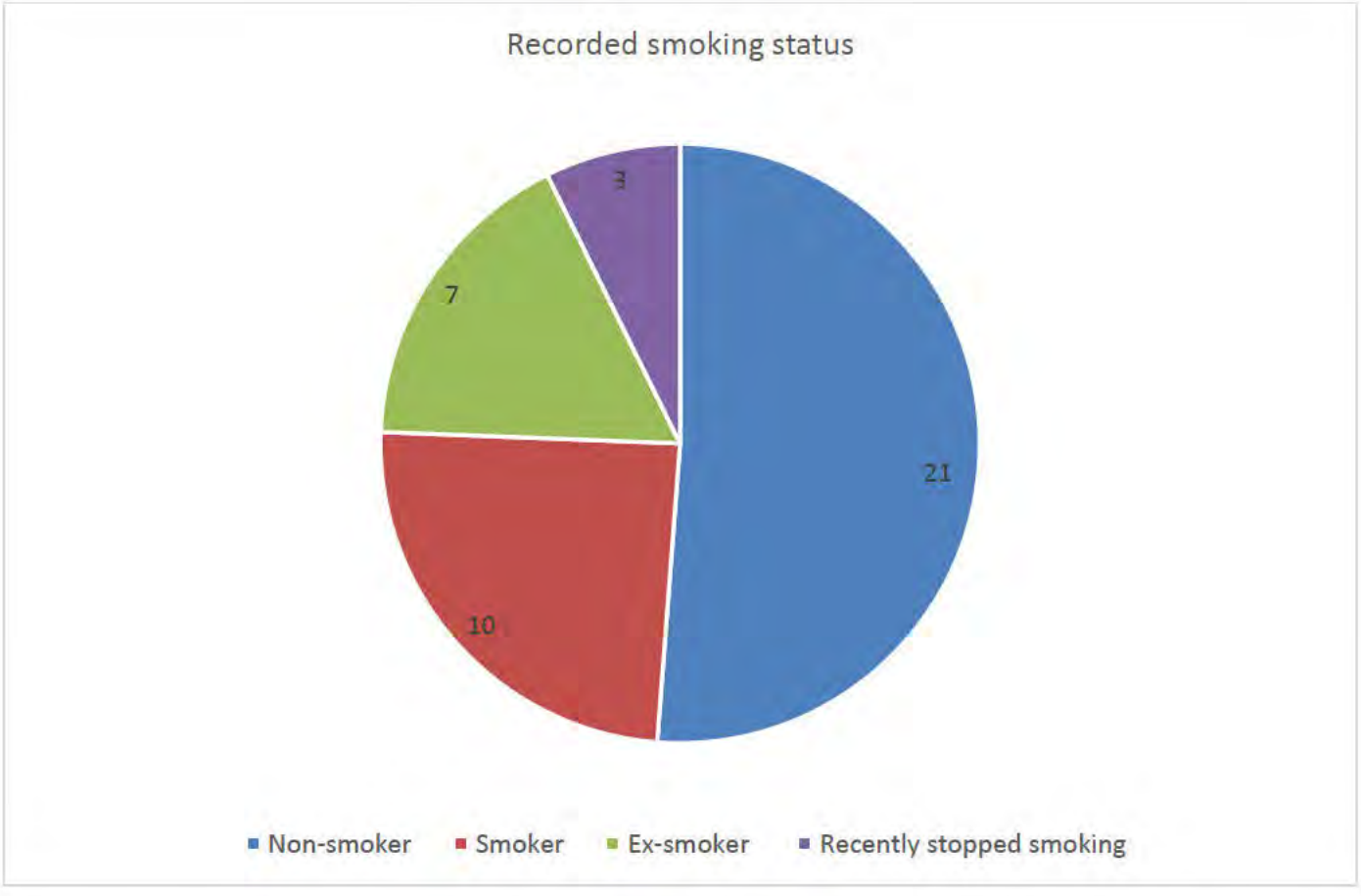
Within the cohort of women reviewed, it was found that 88% of the mothers were of white or white British ethnicity and this is likely to be in keeping with the cohort of women accessing care at Gloucestershire Hospitals NHS Foundation Trust. However, this review was restricted to the maternity records received and therefore the review group are unable to verify whether the rate of neonatal death for women of black or Asian ethnicity was significantly higher than women of white ethnicity.

The review group did not specifically record the IMD deciles for the women, recognising that location of home address does not always reflect the level of vulnerability. However, from the case notes, it was evident that 5 of the 41 records indicated that the women had increased levels of vulnerability, in relation to social,

housing or financial concerns. The common theme for this cohort of women was that they did not receive continuity of care, often failing to receive any holistic midwifery led care when care was predominately led by the Obstetric team. In line with national recommendations, all women should be offered midwifery appointments at appropriate intervals throughout their pregnancy, which enables a holistic assessment of their needs and ensure that patient centred care is provided. In addition, NICE (2010) outlines the importance of flexible approach to care, reflecting the needs of family from a cultural, social and safety perspective.

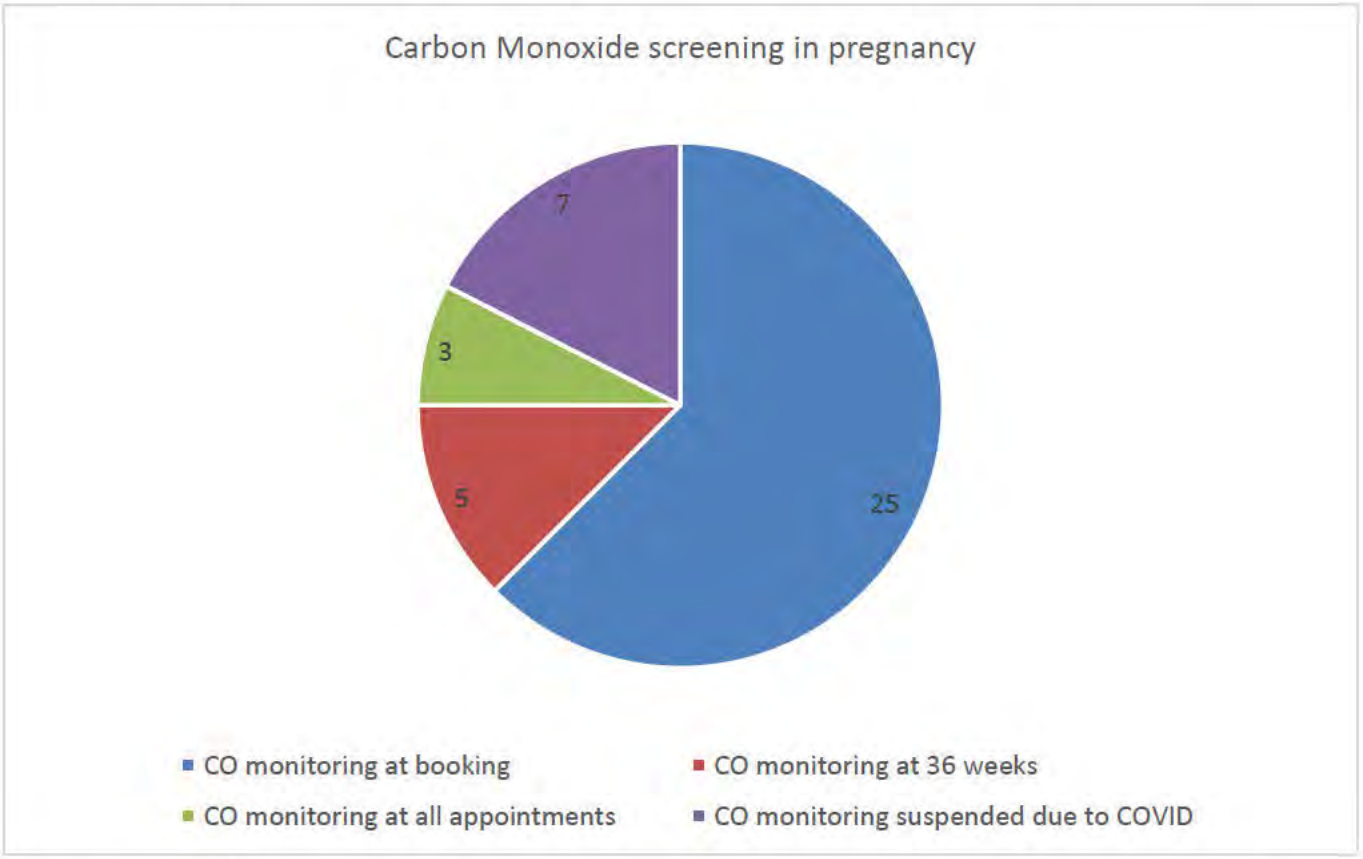
4.2 Smoking

As outlined within the Saving Babies Lives (SBL) Care Bundle, smoking is associated with an increased risk of stillbirth and positively impacts on many other smoking-related pregnancy complications such as premature birth and low birthweight. Consequently, the SBL care bundle requires trusts to record the smoking status for all pregnant people and to offer to undertake a Carbon Monoxide (CO) test at the antenatal booking appointment to identify smokers (or those exposed to tobacco smoke) and referring to stop smoking service/specialist as appropriate. The CO monitoring should be repeated at 36 weeks gestation. The NICE antenatal care guidelines recommends that CO monitoring should be offered at each contact, with referral to smoking cessation services for elevated CO levels. It is recognised that pollution, faulty gas appliances and lactose intolerance can be a source of increased CO levels in non-smoking people and therefore, this screening enables maternity services to undertake a holistic and equitable assessment for all pregnant people during the antenatal period.



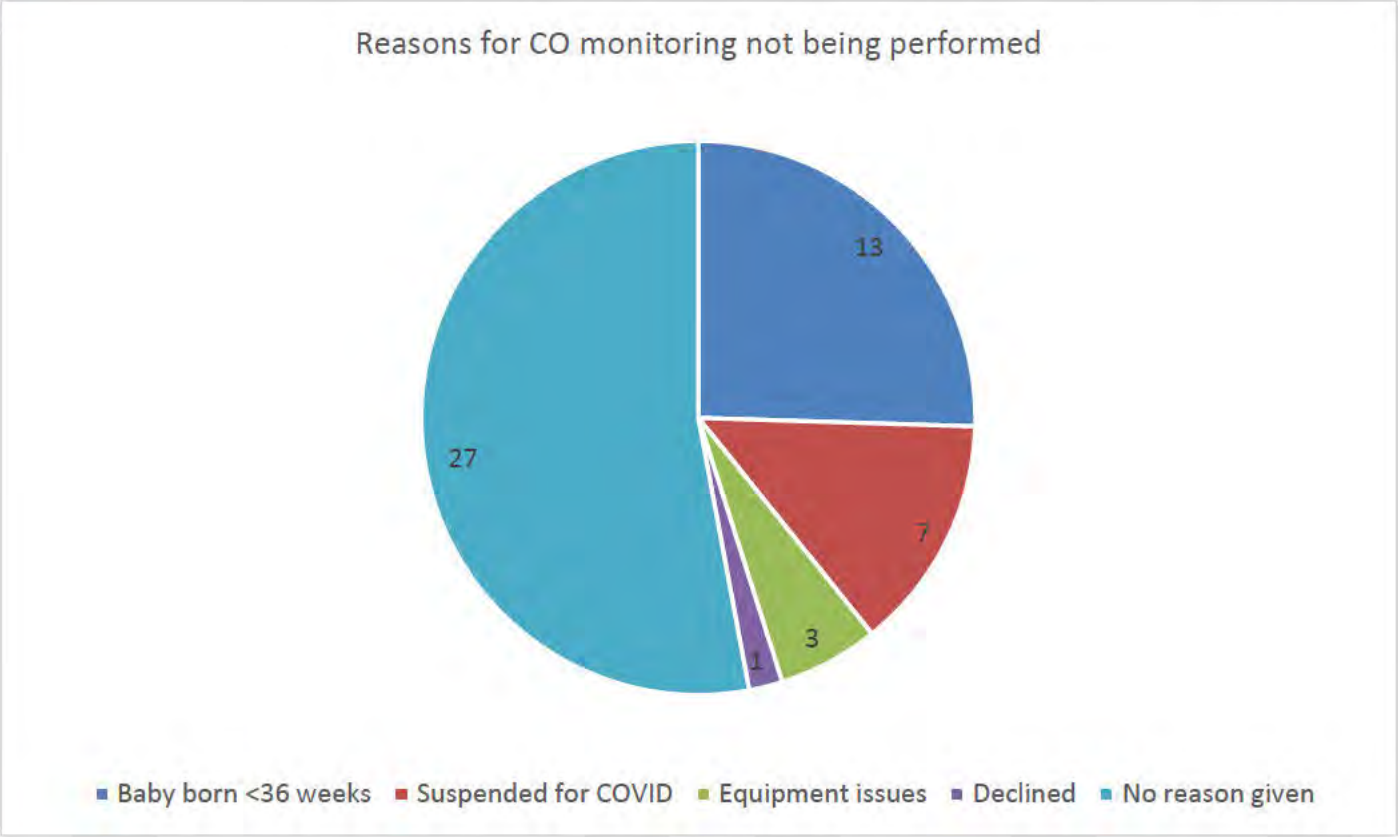
SBL recommends that all smokers and those with elevated CO levels are referred to smoking cessation services and the SBL care bundle version 2, which was applicable to the cases being reviewed recommended that additional CO monitoring is indicated for pregnant people at the 16 or 25-week appointment to identify

smokers who have not engaged with specialist support or those who may have relapsed. Additional monitoring should also be considered at each antenatal appointment for women who smoke or were recorded as recent/ex-smoker at booking. From the 41 cases that were reviewed, CO monitoring was performed at the booking appointment or at the first face-to-face appointment with midwifery services. It is acknowledged that for the period of the review there had been changes to national recommendations, as due to the COVID-19 pandemic, CO monitoring was not recommended, this related to babies born in 2020 and 2021. Therefore, 7 pregnant people were unable to have CO monitoring performed during their pregnancy, and all reported that they were non-smokers at the time of booking. Consequently, it is likely that the inability to undertake this screening did not affect the outcomes for their babies.



For the remaining 34 pregnant people, there was poor documentation to explain why the screening was not performed or whether there had been detailed discussions explaining the rationale for performing the screening. SBL highlights the importance of maternity services providing high quality information to pregnant people before and during their pregnancy to enable them to reduce the risk to their baby. This includes the recommendation to stop smoking and to avoid secondhand smoke. The CO monitoring is a tool to support these conversations with pregnant people.

The review group were not provided with copies of the Trust guidelines relating to the management of smoking in pregnancy and antenatal care guidelines in respect of carbon monoxide screening and therefore are unable to determine whether the Trust follow the SBL care bundle or NICE guidelines.



However, it is evident the CO monitoring was not being undertaken in line with the SBL guidance and there was no documentation to support the rational for the monitoring not being performed.

10 of the pregnant people identified as smokers at the time of booking, but only 4 were referred to smoking cessation services. In line with the current SBL care bundle, all pregnant people who identify as smokers at booking, have recently stopped smoking or have increased CO monitoring, should be automatically referred to smoking cessation services, so that appropriate counselling can be provided and with consent support can be provided to facilitate the pregnant people to stop smoking.

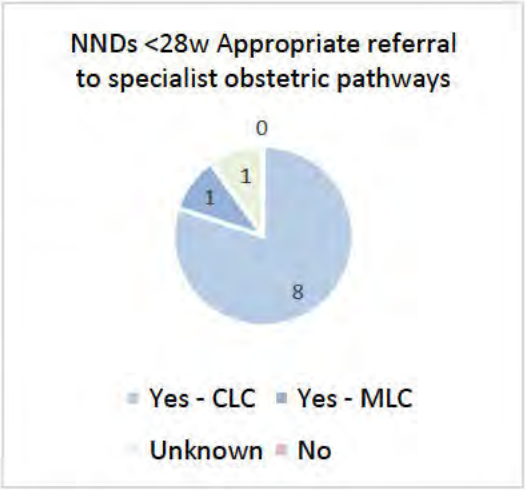
5. Review of deaths <28 weeks gestation

11 cases of the 44 babies which were eligible in the review related to deaths that occurred at less than 28 weeks gestation. Notes were provided for 10 of the cases. All three reviewers separately assessed the notes against the terms of reference and national standards.

Review all deaths <28 weeks to consider:

a. Was there appropriate antenatal referral to specialist obstetric pathways including preterm birth if indicated?

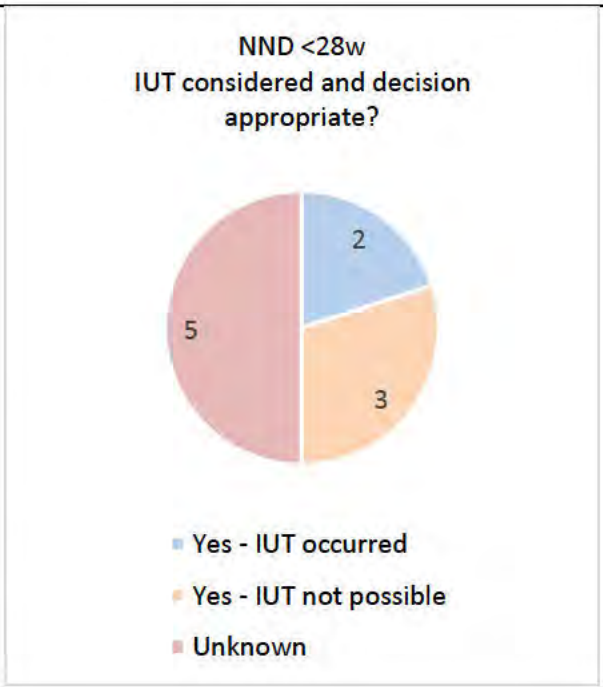
- 8 of the women needed, and were correctly referred for, consultant-led care appropriately at booking.
- 2 women were allocated to midwife-led care, and they did not appear to have any risk factors for pre-term birth. Although for one woman there was no consideration for obstetric referral for underlying health concerns.
- No notes referenced a specific pre-term birth clinic but 9 of the 10 women were correctly assessed for risk of preterm birth and had appropriate care.
- In one case it was not possible to identify whether the mother had been referred to pre-term birth clinic, although from the records provided it was evident that she had a previously intrauterine death at 25 weeks' gestation



- In general care pathway was appropriate for women whose babies died at <28 weeks.
- No specific preterm birth clinic or preterm birth midwife are recorded in the notes.

b. Why the place of birth was Gloucestershire and factors that influenced this?

- 8 of the 10 mothers presented in Gloucestershire with signs of threatened pre-term labour (TPTL).
- Documentation around possible intra-uterine transfer (IUT) is lacking in notes, however.
  - IUT not considered / documented – 5.
  - IUT Considered but not safe – 1.
  - No time for transfer (birth imminent) - 1
  - IUT occurred – 1.
- Of the remaining 2 cases
  - No sign of TPTL but fetal compromise and imminent birth required – 1.
  - IUT in pregnancy – 1
- In at least two the cases the review team felt that there was opportunity during the antenatal admission to consider and arrange transfer (>12-24 hours without uterine activity and mother stable).



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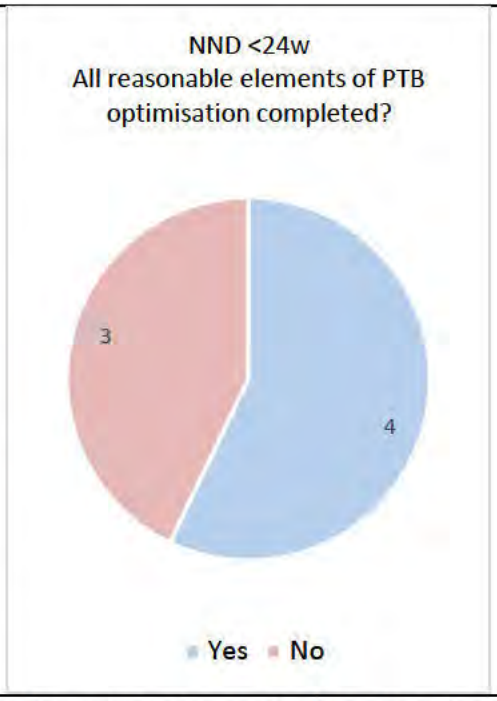
c. ***Was appropriate guidance followed during admissions to the obstetric unit during the antenatal and intrapartum period?***

- 8 of the 10 mothers presented in Gloucestershire with signs of threatened pre-term labour (TPTL).
- In one case the birth occurred very soon after admission and no preterm optimisation was possible. IUT care is described above.
- Of the remaining 7 cases, 3 had no documented evidence of counselling regarding neonatal care and outcomes.
- All 7 women were given at least one dose of steroids
- Magnesium Sulphate was given to 6 of the 7 women.
- Neonatal resuscitation documentation was missing in most of the sets of notes, and it was not possible to assess whether the babies admitted to the Neonatal Unit (NNU) were normothermic on admission, had optimal cord clamping, or had access to maternal breast milk.



In line with the PERI prem care bundle, the trust should ensure that processes are in place to ensure that all elements of the care bundle are considered and/or implemented in a timely manner to optimise the wellbeing of premature babies prior to delivery.

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d. Was the Midwifery / Obstetric and Neonatal Management plan in line with national standards?

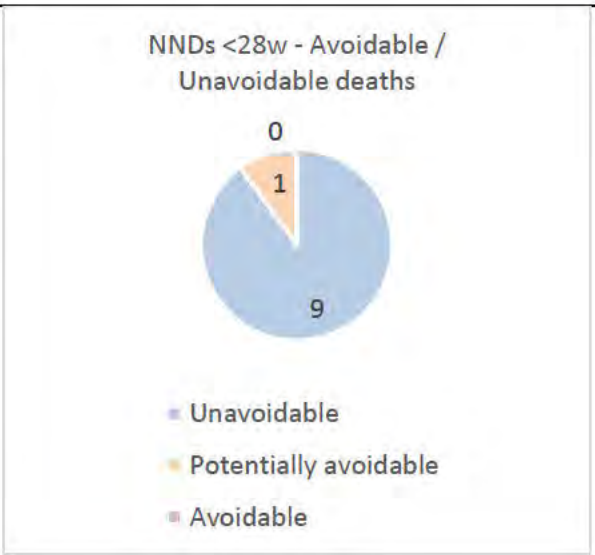
- All women were booked by 12 weeks of pregnancy
- 8 of the 10 women had all the national schedule of midwifery appointments they would expect until the point of birth. 1 did not, and in one case no community antenatal notes were provided.
- All 10 women had appropriate frequency of obstetric appointments.
- There was good evidence of thorough risk assessment in most areas including aspirin risk assessment (90% accurate), domestic violence screening (90%), fetal growth where relevant for gestation.
- Appropriate review and referral for
  - Safeguarding (1 woman)
  - Mental health (4 women)
- Ultrasound scans were performed at the correct gestation and frequencies.
- 5 of the women were smokers or recent ex-smokers. All had some form of CO monitoring, but this was only at the recommended frequency for one woman. COVID restrictions for CO screening were noted to be in place during some of the review period.
- Diabetes screening was performed and followed up appropriately
- The review team could not find evidence of information about reduced fetal movements in any of the sets of notes.

Minimal concerns relate to single elements of incorrect assessment – e.g. CO monitoring, incorrect aspirin risk assessment.

- Excellent examples were seen of antenatal multi-disciplinary team (MDT) care planning for women with premature prolonged rupture of membranes (PPROM)and congenital abnormalities, especially regarding counselling about prognosis, documentation from fetal medicine consultants and liaison with genetic specialists.

e. Whether the systems and processes for transfer are clear and work well?

The review team were not provided with transfer guidelines or an escalation policy.

It was the opinion of the review group that 9 of the 10 cases were unavoidable deaths which was in line with and PMRT care grade A/B. In these cases, prematurity complicated by additional factors such as - Fetal / maternal infection following PPROM. - Congenital abnormality One case of extreme prematurity for a multiple birth was felt to have care issues that probably could have changed the outcome in line with PMRT grade B/C. In this case there was a missed opportunities for IUT so the outcomes for the second twin may have been improved by birth in a tertiary unit.	

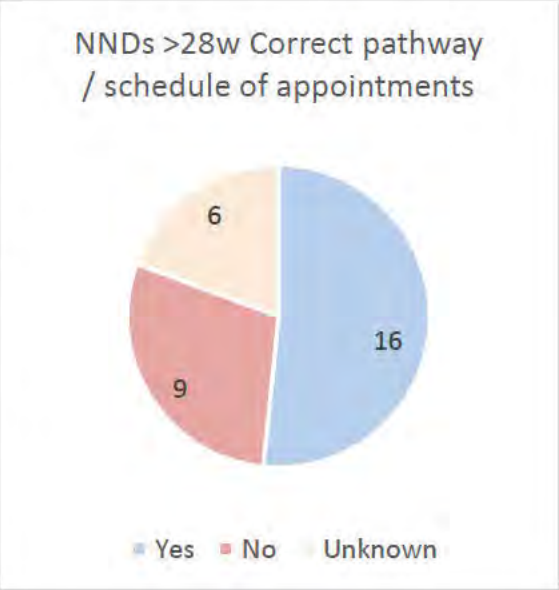
6. Review of Neonatal deaths >28 weeks gestation

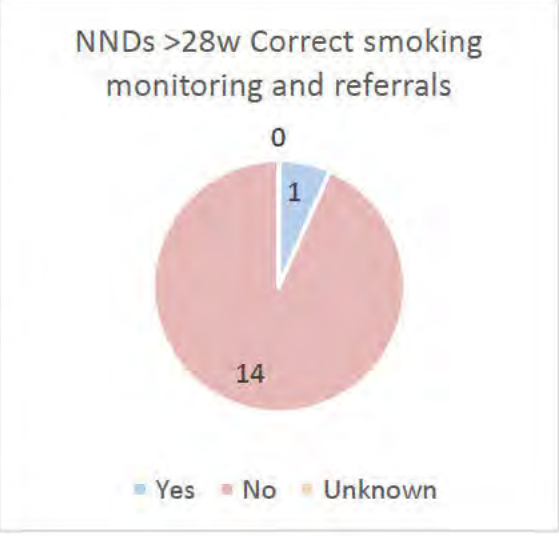
The remaining 33 cases which were eligible for the review related to deaths occurring at over 28 weeks' gestation. 31 sets of notes were provided for the review by the Trust. The remaining two sets of cases were omitted from the review. All three reviewers separately assessed the notes against the terms of reference and national standards.

Review all deaths > 28 weeks to consider:

- **Was the appropriate antenatal care pathway followed in line with national guidance?**

- In 16 out of 31 cases midwifery appointments followed the NICE antenatal schedule of visits up until the point of birth. In 6 cases it was not possible to tell, usually due to a lack of antenatal handheld notes.
- 28 women had appropriate obstetric appointments (or did not require them. For 2 women if was not possible to determine whether obstetric care was appropriate.
- 23 of 31 women booked as per national recommendations at <12 weeks' gestation. For the remaining 6 women - 5 were booked late due to maternal delay in notifying the Trust of pregnancy and one was unclear. 2 women were known to the Early Pregnancy Unit, but care details were not passed on directly to maternity services.
- Midwife-led or obstetric-led care was recommended appropriately for all women.
- Risk assessment at booking
  - In 2 cases substance misuse and safeguarding concerns were noted at booking. Neither woman had correct screening or referrals carried out as planned. One was only assessed and found to have a history of domestic abuse postnatally.
  - 9 women had safeguarding concerns – in 3 cases IARF was not completed antenatally.
  - 15 women reported current or previous mental health concerns – referral and management were felt to be appropriate for these women.
  - 15 women were current or ex-smokers – CO monitoring was carried out at booking and 36 weeks for 9 of these women, one declined. Only one woman had CO monitoring at all appointments. It was unclear whether opt-out referral to Smoking cessation services or NRT was made for the 8 women still smoking at the time of booking.
  - 28 women had appropriate aspirin risk assessment, 2 were unknown and one was not performed as the mother did not present for antenatal care.





- Of the 30 women who booked their pregnancy, the Pre-term birth risk assessment was correct in 28 women and not documented for 1 other woman. • Fetal growth was monitored appropriately by SFH or scans for 28 women. In 2 cases growth was not plotted correctly on growth charts and scans were not performed for reduced SFH. • Diabetes screening was performed and followed up appropriately in all except one woman.	
• Women under obstetric led care should continue to receive routine midwife appointments as per the NICE schedule of care in addition to any obstetric and day assessment appointments they have. • There were some excellent examples of antenatal continuity of care and attempts at engagement for women with multiple vulnerabilities.	

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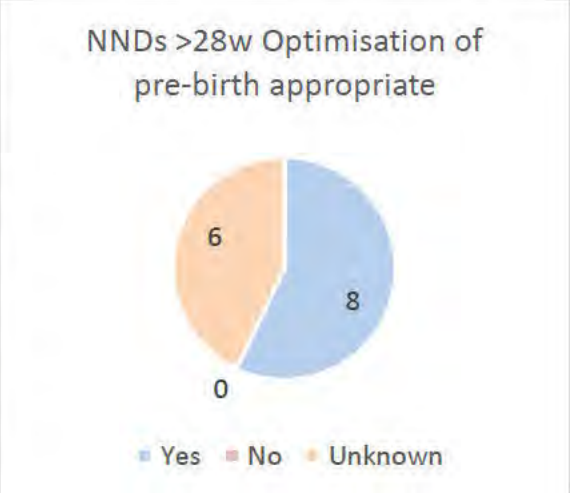
- **Was appropriate guidance followed during admissions to the obstetric unit, birth unit or other setting during the antenatal and intrapartum period.**

- **Was the Midwifery and / Obstetric Management plan in line with national standards.**

• The review team could not find evidence of information about reduced fetal movements in any of the sets of notes. All women with RFM were managed appropriately. • BSOTs assessment was performed for women attending the Day Assessment Unit for unscheduled care. In many cases the RAG rated assessment was not completed and entries did not have dates/times and so it was difficult to assess the urgency with which women were seen. • 9 women were assessed with evidence of threatened pre-term labour (TPTL). - One woman with additional complexity was offered transfer to a tertiary unit but declined, all 8 others were appropriate to birth in Gloucester. • 14 women gave birth between 28-35+6 weeks	

- Steroids were given where time before birth allowed to all women, except one case where administration couldn't be confirmed.
- 4 of the 5 women who birthed <30w had Magnesium sulphate, in one further case there was no time to give.
- Evidence of appropriate neonatal counselling about preterm birth could not be found in 6 reviews where there was time for it to occur.

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- 13 women received labour care with enough time to perform risk assessment and complete a partogram. Of these
  - 5 did not have any intrapartum risk assessment documented at the onset of labour.
  - 2 women did not have a partogram completed in active labour
- Fetal monitoring
  - 11 (of the 13 women) received appropriate fetal monitoring –

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  - 5 women did not have hourly fresh eyes review of their CTG
  - 1 woman was inappropriately treated with IV fluids to correct an abnormal CTG in the absence of hypotension

- Resuscitation notes were often lacking in the documentation, and neonatal notes were not provided (though discharge summaries were sometimes included). It is not possible to provide detailed assessment of the quality of immediate resuscitation, but where documentation was provided, it does appear to be performed in line with national algorithms and for neonatal/paediatric medical team to be present in a timely way.
- Debriefing was regularly seen to be performed postnatally appropriately with excellent detail in the documentation and compassionate and proactive care.
- The review group considered that there were indications that national standards were not followed for 10/31 cases reviewed.

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- **Were there any missed opportunities to escalate associated with any aspect of fetal wellbeing in the antenatal or intrapartum period?**

9 of the 31 cases were considered to have missed opportunities/care issues were identified that likely could have changed the outcome in line with PMRT care grade C.	**Issues**
This section has been removed to protect the anonymity of individuals involved	• CTG interpretation • Caesarean birth timing
	• CTG interpretation and management
	• Delay in escalation • CTG monitoring • Lack of recognition of obstructed labour • Poor management of impacted fetal head – anticipation and communication.
	• No obstetric review for blood-stained liquor in the presence of an abnormal fetal monitoring. • Delay in escalation. • Delay in delivery
	• Ambulance transfer • Doctor seniority inappropriate for initial review • Delay in senior review • Paediatric team delay

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	• Unable to obtain urgent GP / neonatal review – delayed diagnosis. • Feeding and wellbeing checks not complete
	• Poor risk assessment for sepsis. • Missed opportunities for preterm birth optimisation.
	• CTG interpretation and management • Delay in escalation • Delay in assisted vaginal birth

- **Has an internal review taken place (if not done by MSNI) and was the quality of the review and recommendations appropriate?**
- **Were the reviews appropriate to the circumstances?**

- PMRT reports and grading were not always felt to be representative of the quality of the care against national guidelines. There were many examples where missed elements of potentially relevant antenatal care were evident, and care was graded as 'A' or "no issues with care", when 'B' or "issues which made no difference to the outcome for the baby" or 'C' "issues which may have made a difference to the outcome for the baby" were more appropriate.
- Actions plans were felt to be inadequate – actions were often weak and non-specific, relating to having discussions with staff only. No time frames, follow up, or audit of effectiveness were included to provide assurance of learning and prevent recurrence.
- No external reviewers were present for any of the PMRTs included in the notes, which has been increasingly an expectation over the period being reviewed. Staff members involved in the incidents did appear to be present and involved against normal protocol.

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the anonymity of individuals involved

- **Has the Trust has implemented the recommendations that came from the reviews?**

No specific action plans, no HSIB reports and no benchmarking for PMRT / Saving Babies Lives or Preterm birth toolkits was provided by the Trust. PMRT reports that were supplied were reviewed as above but no completed action plans were included. It has not been possible for the review group to comment on the on whether actions from internal or external reviews have been implemented.

- **Consider whether there are themes that emerge when reviewing the cases as a group rather than individually.**

Overall themes

1. Many of the reviewed notes were incomplete, and, in three cases, notes were not provided. All these cases should have had a PMRT review, and it is of some concern, and surprise given the recent increase in external scrutiny, that full sets of notes, including those from all involved trusts, were not gained for those reviews, and could not be provided to this review group. This calls into question the completeness and quality of local PMRT reports from that time. The move from paper-based systems to electronic patient records (BadgerNet) appears to improve the completeness of notes.

2. Care for women whose babies died at <28 weeks was generally effective, with 9 out of 10 deaths unavoidable, and one further probably unavoidable.
   - Documentation was not always clear regarding what discussions had occurred about recommended place of birth and why women presented for care in preterm labour in Gloucester.
   - There was also a lack of information in notes about considering intra-uterine transfers and why this was not done. This would not have affected the outcomes for the babies in this group.

3. Care for women in the >28 weeks was more mixed with 9 reviewed cases which the care provided were most likely to be in line with PMRT care grade C .

Antenatal care

4. There was poor evidence in the notes that appropriate discussion and risk assessment had occurred around: -
   - Reduced fetal movements –
   - Place of birth, including transfer from freestanding midwifery unit (times / reasons)
   - Domestic abuse / safeguarding

5. Actions for women who smoke in pregnancy were incomplete. CO monitoring was regularly not performed according to guidance and there was poor evidence that referral occurred to smoking cessation services or that nicotine replacement was offered.

6. Women receiving obstetric led care did not always receive the correct midwifery schedule of appointments.

7. BSOTs triage documentation was often incomplete in notes, and it was not possible to determine appropriateness of timing for reviews.

8. For some women with multiple and complex vulnerabilities there was a lack of holistic midwifery care, particularly when pregnancy was complicated by need for frequent fetal medicine / obstetric appointments. A lack of continuity was noted and lack of planning for women without their own transport and with language concerns.

Intrapartum care

9. Inadequate CTG monitoring, inaccurate CTG interpretation (including use of Dawes-Redman criteria in early labour), lack of systematic reporting of findings and inappropriate response to abnormal CTG was a feature in several of the neonatal deaths >28 weeks as described above. This was combined with delay in escalation and decision making over timing of birth.

10. Management of blood-stained liquor did not trigger holistic assessment and referral if necessary.

11. Neonatal resuscitation notes were often missing from the documentation provided. Where it was recorded it was performed well and in line with NLS algorithms. Transfer to the NNU was timely.

Postnatal care

12. Referral systems for babies under midwifery care who are found to be unwell in community were unclear and there were delayed reviews and treatment.

7. Findings and Strategic Recommendations

7.1 Summary of General Findings

Equity and Health Inequalities

- National MBRRACE data highlights persistent health disparities in perinatal outcomes, with higher stillbirth and neonatal mortality rates among women from deprived backgrounds and Black and Asian ethnicities.
- Most reviewed cases (88%) indicated that women were of White ethnicity, aligning with the local demographic profile, but the review was limited to available maternity records, preventing accurate analysis of ethnic disparities in neonatal mortality and morbidity.
- Social vulnerability was evident in 5 of 41 cases, associated with housing, financial, and social instability, yet continuity of midwifery care was lacking, particularly for women under obstetric-led care. One mother did not book for maternity care and therefore, it was not possible to assess her social vulnerability from the notes provided.
- A holistic, flexible approach to antenatal care, as recommended by NICE (2010), was implemented consistently and there was a failing to account for complex social determinants of health.

Smoking and Compliance with National Standards

- Smoking remains a significant risk factor for adverse pregnancy outcomes, with the Saving Babies Lives (SBL) Care Bundle mandating universal CO monitoring and smoking cessation referrals.
- COVID-19-related restrictions affected CO monitoring for 7 cases, but inconsistent screening and documentation persisted beyond this period, indicating system-wide non-compliance with SBL guidelines.
- Poor documentation of CO monitoring decisions, with no recorded justification for missed screenings or clear evidence of patient education regarding the risks of smoking in pregnancy.
- Failure to systematically refer smokers to cessation services, with only 4 of 10 identified smokers receiving appropriate intervention.

7.2 Strategic Recommendations

Addressing Health Inequalities and Strengthening Holistic Care

- Implement a targeted maternal health equity strategy, integrating social risk screening into routine antenatal care to identify and support women with housing, financial, and social vulnerabilities.
- Mandate continuity of midwifery care models for high-risk women, ensuring holistic assessment and culturally responsive care planning.

- Develop a multidisciplinary social care pathway, incorporating obstetric, midwifery, and safeguarding teams to proactively address complex social needs.

- Standardise ethnicity-based perinatal outcome audits, ensuring neonatal mortality data is disaggregated by ethnicity and deprivation index for targeted intervention planning.

Ensuring Compliance with Smoking Cessation Guidelines

- Embed universal CO monitoring in routine antenatal care, ensuring compliance with the SBL Care Bundle through automated prompts in electronic records (EPRs).

- Mandate automatic smoking cessation referrals for all pregnant smokers, recent ex-smokers, and those with elevated CO levels, ensuring all women receive evidence-based cessation support.

- Implement structured patient education on smoking risks, using standardised information materials, and counselling protocols to improve patient engagement.

- Conduct audit tracking of CO screening and smoking cessation referrals, with mandatory compliance reporting to governance teams.

8. Neonatal Deaths <28 Weeks: Key Findings and Strategic Recommendations

8.1 Antenatal Referral to Specialist Pathways

Key Findings:

- Appropriate referral: 8/10 women were correctly referred for consultant-led care at booking.
- Midwife-led care allocation: 2 women were allocated to midwife-led care, with unclear consideration for obstetric referral for underlying health concerns.
- Preterm birth risk assessment: 9/10 women were correctly assessed for preterm birth risk, though no documentation referenced a dedicated preterm birth clinic.
- Documentation gap: One woman with a prior IUD at 25 weeks had no recorded risk assessment for preterm birth.

To optimise maternal risk stratification and ensure timely interventions for pregnancies at risk of preterm birth, the following high-level recommendations are proposed:

1. Optimised Referral Framework for High-Risk Pregnancies

- Reinforce adherence to standardised consultant-led referral criteria at initial booking to ensure appropriate maternal risk stratification.
- Establish robust documentation protocols to enhance precision in risk assessment and referral decision-making, minimising inconsistencies.

2. Systematic Integration of Preterm Birth Clinics

- Standardise a dedicated preterm birth clinic referral process to ensure systematic monitoring and targeted interventions for at-risk pregnancies.
- Implement mandatory documentation of preterm birth risk assessments and clinic involvement to enhance care continuity and prevent oversight.

3. Standardisation of Risk Assessment Documentation

- Develop a comprehensive maternal risk assessment framework to ensure systematic identification and documentation of preterm birth risk factors, including prior intrauterine fetal demise (IUFD).
- If possible, implement a consultant-led secondary review mechanism for ambiguous or high-risk cases to enhance clinical decision-making accuracy.

In summary:

Establish a dedicated Preterm Birth Clinic, led by a preterm birth specialist midwife, with clear referral criteria aligned with NICE guidance on Preterm Labour and Birth (NG25).

- Embed preterm birth risk assessments into the electronic patient record badger notes system, ensuring documentation of all assessments, previous pregnancy outcomes, and risk-based referrals.
- Standardise multidisciplinary case reviews for women with previous second-trimester losses or preterm births, ensuring early targeted interventions.

8.2 Place of Birth, Escalation, and In-Utero Transfer (IUT) Considerations

Key Findings:

- No formal transfer guidelines or escalation policy were provided to the review team.
- Lack of IUT consideration: In 5 cases, IUT was not considered or not documented.
- Limited transfer attempts: Only one woman underwent IUT, while one case was deemed unsafe, and one was too imminent for transfer.
- Potential missed IUT opportunities: In at least two cases, the review team identified delayed transfer planning despite a 12–24-hour window of stability.
- Missed IUT opportunity in one case of extreme prematurity in a multiple pregnancy, where birth in a tertiary unit may have improved neonatal outcomes.
- Majority of deaths were deemed unavoidable (9/10 cases) due to extreme prematurity, infection, or congenital anomalies.

Deficiencies in in-utero transfer (IUT) documentation and decision-making were noted, with missed opportunities for transfer in some cases. The absence of clear transfer guidelines and an escalation policy poses a risk to optimal maternal and neonatal outcomes. While most neonatal deaths were deemed unavoidable, missed opportunities for in-utero transfer (IUT) highlight the need for structured decision-making frameworks. To ensure optimal neonatal outcomes, the following recommendations are proposed:

1. **Standardise IUT Decision-Making Protocols**

- Develop comprehensive, evidence-based transfer protocols, ensuring clear criteria for IUT consideration, particularly for extreme preterm and multiple births.
- Implement clear criteria and pathways for IUT consideration in all cases of threatened preterm labour (TPTL) or fetal compromise.
- Require senior obstetric review for all women admitted with preterm concerns, ensuring timely risk assessment and transfer planning.

2. Improve IUT Documentation and Clinical Oversight

- Introduce mandatory documentation fields in the Electronic Patient Record system to record IUT assessment, including whether it was considered, contraindicated, or not feasible.
- Require proactive risk stratification at admission, ensuring early consideration of transfer where stability allows.

3. Optimise Transfer Timing in Stable Cases

- Reinforce clinical guidelines for antenatal transfer when >12–24 hours of stability is observed, ensuring that transfer feasibility is revisited proactively.
- Enhance communication protocols with tertiary centres to facilitate earlier planning for potential IUT.

4. Strengthen Staff Training and Decision-Making Support

- Implement regular training sessions on preterm labour management, with a focus on early identification of IUT-eligible cases.
- Develop decision-support tools for obstetric teams to streamline IUT consideration and ensure timely intervention.

5. Enhance Review and Learning from Transfer-Related Outcomes

- Conduct structured case reviews for all births <28 weeks, assessing whether transfer was considered, feasible, and appropriately actioned.
- Implement structured morbidity and mortality reviews, ensuring system-wide learning from missed transfer opportunities.

In summary:

- Implement a formalised IUT decision-making protocol, requiring mandatory senior obstetric review for all preterm admissions, ensuring timely transfer assessment and documentation.
- Develop a structured IUT escalation policy, integrating real-time decision-support tools within EPR to flag eligible cases.
- Enhance communication with tertiary units, ensuring proactive liaison for high-risk women and avoiding delays in securing neonatal intensive care unit (NICU) capacity.
- Conduct systematic audits of IUT decision-making, identifying trends in missed transfer opportunities and refining escalation pathways accordingly.

8.3 Adherence to National Guidance During Antenatal and Intrapartum Admission

Key Findings:

- Missed neonatal counselling: In 3 of 7 eligible cases, there was no documented evidence of preterm birth counselling regarding neonatal care and prognosis.
- Steroid administration: All eligible women received at least one dose, except one case where administration could not be confirmed.
- Magnesium Sulphate compliance: Given to 6 of 7 eligible women, with one omission due to birth occurring too soon.
- Neonatal resuscitation documentation gaps: Missing in most cases, preventing assessment of immediate neonatal care, thermoregulation, and optimal cord clamping.

Gaps in neonatal counselling, neuroprotective interventions, and resuscitation documentation were identified. The following recommendations will enhance compliance with national guidelines:

1. Standardise Preterm Birth Counselling and Documentation

- Implement a mandatory neonatal counselling pathway for all women admitted with TPTL with structured EPR templates for documentation.
- Conduct regular audits to ensure counselling is consistently provided and recorded.

2. Optimise Preterm Birth Interventions

- Ensure timely completion of antenatal corticosteroid courses and full adherence to Magnesium Sulphate protocols using Electronic Patient Record forms.
- Establish a compliance monitoring system to track administration and identify gaps.

3. Improve Neonatal Resuscitation and Immediate Postnatal Care Documentation

- Standardise resuscitation and postnatal care documentation, ensuring recording of cord management, normothermia, and early feeding practices.
- Implement routine neonatal case reviews and structured multidisciplinary handovers to improve care transitions.

4 Enhance Clinical Oversight and Training

- Introduce targeted training and real-time checklists for obstetric and neonatal teams to ensure compliance with preterm birth pathways.

- Strengthen quality assurance measures, including periodic audits and structured feedback loops.

In summary:

- Standardise antenatal counselling for preterm birth, requiring documented evidence of discussions on survival rates, resuscitation, and palliative care options.
- Enhance steroid and magnesium sulphate administration tracking, embedding automated reminders in the EPR system to prompt timely administration.
- Implement a structured neonatal resuscitation documentation protocol, ensuring complete recording of resuscitation efforts, thermoregulation, cord management, and maternal breast milk initiation.

8.4 Midwifery, Obstetric, and Neonatal Management Compliance with National Standards

Key Findings:

- Timely booking compliance: 100% of women booked before 12 weeks.
- Midwifery continuity gaps: 8 of 10 women received full midwifery appointments, but one had incomplete records, and one lacked community antenatal notes.
- Comprehensive risk assessment compliance:
  - Aspirin risk assessment: 90% compliance (1 case missed, 2 unknown).
  - Domestic violence screening: 90% completion.
  - Fetal growth monitoring: Appropriate in 29 cases, but 2 had incorrect SFH plotting and missed growth scans.
  - Diabetes screening: Appropriate in all but one case.
- Smoking cessation support gaps:
  - 5 women were smokers or recent ex-smokers, but only one had CO monitoring at the recommended frequency.
  - No clear evidence of opt-out referrals to smoking cessation services for 8 active smokers.
- Multidisciplinary team (MDT) care planning: Excellent MDT collaboration was seen in cases of PPROM and congenital abnormalities.

In summary:

- Ensure continuity of midwifery care for obstetric-led women, with scheduled midwifery reviews incorporated into high-risk pregnancy care pathways.
- Strengthen compliance with fetal growth monitoring protocols, embedding automated EPR alerts for plotting errors or missed growth scans.
- Mandate smoking cessation referrals for all pregnant smokers, with real-time tracking of CO monitoring compliance and automated prompts for re-screening at 16, 25, and 36 weeks.
- Expand MDT case planning for high-risk pregnancies, ensuring a structured care plan involving fetal medicine, neonatology, and maternal medicine specialists.

9. Neonatal Deaths >28 Weeks: Key Findings and Strategic Recommendations

9.1 Adherence to Antenatal Care Pathways

Findings:

- Compliance with the NICE antenatal schedule was inconsistent, with 16/31 women receiving appropriate midwifery care, while 6 cases had insufficient documentation.
- Obstetric appointments were appropriately provided to 28/31 women, but completeness of care was unclear in two cases.
- Risk assessments at booking were broadly appropriate, but gaps existed in safeguarding, mental health, and smoking cessation pathways.
- Fetal growth monitoring was suboptimal in two cases, with incorrect plotting of SFH and missed scans.
- Diabetes screening was well adhered to, with one exception.

Recommendations:

- Enhance digital integration of antenatal records to prevent missing documentation and facilitate continuity of care.
- Standardise risk assessment protocols, ensuring all safeguarding concerns, mental health needs, and smoking cessation referrals are actioned and documented.
- Introduce routine audit cycles to track adherence to fetal growth surveillance protocols and identify gaps in SFH plotting or scan scheduling.
- Ensure that women under obstetric-led care receive scheduled midwifery appointments, reinforcing continuity of care.

9.2 Compliance with Antenatal and Intrapartum Guidelines

Findings:

- Lack of documentation regarding RFM education, though management of RFM was appropriate.
- Inconsistent RAG-rated assessments in the Day Assessment Unit, making it difficult to assess urgency of reviews.
- Appropriate use of corticosteroids and Magnesium Sulphate, except for one unconfirmed case.

- Gaps in preterm birth counselling, despite available time for discussion in six cases.
- Deficiencies in intrapartum risk assessment and partogram documentation, affecting five and two women, respectively.
- Suboptimal fetal monitoring, including inappropriate use of IA and Dawes-Redman CTG analysis in labour.
- Missing neonatal resuscitation notes, limiting assessment of immediate newborn care.

Recommendations:

- Mandate RFM counselling documentation in antenatal records and audit compliance.
- Strengthen triage assessment protocols, ensuring RAG-rated assessments are consistently completed and timestamped.
- Standardise preterm birth counselling for all women at risk, embedding clear documentation in patient records.
- Reinforce intrapartum risk assessment training to ensure partogram completion and timely escalation of concerns.
- Enhance fetal monitoring education, particularly in recognising and escalating abnormal CTGs.
- Implement a standardised neonatal resuscitation documentation template, ensuring comprehensive recording of postnatal interventions.

9.3 Escalation and Missed Opportunities in Fetal Wellbeing

Findings:

- 9/31 deaths were considered potentially could have been avoidable in line with PMRT care grade C , with missed opportunities in CTG interpretation, caesarean timing, and escalation of intrapartum concerns. These cases require to have further assessment by the governance team to make sure holistic care analysis of the mother and baby is in place.
- Delays in obstetric review and decision-to-birth timing contributed to poor outcomes in 12 cases (relating to babies born >28 weeks gestation).
- Inappropriate interventions (e.g., IV fluids for abnormal CTGs) delayed necessary obstetric management.
- Failure to recognise obstructed labour, leading to delays in intervention and complications such as impacted fetal head (IFH).
- Neonatal risk assessment and postnatal safety netting failures, including inadequate meconium-stained liquor monitoring, and feeding assessments.

Recommendations:

- Ensure CTG training is in line for all professional groups with national core competency framework (NHS England, 2023). Strengthen and multidisciplinary reviews, ensuring clear escalation pathways and appropriate interpretation of fetal distress.
- Implement real-time decision-support tools for categorising and escalating obstetric emergencies, reducing delays in caesarean birth.
- Reinforce labour risk assessment protocols, ensuring holistic evaluation of fetal wellbeing and maternal risk factors.
- Standardise neonatal risk assessment tools for postnatal feeding and weight monitoring, preventing delayed diagnoses of neonatal complications.

9.4 Compliance with National Standards in Midwifery and Obstetric Care

Findings:

- High-quality debriefing practices were documented, demonstrating compassionate postnatal care and appropriate documentation.

Recommendations:

- Continue standardised postnatal debriefing pathways and incorporate structured reflective practice into clinical governance meetings.
- Expand debriefing audits to ensure consistency in support offered to bereaved families.

9.5 Quality and Integrity of Internal Reviews

Findings:

- Incomplete PMRT reports were noted, with some cases still listed as "in progress" despite being 2-5 years old.
- Significant documentation gaps in antenatal and neonatal care records, raising concerns about the thoroughness of internal reviews.
- Quality of care grading inconsistencies, with some cases assigned an "A" rating despite evident missed opportunities.
- Weak action plans, often lacking specific interventions, timeframes, or mechanisms for audit and follow-up.
- No external reviewers were involved in PMRTs, against best practice expectations.

- Consultant decision-making accountability concerns, with unexplained overturning of critical care decisions without documentation or review.

Recommendations:

- Ensure timely completion of PMRT reviews, with clear timelines for case closure and accountability for delays.
- Mandate full documentation of all elements of antenatal and neonatal care, preventing critical omissions in internal reviews.
- Enhance case grading accuracy, ensuring care ratings reflect objective assessments of missed opportunities.
- Strengthen action plans, incorporating measurable interventions, defined timelines, and mandatory follow-up audits.
- Require external review participation in all PMRT cases, with appropriate external specialities for cases involving complex decision-making or avoidable outcomes.
- Implement mandatory consultant documentation protocols, ensuring all decision reversals are justified and recorded.
- Establish a robust governance framework to track and ensure implementation of all internal and external recommendations.
- Mandate regular benchmarking against national safety initiatives, ensuring compliance with best practice guidelines.
- Introduce formal reporting mechanisms to monitor progress on action plans, with clear accountability and oversight structures.

10. High-Level Quality Report: Themes and Strategic Recommendations

10.1 Summary of Key Themes

Documentation and Record-Keeping

- Deficiencies in documentation across multiple cases, including missing or incomplete records, particularly in the antenatal and early neonatal resuscitation phases.
- Failure to provide full sets of notes.
- PMRT Reviews raises concerns about the rigor and completeness of local reviews.
- Transition to electronic patient records (Badgernet) appears to be improving completeness but has not yet fully mitigated documentation gaps.

Antenatal Care

- Suboptimal risk assessment and documentation in key areas, including reduced fetal movements, domestic abuse screening, and fetal medicine pathways for high-risk pregnancies.
- Inadequate referral and intervention for maternal smoking, with non-compliance in CO monitoring, smoking cessation referrals, and nicotine replacement therapy (NRT) offers.
- Gaps in holistic midwifery care for women with complex vulnerabilities, particularly in cases where multiple obstetric and fetal medicine appointments led to fragmented care.
- Failure to ensure appropriate midwifery continuity for women receiving obstetric-led care, affecting care planning and risk stratification.
- Incomplete documentation of triage assessments (BSOTs), making it difficult to determine the urgency and appropriateness of reviews.

Intrapartum Care and Clinical Decision-Making

- Deficiencies in CTG monitoring, inaccurate interpretation, and delays in escalation contributed to avoidable neonatal deaths in some cases >28 weeks.
- Inappropriate use of Dawes-Redman CTG analysis in early labour, leading to misinterpretation of fetal wellbeing and missed opportunities for early intervention.
- Delays in escalation and suboptimal decision-making regarding timing of birth, impacting some neonatal outcomes.
- Management of blood-stained liquor was inconsistent, with missed opportunities for further investigation and escalation.

- Neonatal resuscitation documentation was often missing, making it difficult to fully assess the quality of immediate newborn care, though when recorded, resuscitation appeared in line with Newborn Life Support (NLS) guidelines.

Postnatal and Community-Based Neonatal Care

- Referral pathways for unwell neonates in the community were unclear, leading to delays in assessment and treatment for at-risk babies.

10.2 Strategic Recommendations

Strengthening Clinical Governance and Documentation

- Mandate full integration of EPR across all care settings, ensuring comprehensive, accessible, and standardised documentation.
- Implement a zero-tolerance policy for missing documentation in mortality reviews, with a mandatory cross-check process before PMRT submission.
- Standardise neonatal resuscitation documentation, ensuring consistent, structured recording of all immediate postnatal interventions.
- Introduce real-time audit dashboards for fetal monitoring, triage assessments, and antenatal appointments to flag incomplete records and drive compliance.

Optimising Antenatal Risk Management and Continuity of Care

- Reinforce structured risk assessment protocols for fetal movements, domestic abuse, and safeguarding, ensuring full compliance with national guidance.
- Implement an automated alert system in EPR to prompt clinicians when CO monitoring, smoking cessation referrals, or NRT offers are overdue or missing.
- Strengthen midwifery continuity models for women under obstetric-led care, ensuring holistic care planning and proactive engagement for women with complex social and medical needs.
- Standardise BSOTs triage documentation, incorporating mandatory time-stamped risk stratification to enhance clinical oversight and escalation.

Enhancing Intrapartum Safety and Decision-Making

- Introduce a multidisciplinary CTG interpretation training program, including case-based reviews and mandatory competency assessments for all obstetric and midwifery staff.
- This includes training to prevent inappropriate use of Dawes-Redman CTG analysis in labour.
- Develop an escalation protocol with defined triggers for senior obstetric review and decision-to-birth timing to reduce delays in intervention.
- Establish a formal process for reviewing all cases of blood-stained liquor, ensuring consistent assessment and escalation criteria are followed.

Strengthening Postnatal and Neonatal Safety Netting

- Develop a structured escalation and referral pathway for neonates in the community, ensuring timely access to hospital-based assessment and intervention.

Improving Oversight of Mortality Reviews and Learning from Adverse Outcomes

- Implement external oversight for PMRT reviews for all cases, with appropriate external specialities for cases involving complex decision-making or potentially avoidable outcomes.
- Strengthen grading accuracy in PMRTs, ensuring missed care elements are appropriately categorised and reflected in action plans.
- Mandate time-bound, outcome-focused action plans for all mortality reviews, with clear follow-up audits to assess impact and learning.

11. References

Care Quality Commission, 2024. *National review of maternity services in England 2022 to 2024*. Available from https://www.cqc.org.uk/publications/maternity-services-2022-2024 accessed on 12 February 2025.

Care Quality Commission, 2025. *CQC takes action to drive improvements in the quality and safety of maternity services at Gloucestershire Hospitals NHS Foundation Trust.* Available from https://www.cqc.org.uk/press-release/cqc-takes-action-drive-improvements-quality-and-safety-maternity-services-0 accessed on 10 March 2025.

Department of Health, 2016. *Safer Maternity Care. Next steps towards the national maternity ambition.* Available from https://assets.publishing.service.gov.uk/media/5a80efa3ed915d74e33fd3d7/Safer_Maternity_Care_action_plan.pdf accessed on 01 September 2024.

Health Innovation West of England, 2020. *PERIPrem.* Available from https://www.healthinnowest.net/our-work/transforming-services-and-systems/periprem/ accessed on 01/09/2024.

National Institute of Clinical Excellence, 2010. *Pregnancy and complex social factors: a model for service provision for pregnant women with complex social factors.* Available from https://www.nice.org.uk/guidance/cg110/chapter/Recommendations#general-recommendations-2 accessed on 01 September 2024.

National Institute for Clinical Excellence, 2021. *NICE Guideline, 2021 – Antenatal care.* Available from https://www.nice.org.uk/guidance/ng201/resources/antenatal-care-pdf-66143709695941 accessed on 01 September 2024.

National Perinatal Epidemiology Unit,2024. *Perinatal Mortality Review Tool.* Available from https://www.npeu.ox.ac.uk/pmrt#:~:text=The%20PMRT%20is%20designed%20to%20support%20the%20review,of%20their%20baby%27s%20death%20that%20will%20take%20place. Accessed on 10 March 2025.

NHS England, 2016. *Saving Babies' Lives. A care bundle for reducing stillbirth.* Available from https://www.england.nhs.uk/wp-content/uploads/2016/03/saving-babies-lives-car-bundl.pdf accessed on 01/09/2024.

NHS England, 2019. Saving Babies' Lives Version Two. A care bundle for reducing perinatal mortality. Available from https://www.england.nhs.uk/wp-content/uploads/2019/03/Saving-Babies-Lives-Care-Bundle-Version-Two-Updated-Final-Version.pdf accessed on 01/09/2024.

NHS England, 2023. Saving babies' lives: version 3. A care bundle for reducing perinatal mortality. Available from https://www.england.nhs.uk/long-read/saving-babies-lives-version-3/ accessed on 01/09/2024.

NHS England, 2023. Core competency framework v2: Minimum standards and stretch targets. Available from: NHS England » Core competency framework v2: Minimum standards and stretch targets. Accessed on 20/03/25.

Nuffield Trust, 2024. *Stillbirths and neonatal and infant mortality*. Available from https://www.nuffieldtrust.org.uk/resource/infant-and-neonatal-mortality accessed on 12 February 2025.

Ockenden, D., 2022. *Ockenden Report Final – FINDINGS, CONCLUSION AND ESSENTIAL ACTIONS FROM THE INDEPENDENT REVIEW OF MATERNITY SERVICES at the Shrewsbury and Telford NHS Foundation Trust*. Available from https://assets.publishing.service.gov.uk/media/624332fe8fa8f527744f0615/Final-Ockenden-Report-web-accessible.pdf accessed on 12 February 2025.

The MBRRACE-UK Collaboration, 2024. Persistent inequalities remain in rate of stillbirth and neonatal deaths in the UK. Available from https://www.npeu.ox.ac.uk/news/2570-persistent-inequalities-remain-in-rates-of-stillbirth-and-neonatal-deaths-in-the-uk?highlight=WyJtYXRlcm5hbCIsImRlYXRoIiwicmF0ZSIsImJsYWNrIiwid29tZW4iXQ==#:~:text=The%20MBRRACE%2DUK,all%20neonatal%20deaths accessed on 12 February 2025.

12. GLOSSARY

APH	Antepartum haemorrhage – vaginal bleeding from or into the genital tract occurring from 24 weeks of pregnancy and prior to the birth of the baby.
BSOTS	Birmingham symptom specific obstetric triage system, provides a standardises system for assessing and prioritising women presenting with pregnancy related problems to concerns in maternity triage.
Cervical Cerclage	A procedure whereby stitches are placed around the cervix to keep it closed during pregnancy, usually when there is a risk of premature birth.
CO	Carbon monoxide screening, to monitor the level of carbon monoxide in the mother's breath.
CQC	Care Quality Commission – the independent regulator for health and social care in England.
CTG	Continuous cardiotocograph – a machine that continuously monitors the baby's heart rate and uterine activity to assess the wellbeing of the baby.
Dawes-Redman	A computerised system to assess CTG during the antenatal period and prior to the presence of uterine contractions and induction of labour.
EPR	Electronic patient record. Badgernet is the system commonly used by trusts for the management of maternity and neonatal records.
IMD	Index of multiple deprivation – this indicates the level of deprivation by postcode.
IUFD	Intra-uterine fetal demise or stillbirth, where the baby dies before they are born.
IUT	In-utero or intrauterine transfer. The transfer of the mother and her baby to another hospital, prior to the baby's birth.
MBRRACE	Mothers and Babies reducing risks through audits and confidential enquiries across the UK. This is a national programme that conducts surveillance and investigates causes of maternal, stillbirth, neonatal and infant deaths in the UK.
MDAU	Maternity Day Assessment Unit – for monitoring the wellbeing of mother and baby for any pregnancy related concerns during the antenatal period.
MDT	Multidisciplinary team – a team of health professionals from various specialities who work together to improve the outcome for the mother and baby.
MNSI	Maternity and Neonatal Safety Investigations – an independent body hosted by CQC to undertake a review of care following a pre-determined patient safety incident, including neonatal death or brain injury following the onset of labour for babies born at 37 weeks of pregnancy.
NICE	National Institute for Clinical Excellence – provides evidence-based policies and guidelines for healthcare professionals.
NLS	Neonatal life support
NNU	Neonatal Unit – a specialist unit that provides care for premature, small and sick babies.
PERI Prem	A series of recommendations to optimise the wellbeing of a baby when premature birth is anticipated.
PMRT	Perinatal Mortality Review Tool – a structured system for undertaking reviews of care following the death of a baby.
PTB	Preterm birth
PROM	Prolonged rupture of membranes
PPROM	Premature prolonged rupture of membranes
RAG	Red, Amber, Green – a rating system used within the BSOTS triage system to

	determine the urgency of assessment for women presenting in MDAU.
RCOG	Royal College of Obstetricians and Gynaecologists. The professional body that sets standards, provides education and guidelines for obstetric and gynaecological care.
RFM	Reduced fetal movements – a reduction in the number of baby movements felt by the mother during pregnancy. Reduced movements are an indicator for an inpatient assessment in MDAU to assess the wellbeing of the baby.
SBL	Saving Babies Lives – a series of evidence-based recommendations, which aims to reduce the rate of stillbirths and neonatal deaths.
Sepsis	A potentially life-threatening condition caused by the body's extreme response to infection and requires prompt assessment and management.
SROM	Spontaneous rupture of membranes either before or during labour.
TPTL	Threatened pre-term labour. The onset of regular uterine contractions and cervical changes before 37 weeks of pregnancy, potentially leading to pre-term birth.
UKOSS	UK Obstetric Surveillance System – a UK wide system to study uncommon disorders in pregnancy

Appendix 1

TERMS OF REFERENCE

Assurance review – Neonatal Death Review 2020-2023

Women and Children's division
Gloucester Hospitals NHS Foundation Trust
July 2024 (Updated 05 September 2024)

1. Background

Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT) Maternity services provide s approximately 5500 - 6000 births in Gloucestershire each year. The maternity service in Gloucestershire offers women/birthing people all four options for birth: an Obstetric Led Delivery Suite and Alongside Midwifery-led Unit (AMU) based in the Women's Centre in Gloucester Royal Hospital, 2 Freestanding Midwifery Led Units (FMU) within Cheltenham General Hospital and Stroud Maternity Hospital and the option of a homebirth. Most midwives work in either community or hospital-based roles however there are a small number of midwives who work within two continuity of carer teams (one in Gloucester and one in Cheltenham) and in hybrid roles where midwives work both within the community and the hospital. Obstetric care is carried out at Gloucester Royal Hospital in the Women's Centre and Stroud and Cheltenham antenatal clinic. There are 13 Consultant obstetricians with specialisms in fetal medicine, obstetric medicine, preterm birth prevention, perinatal mental health and substance abuse.

The Neonatal Unit is a busy Level 2 unit with a cot capacity of 28. Babies are looked after from 27 completed weeks or 28 weeks for twins. Neonates less than 28 weeks and requiring intubation can be managed by the Unit for 48 hours. For Neonates less than 28 weeks gestation requiring ongoing clinical care and transfer decisions are made in conjunction with either the SONAR team or tertiary units within the Regional Network.

There are 7 Neonatal Consultants, all of whom are full time on the Neonatal Rota. There is 24-hour cover, 7 days per week across all 3 tiers of the rota. There is a separate Paediatric and Neonatal Rota.

The Neonatal Unit is also staffed by Neonatal Nurses, a proportion of whom have Qualification in Speciality.

The Gloucestershire LMNS has a single site provider within its geographical boundary and therefore has a formal buddy arrangement with Bath, Swindon & Wiltshire LMNS. The Gloucestershire LMNS supports a process to obtain external expert clinical opinion for all 4 Trusts within the 2 LMNS's for PMRT meetings and Patient Safety Incident review.

National reports (East Kent, Telford and Shrewsbury and the forthcoming Nottingham report) have rightly led to intense national scrutiny for maternity services.

The GHNHSFT Maternity service has been subject to a Care Quality Commission (CQC) inspection receiving an **Inadequate** rating following an inspection in April 2022. The Trust received a recent Section 29a Notice from the CQC which related to clinical incidence closure and L3 Safeguarding

Training
In response to the Inadequate rating the trust was entered into the NHSE Maternity Safety Support Programme (MSSP) programme with exit criteria agreed.

Following this CQC rating the service has been subject to national media interest. In January 2024 BBC Panorama aired an investigative programme into Gloucestershire Maternity Services. One of the focus points was on maternal death rates.

In May 2024 the Trust were issued with a Section 31 warning notice.

The MBBRACE data identified an increase rate of neonatal deaths in years 2020 – 21 and 2022 – 2023:

1. Neonatal mortality

Deaths of children aged under 28 days. Mortality rates are presented per 1,000 infant population.

Table 1. Number and rate of neonatal deaths, by year

ICB: NHS Gloucestershire Data source: NCMD, ONS Census (2021)

Comparison with England average ● Over 5% higher ● Within 5% ● 5 - 15% lower ● Over 15% lower

	Your ICB		England
	Neonatal deaths	Rate per 1,000 infants	Rate per 1,000 infants
2019-20	10	1.7 ●	2.5
2020-21	16	2.7 ●	2.4
2021-22	11	1.9 ●	2.5
2022-23	22	3.8 ●	2.7
Total	**59**	**2.5** ●	**2.5**

With such local and national scrutiny on mortality rates the recently appointed Chief Executive wishes to commission an external review of the data relating to neonatal death rates and the review processes relating to oversight of the neonatal deaths with the intention to demonstrate transparency and openness, confirm that the Trust statement on maternal mortality is in line with national reporting requirements such as MBBRACE and ensure that all possible leaning has taken place.

1. Scope and Output

The time period of this assurance review will a case review of all deaths as defined above that occurred between 2020-2023(calendar years).

The review will cover all of the maternity pathway, until the point of the baby's transfer to the Neonatal Unit where relevant.

The review will address the following:

1. Review the neonatal mortality data and consider whether the Trust is an outlier and reconcile with the opinion of MBBRACE and the Trust's response to Panorama

2. Review all deaths <28 weeks to consider:
    a. Was there appropriate antenatal referral to specialist obstetric pathways including preterm birth if indicated.
    b. Why the place of birth was Gloucestershire and factors that influenced this.
    c. Was appropriate guidance followed during admissions to the obstetric unit during the antenatal and intrapartum period?

d. Was the Midwifery / Obstetric and Neonatal Management plan in line with national standards?
e. Whether the systems and processes for transfer are clear and work well

3. Review all deaths > 28 weeks to consider:
    a. Was the appropriate antenatal care pathway followed in line with national guidance?
    b. Was appropriate guidance followed during admissions to the obstetric unit, birth unit or other setting during the antenatal and intrapartum period?
    c. Were there any missed opportunities to escalate associated with any aspect of fetal wellbeing in the antenatal or intrapartum period.
    d. Was the Midwifery and / Obstetric Management plan in line with national standards?
    e. Has an internal review taken place (if not done by MSNI) and was the quality of the review and recommendations appropriate?
    f. Were the reviews appropriate to the circumstances.
    g. Has the Trust has implemented the recommendations that came from the reviews.
    h. Consider whether there are themes that emerge when reviewing the cases as a group rather than individually.

Findings and any recommendations arising from the analysis should be presented as a report to the Chief Executive and be written in an accessible way for wider public scrutiny.

Appendix 2: PERIPrem Care Bundle

Perinatal Excellence in Reducing Injury in Premature birth:

a bundle of perinatal interventions that will contribute to a reduction in brain injury and neonatal mortality across the South West of England by optimising;

Supporting compliance with the complete bundle for all eligible mothers and their babies born at less than 34 weeks gestation to improve the optimisation and stabilisation of the very preterm infant

Place of Birth

Babies delivered at less than 27 weeks or with an expected birth weight of under 800 grams (less than 28 weeks for multiple births) should be born in a maternity service on the same site as a designated NICU.

[Ref: 1,2,3,4,]

Antenatal Steroids

Mothers who give birth at less than 34 weeks gestational age should receive the correctly timed, full course of antenatal steroids.

[Ref: 2,4,5,6]

Antenatal Magnesium Sulphate

Mothers who give birth at less than 30 weeks gestational age should receive antenatal Magnesium Sulphate.

[Ref: 2,4,5,6]

Intrapartum Antibiotic Prophylaxis

95% of women in established preterm labour (less than 34 weeks gestation) to receive intrapartum Antibiotic Prophylaxis at least 4 hours prior to birth.

[Ref: 12]

Optimal Cord Management

Babies born at less than 34 weeks gestational age should have their cord clamped at or after one minute.

[Ref: 2,4,7]

Normothermia

Babies born at less than 34 weeks gestational age should have a temperature on admission which is both between 36.5–37.5°C and measured within one hour of birth.

[Ref: 2,4]

Early Maternal Breast Milk (MBM)

Babies born at less than 34 weeks gestational age should receive MBM within 6 hours of birth.

Units should monitor (and aim to increase) rates of first MBM within 6 hours of birth for babies born at less than 34 weeks gestational age.

MBM feeding at 14 days - Units should monitor (and aim to increase) rates of babies born at less than 34 weeks gestational age receiving MBM at 14 days of age.

[Ref: 2,8]

Caffeine

Babies should be started on caffeine as soon as possible (aim within the first 6 hours... NICE says: "starting it as early as possible and ideally before 3 days of age") in all babies:

- Less than 30 weeks gestation (consider 32 - 34 weeks)
- Birth weight less than 1500g

[Ref 9,10]

Probiotics

Babies (less than 32 weeks, less than 1500g birth weight) should be commenced on a multi strain probiotic of choice on the first day of life.

[Ref 11]

Volume Guarantee (VG) or Volume Targeted Ventilation (VTV)

For babies who need invasive ventilation, use volume-targeted ventilation (VTV) in combination with synchronised ventilation as the primary mode of respiratory support.

[Ref 10]

Prophylactic Hydrocortisone

Babies born <28 weeks gestation should receive prophylactic hydrocortisone from day 0 of life.

[Ref 10]

Evaluating the impact

The Health Innovation South West was commissioned to evaluate the impact of PERIPrem with a quantitative evaluation, published in BMJ Open Quality, and an evaluation on the barriers and enablers to the implementation of PERIPrem published in Research Square. Explore the findings in a bite sized summary of the evaluation. [Ref 13-15]

The use of magnesium sulphate came from our earlier collaborative, PReCePT. The national rollout of this by the AHSN Network (now known as the Health Innovation Network) using a QI approach has been found effective according to an evaluation by the National Institute for Health and Care Research (NIHR). The findings, led by researchers at the University of Bristol, are published in the Archives of Disease in Childhood. [Ref 16-17]

1. NHS England: Neonatal Critical Care Transformation Review (2019) https://www.england.nhs.uk/publication/implementing-the-recommendations-of-the-neonatal-critical-care-transformation-review
2. NNAP (RCPCH) 2020 Audit standards, set by NNAP Project Board. https://www.rcpch.ac.uk/sites/default/files/2019-11/nnap_2020_audit_measures_guide_v1.0_191119_0.pdf
3. Helenius K, Longford N, Lehtonen L, Modi N, Gale C. Association of early postnatal transfer and birth outside a tertiary hospital with mortality and severe brain injury in extremely preterm infants: observational cohort study with propensity score matching. bmj. 2019 Oct 16;367:l5678.
4. BAPM: Perinatal Management of Extreme Preterm Birth Before 27 Weeks of Gestation (2019). Available at www.bapm.org
5. NICE Guidance for Preterm Birth (2019) https://www.nice.org.uk/guidance/ng25
6. Doyle LW, Crowther CA, Middleton P, et al. *Magnesium sulphate for women at risk of preterm birth for neuroprotection of the fetus. Cochrane Database Syst Rev 2009:CD004661*
7. Rabe H, Gyte GML, Díaz-Rossello JL, Duley L. Effect of timing of umbilical cord clamping and other strategies to influence placental transfusion at preterm birth on maternal and infant outcomes. Cochrane Database of Systematic Reviews 2019, Issue 9. Art. No.: CD003248. DOI: 10.1002/14651858.CD003248.pub4.
8. Parker MG, Melvin P, Graham DA et al. Timing of First Milk Expression to Maximize Breastfeeding Continuation Among Mothers of Very Low-Birth-Weight Infants. Obstet Gynecol. 2019;133(6):1208-1215
9. https://wwwneonatalnetwork.co.uk/media/10703/swnn-guideline-caffeine-use-in-preterm-infants-ni.pdf
10. Specialist neonatal respiratory care for babies born preterm, NICE guideline [NG124]Published date: April 2019 https://www.nice.org.uk/guidance/ng124/chapter/Recommendations
11. http://www.neonatalnetwork.co.uk/media/888/swnn-guideline-probiotics-in-preterm-babies-final-january-2016-version-02.pdf
12. https://www.bapm.org/resources/295-rp-publications-review-antenatal-optimisation-edition
13. https://healthinnovationsouthwest.com/news/new-evaluation-shows-quality-improvement-project-is-improving-care-for-premature-babies
14. https://www.researchsquare.com/article/rs-1550325/v1
15. https://swahsn.com/wp-content/uploads/2022/08/A4-PERIPrem-Bitesize-evaluation-V8.pdf
16. https://fn.bmj.com/content/early/2023/01/03/archdischild-2022-324579
17. https://www.healthinnovwest.net/our-work/case-study/precept-preventing-cerebral-palsy-in-preterm-babies

Appendix 3: PMRT recommended attendance