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Neonatal Mortality Review: Understanding factors which may have contributed to the national increase in neonatal mortality in Scotland during 2021/22

February 2024

NHS SCOTLAND

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The death of a baby is a devastating and traumatic experience for parents and families, no matter what the cause. Babies die every year in Scotland for a number of reasons, including prematurity and congenital conditions. Although increasingly small and sick babies now survive neonatal intensive care, there will be some babies for whom this is not the case. This does not necessarily reflect any shortcomings in maternity or neonatal care but may mean that the baby was simply born too early or too unwell to survive. However, it is important to acknowledge that some deaths may have been preventable had the management of the pregnancy, labour or the baby after birth been different. In considering neonatal deaths, it is important to acknowledge that maternity care is inextricably linked with neonatal care and that the health of the mother will impact upon the wellbeing of the baby. To inform practice and prevent as many baby deaths as possible, review of both maternity and neonatal care is an essential part of midwifery, obstetric and neonatal practice.

Commission

This review was commissioned after data published in the COVID-19 Wider Impacts Dashboard showed an increase in neonatal mortality in Scotland in September 2021 and March 2022, which breached Public Health Scotland (PHS) statistical control limits. The Minister for Public Health, Women's Health and Sport commissioned Healthcare Improvement Scotland to take forward a review in relation to this increase. The scope of this review covers reported neonatal deaths across Scotland between 1 April 2021 and 31 March 2022. During this review period, there were 135 neonatal deaths in Scotland.

The purpose of this review was to assess and determine whether there were any themes, underlying causes or safety factors, from both a clinical and system perspective, which contributed to the national increase in neonatal deaths and, if there were, to identify key learning points and make recommendations for improvements in the quality of care. This review was designed to avoid duplicating any matters which were, or had been, the subject of other review, investigation or audit processes and did not carry out further detailed reviews of individual neonatal deaths.

How this review was carried out

To conduct this review, an independent chair was appointed alongside a neonatal mortality review team from Healthcare Improvement Scotland. An Expert Review Group was established, comprising of representatives from maternity, obstetric and neonatal services across Scotland, together with clinical experts from out with Scotland and representatives from Sands, a third sector organisation that works to save babies' lives and support bereaved families.

Data were gathered on all neonatal deaths which had occurred during the review period. Having this data allowed the neonatal mortality review team to request local review reports from NHS boards for analysis. Analysis of the local review reports was conducted by three members of the Expert Review Group (two consultant obstetricians and one consultant neonatologist) alongside the review Chair. Qualitative analysis (which involves analysing non-numerical data) was also carried out on relevant free text content from local review reports. Findings from the analyses are outlined in this report.

As well as conducting analysis on local review reports, data analysis was carried out by Healthcare Improvement Scotland. For this, publicly available national data from various sources, in addition to a bespoke dataset provided by PHS, were analysed to assess factors such as, a possible increase in the crude neonatal mortality rate in 2021/22 compared with preceding years, changes in the live birth population in 2021/22 compared with preceding years and changes in the rate of specific causes of neonatal death in 2021/22 compared with preceding years. Findings from this analysis are outlined in this report.

This review also explored other relevant considerations for healthcare services during the review period, namely the COVID-19 pandemic and healthcare staffing.

Summary of findings

The main findings of this review are as follows:

- There was a significant increase in neonatal mortality in Scotland in 2021/22. The number of additional neonatal deaths in Scotland in 2021/22 compared to the previous four years is estimated at 30. UK-wide data describe an increase in neonatal mortality across all four devolved nations for those babies born after 24 weeks' gestation in 2021. In 2022/23, the neonatal mortality rate in Scotland returned to that observed between 2015 and 2020. However, at the time of writing this report, provisional data from January to September 2023 suggest a return to higher neonatal mortality rates in 2023.
- More babies than expected were born before 28 weeks' gestation in Scotland in 2021/22. Since babies born before 28 weeks' gestation have a higher neonatal mortality rate than babies born later in pregnancy, babies born before 28 weeks' gestation contributed to the overall increase in neonatal deaths in Scotland in 2021/22.
- There was a significant increase in the neonatal mortality rate for babies born at 32-36 weeks' gestation in Scotland in 2021/22. Ten of the 25 babies born at 32-36 weeks' gestation had a congenital condition incompatible with survival and a further three had either a major congenital or genetic condition which contributed to their death. From the data available to us, we were unable to determine if this reflected a change in the incidence of congenital conditions, or a change in the management of babies affected by major congenital conditions, and / or how much of the increase in neonatal mortality for babies born at 32-36 weeks' gestation in 2021/22 could be attributed to congenital conditions. Changes in neonatal mortality for this gestation group (32-36 weeks) should be a focus in the implementation of the recommendations in this report.
- The registered causes of neonatal deaths in Scotland in 2021/22 were broadly similar to those in previous years, with no new or unusual causes of death identified. Data suggest a possible higher rate of labour and delivery problems, but this does not explain in full the increase in neonatal mortality in 2021/22.
- Only one NHS board had a stabilised and adjusted neonatal mortality rate 5% or more higher than similar neonatal units across the UK. In 2021/22, there were 13 neonatal deaths in this NHS board, which equates to one death more than would have been anticipated.

- There was almost twice the number of neonatal deaths in babies born of multiple births than would have been anticipated. This increase would have contributed to the increased neonatal mortality rate in 2021/22 and is likely associated with the higher proportion of multiple births that were very preterm.
- It was not possible to draw any conclusions regarding the impact of ethnicity on neonatal mortality in 2021/22, due to insufficient recording of maternal ethnicity.
- There was significant variation in the quality of local review reports into neonatal deaths in Scotland submitted by NHS boards for the purpose of this review which is likely to have resulted in missed opportunities for learning. This limited the conclusions which could be reached by the Review Panel. As only local review reports for 2021/22 were considered, it is not possible to comment on how these reports compared with preceding years.
- From the information available in the local review reports, we did not find evidence of systemic failures of maternity or neonatal care, either across Scotland as a whole, or in any one NHS board, that would account for the significant increase in neonatal deaths in 2021/22. Nor did we identify either unusual factors or a cluster of any one factor to explain the increase in neonatal deaths in this period. Without comparative data from preceding years, we could not determine how many neonatal deaths in 2021/22 were potentially preventable.
- Whilst it is possible that the direct and indirect effects of the COVID-19 pandemic may have contributed, at least in part, to the increase in neonatal mortality in Scotland 2021/22, it is not possible to draw conclusions about this from the information available to this review.

Recommendations

The recommendations outlined below should be considered in the context of the wider findings set out in this report. It is important that the recommendations are considered together rather than in isolation. Early signals in the data cannot be fully understood without timely and appropriate review of neonatal deaths.

Recommendation 1
NHS boards should work together, and with relevant national organisations, to consider the findings of this review and to identify any improvements that can be made to the existing systems for responding to early signals in the data indicating an increase in neonatal deaths at a local and national level. This should help to improve understanding of any emerging contributory factors and ensure timely response. This work should include learning from relevant developments in other parts of the UK.

Recommendation 2
NHS boards should work together, and with relevant national organisations, to improve the recording of ethnicity data in maternity services, given the significant gaps in this data and the importance of understanding and addressing potential health inequalities.

Recommendation 3
NHS boards should work together and with relevant national organisations to ensure that local perinatal mortality reviews and Significant Adverse Event Reviews (SAER) are carried out consistently and in a timely manner, and are of appropriate quality, with findings and actions set out clearly in reports including the rationale for the outcome grading. Where more than one NHS board is involved in conducting a local review, it is essential that there is clarity about each board's responsibility, and that there is good communication between boards to ensure that there is no avoidable delay in completing the local review.

Recommendation 4
Healthcare Improvement Scotland should engage with the Scottish Government, NHS boards, and relevant national organisations to consider the findings from this review, and agree the actions required to implement recommendations 1-3 above, together with any further actions necessary to improve the quality and safety of maternity and neonatal services. This should include sharing learning with relevant organisations across the UK.

Acknowledgements

We would like to thank all NHS boards for providing information, data and documentation, in the form of local review reports, to support this review. We would also like to thank our Expert Review Group who allocated time to provide expert clinical advice and specialist knowledge to this review, in particular our three external clinical experts who formed our Review Panel for conducting the analysis of local review reports, and members of our Internal Reference Group. We would also like to give a special mention to PHS for providing national data, including a bespoke dataset, to inform this review and Sands (the stillbirth and neonatal death charity) for their support in ensuring this review took account of the recognised impact on bereaved parents and families.

Dr Helen Mactier

Chair of the Neonatal Mortality Review

Retired Consultant Neonatologist and Honorary Senior Research Fellow (University of Glasgow)

Background

The COVID-19 Wider Impacts Dashboard [(1)] was developed by Public Health Scotland (PHS) to provide an overview of changes in both health and healthcare during the COVID-19 pandemic, and centralised data from a range of different teams for monitoring purposes. Data published in the dashboard in May 2022 showed an increase in neonatal mortality in Scotland in September 2021 and March 2022, which breached PHS statistical control limits. Data also suggested a sustained period in mid-2021 when neonatal mortality rates were higher than the rate from July 2017 to February 2020. Further information on neonatal mortality can be found on page 9.

On 17 August 2022, the Minister for Public Health, Women's Health and Sport commissioned Healthcare Improvement Scotland to take forward a review in relation to this significant increase in neonatal mortality. The scope of this review covered reported neonatal deaths across Scotland between 1 April 2021 and 31 March 2022. This review was informed by relevant data and clinical expertise which included taking account of NHS board local reviews of neonatal deaths that had been undertaken using the standardised Perinatal Mortality Review Tool (PMRT), or an alternative local review tool, and which may have also been subject to a Significant Adverse Event Review (SAER).

On 30 September 2022, the Minister for Public Health, Women's Health and Sport wrote to all NHS board chief executives in Scotland to advise of this national review. The letter also asked NHS boards for support in completing outstanding local perinatal mortality reviews and, where appropriate, the maternity and neonatal adverse event review process for Scotland in a timely manner, as data from the local reviews were to be an integral part of this review.

The purpose of this review was to assess and determine whether there were any themes, underlying causes or safety factors, from both a clinical and system perspective, which contributed to the national increase in neonatal mortality and, if there were, to identify key learning points and make recommendations for improvements in the quality of care. This review considered the systems, processes, and governance for the delivery of care which were relevant to the review scope. This review was designed to avoid duplicating any matters which were, or had been, the subject of other review, investigation or audit processes and did not carry out further detailed reviews of individual neonatal deaths.

The neonatal mortality review team aimed to carry out this review in a sensitive and considerate manner, to minimise the potential for adding to the distress already experienced by affected families. Information about this review was published on the Healthcare Improvement Scotland website, which had links to bereavement support available on the Scottish Government website and the National Bereavement Care Pathway website.

Whilst this report uses the terms 'women' and 'mother', the neonatal mortality review team acknowledges the importance of including all people who give birth, including trans men and non-binary people.

Whilst the focus of this review is on neonatal deaths, it is important to acknowledge that during the time covered by the review thousands of mothers and babies in Scotland experienced a safe pregnancy, labour and birth. This review was carried out by Healthcare Improvement Scotland, with the support of an independent chair and an expert review group. The findings are outlined in this report.

Neonatal Care in Scotland

How is neonatal care provided in Scotland?

Neonatal care is care provided to any baby in the first 28 days of life [(2)]. The majority of newborn babies are well and receive their neonatal care in the postnatal ward of the maternity facility in which they are born and / or at home. Providers of this type of neonatal care include midwives, health visitors, paediatricians and general practitioners as well as parents, family and friends.

Approximately one in eight babies born in Scotland will require some additional neonatal care, provided either in a transitional care unit alongside their mother or in a neonatal unit [(3)]. Most of these babies only need a few days of additional care before being able to go home. A small minority of babies will require ongoing care in a neonatal unit or paediatric ward.

Neonatal units are defined according to the complexity of neonatal care which is provided [(4)(5)]. They are managed in Scotland within a Strategic Network (the Scottish Perinatal Network) to facilitate collaboration across maternity and neonatal services and support the best possible outcomes for mothers, babies and families. There are three categories of neonatal units:

- **Special Care Units (SCUs)** (formerly known as Level 1 units): these neonatal units provide special care (e.g. tube feeding and / or intravenous antibiotic therapy for babies who are born no more than eight weeks preterm) for their own local population. They may also, by agreement with their NHS board and the network, provide some high dependency services (e.g. some forms of breathing support).
- **Local Neonatal Units (LNUs)** (formerly known as Level 2 units): these neonatal units provide special care and also more specialised high dependency care, including assisted ventilation. LNUs also provide intensive care for those babies predicted to require less complex or shorter-term neonatal intensive care.
- **Neonatal Intensive Care Units (NICU)** (formerly known as Level 3 units): these neonatal units provide the full range of medical neonatal care for their local population as well as additional specialist care (which may include surgical and / or cardiac services) for babies and their families referred from elsewhere in the network. It is recommended that women who are at high risk of delivering before 27 completed weeks' gestation (before 28 weeks' gestation for twins or higher order pregnancies) and / or a baby expected to weigh less than 800g should, if possible, be transferred before delivery to a maternity facility co-located with a NICU [(6)(7)].

Medical and nursing / midwifery staff in all neonatal and maternity units in Scotland are trained to provide emergency care for unexpectedly sick or preterm newborn babies until the baby can be transferred safely for ongoing high dependency or intensive care. The transfer of babies for neonatal care (and / or subsequently back to nearer home) is undertaken by the Scottish Neonatal Transport Service (Neonatal ScotSTAR), a division of the Scottish Ambulance Service.

Neonatal intensive care is needed for approximately one in 50 babies born in Scotland [8] and requires very specialised nursing and medical support. In recognition of this, in common with other highly specialised, low volume interventions and commensurate with neonatal care in other parts of the UK and across the world, the *Best Start: A Five-year forward plan for the improvement of maternity and neonatal services in Scotland* [9] concluded that the existing provision of neonatal intensive care should be concentrated in three to five neonatal units. During the period of this review, the 15 neonatal units with the Scottish Perinatal Network were categorised as outlined in Table 1.

Table 1:

NHS board	Hospital	Level
NHS Ayrshire & Arran	University Hospital Crosshouse	LNU
NHS Borders	Borders General Hospital	SCU
NHS Dumfries & Galloway	Dumfries & Galloway Royal Infirmary	SCU
NHS Fife	Victoria Hospital	NICU*
NHS Forth Valley	Forth Valley Royal Hospital	LNU
NHS Grampian	Aberdeen Royal Infirmary	NICU
	Dr Gray's Hospital	SCU
NHS Greater Glasgow and Clyde	Royal Hospital for Children	NICU
	Princess Royal Maternity	NICU
	Royal Alexandra Hospital	LNU
NHS Highland	Raigmore Hospital	LNU
NHS Lanarkshire	University Hospital Wishaw	NICU
NHS Lothian	Simpsons Centre for Reproductive Health, Edinburgh Royal Infirmary	NICU
	St John's Hospital	SCU
NHS Tayside	Ninewells Hospital	NICU
NHS Orkney	-	-
NHS Shetland	-	-
NHS Western Isles	-	-

** While still designated a NICU during the period of this review, there was an agreement in place that mothers predicted to deliver before 27 completed weeks' gestation (< 28 weeks' gestation for multiple pregnancy) and / or babies born before 27 weeks' gestation or weighing < 800 g) would be moved to Simpsons Centre for Reproductive Health, Edinburgh Royal Infirmary.*

What is a neonatal death?

It is important to recognise that, although increasingly small and sick babies now survive neonatal intensive care, there will be some babies for whom this is not the case. This does not necessarily reflect any shortcomings in maternity or neonatal care but may mean that the baby was simply born too early or too unwell to survive. Similarly, a small group of babies are born annually in Scotland in whom a condition has been identified antenatally which means they will not survive, and for whose families termination of the pregnancy is not the preferred option.

Babies die every year in Scotland for a number of reasons, including prematurity, major congenital conditions (also known as birth defects), infection and birth asphyxia (when the baby is deprived of oxygen either before, or around the period of birth). Some of these deaths may have been preventable had the management of the pregnancy, labour or the baby after birth been different. However, even with provision of the very best maternity and neonatal care, some neonatal deaths are not preventable.

A neonatal death is defined as that of a baby of any gestation who showed signs of life at birth and died within the first four weeks of life (up to 28 days after birth). This can include very preterm babies born before 22 weeks' gestation, for whom there is no realistic prospect of survival, and babies with non-survivable major congenital conditions [(10)].

Other definitions of a baby death include:

- **Stillbirth:** a baby who is delivered after 24 completed weeks' gestation and does not show signs of life. Babies born before 24 completed weeks' gestation who have died before birth cannot be registered as stillborn.
- **Late fetal loss:** defined by Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK) as a baby who completes at least 22 weeks' gestation and is born before 24 completed weeks' gestation, but who had died before birth.
- **Perinatal death:** the loss of a baby, where 'perinatal' refers to the latter part of pregnancy and the first few days or weeks of life. The precise definition of a perinatal death varies slightly between organisations. The MBRRACE-UK definition of extended perinatal mortality includes stillborn babies and neonatal deaths of those babies born from 24 weeks' gestation [(11)]; within this review, and consistent with National Records of Scotland (NRS) reporting, we include all neonatal deaths, regardless of gestation.

The Memorial Book of Pregnancy and Baby Loss Prior to 24 Weeks ('the Memorial Book') is available for anyone who has experienced pregnancy or baby loss prior to 24 weeks. The Memorial Book, produced jointly by the Scottish Government and NRS, offers parents an opportunity, if they wish, to commemorate their loss with a physical record and may offer comfort to those who wish to have a record of their loss. It was developed after listening to people who have experienced a pregnancy or baby loss prior to 24 weeks of pregnancy and is a free and entirely optional service [(12)].

When a neonatal death occurs, how are reviews carried out?

The death of a baby is a devastating and traumatic experience for parents, no matter what the cause. To inform future practice and prevent as many baby deaths as possible, review of both maternity and neonatal care is an essential part of midwifery, obstetric and neonatal practice. Reviewing cases has been normal practice in Scotland, and across the wider UK, for many decades.

When a baby is born alive after 20 completed weeks' gestation, and dies in the first 28 days of life, the death should be reported to the National Perinatal Surveillance, currently overseen by MBRRACE-UK. Further information on MBRRACE-UK can be found on page 13.

For babies born after 22 completed weeks' gestation, it is recommended that a formal local review will be undertaken by the local combined maternity and neonatal team, ideally with external input to ensure objectivity. Most commonly, this process utilises the PMRT, which was launched in 2018 [13].

The PMRT aims to support systematic, multidisciplinary, high-quality reviews of the circumstances and care leading up to and surrounding each stillbirth and neonatal death, as well as the deaths of babies who, having received neonatal care, die in the first year of life but after 28 days. The PMRT is not intended for the review of cases where the baby is born alive after a termination of pregnancy but subsequently dies, or where the pregnancy finishes before 22 completed weeks' gestation. The PMRT aims to:

- facilitate 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
- provide a clear understanding of why each baby died, accepting that this may not always be possible even when full clinical investigations have been undertaken; this will involve a grading of the care provided
- ensure a structured process of review, learning, reporting, and actions to improve future care and,
- facilitate the production of a report for parents which includes a meaningful, plain language explanation of why their baby died and whether, with different actions, the death of their baby might have been prevented.

The PMRT is commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of the Department of Health and Social Care (England), NHS Wales, the Health and Social Care Division of the Scottish Government and the Northern Ireland Department of Health. In 2021, a review of care using the PMRT was started for 94% of all neonatal deaths across the UK. In Scotland, use of the PMRT is lower, at 62% of all neonatal deaths, accounted for largely by the fact that NHS Greater Glasgow and Clyde utilises its own review process for neonatal deaths [14].

As part of the perinatal mortality review process, the care provided is graded (between 1 and 4) by the NHS board according to whether the outcome might have been different if different care had been provided. The three stages of care are outlined below, along with Table 2 which provides definitions of the four outcome gradings:

- care for the mother and her baby up to the point of birth
- care for the baby from birth until death, and
- care of the mother following confirmation of the death of her baby.

Table 2:

Outcome Gradings	
1	Appropriate care - well planned and delivered with no care or service delivery problems identified.
2	Care or service delivery problems were identified, and lessons can be learned although this did not affect the final outcome.
3	A different plan and / or delivery of care may have resulted in a different outcome though uncertainty regarding impact on patient outcome / event.
4	A different plan and / or delivery of care, on balance of probability, would have been expected to result in a more favourable outcome, i.e. how the case was managed had a direct impact on the level of harm.

Other types of local reviews can be carried out in the event of a child death. These include:

- **SAER** [15][16] - a significant adverse event (SAE) can be described as an unexpected or avoidable event that could have resulted, or did result, in unnecessary serious harm or death. The purpose of a SAER is to determine what happened, how it happened, why it happened, and whether there are learning points for the service, wider organisation or nationally. The review should examine the processes of care delivery to identify if any system failures occurred which contributed to the adverse event and the outcome.
- **Sudden Unexpected Death in Infancy (SUDI)** - a SUDI is deemed to have occurred where there is no known pre-existing condition which would make the death predictable. Whilst rare, there are on average 25 cases per year in Scotland (based on data from 2015-2021) [17]**.** Most SUDIs occur after the first four weeks of life, but occasionally the death is in the neonatal period. A SUDI review is a multidisciplinary case discussion which is held shortly after the final post-mortem examination report is available and will include any professional relevant to that particular case. The purpose is to discuss all aspects of the death, including possible causes or contributing factors, to see what lessons can be learned and to plan support for the family, particularly in identifying support needs for any future pregnancies.

Review Methodology

The purpose of this review was to assess and determine whether there were any themes, underlying causes, or safety factors, from both a clinical and system perspective, which contributed to the national increase in neonatal mortality in Scotland between 1 April 2021 and 31 March 2022.

To do this, Healthcare Improvement Scotland assembled a neonatal mortality review team, which consisted of a senior reviewer, programme manager, project officer and administrative officer. Dr Helen Mactier, a recently retired consultant neonatologist and honorary senior research fellow within medicine (University of Glasgow), was appointed as the independent Chair of this review. The methodology for this review was developed by the neonatal mortality review team in consultation with the review Chair.

Expert Review Group

An Expert Review Group was established, comprising of representatives predominantly drawn from maternity, obstetric and neonatal services across Scotland, together with clinical experts from out with Scotland and representatives from Sands (the Stillbirth and neonatal death charity). To recruit members to this group, the programme team wrote to individuals directly or wrote to relevant organisations and asked for a nominated representative. The aim of the Expert Review Group was to:

- act as a consultative body and provide expert advice and knowledge to this review
- provide key findings and recommendations for improvement
- consider key documents and data submitted by stakeholders including data from NHS boards and,
- assess relevant data and information taking account of best practice guidelines, clinical standards and any other relevant protocols and guidance.

More information on the Expert Review Group can be found in Appendix 3 and 4.

Internal Reference Group

An Internal Reference Group was established, comprising of representatives from Healthcare Improvement Scotland teams with knowledge in areas relevant to this review. The aim of the Internal Reference Group was to:

- provide advice on the design and delivery of the Neonatal Mortality Review
- act as a ‘sounding board’ for the neonatal mortality review team
- ensure links were made with other relevant programmes of work and,
- provide advice and support on communication and engagement with stakeholders.

National Records of Scotland

NRS is a non-ministerial department of the Scottish Government. Its purpose is to collect, preserve and produce information about Scotland's people and history, and make this information available to inform current and future generations. The neonatal mortality review team requested information from NRS on all reported neonatal deaths which took place during the review period. Between 1 April 2021 and 31 March 2022, there were 135 neonatal deaths in Scotland.

MBRRACE-UK

MBRRACE-UK is the group appointed by the HQIP to run the national maternal, newborn and infant clinical outcome review programme. The aim of MBRRACE-UK is to produce national recommendations to improve care and to ensure that services provided for mothers and babies before, during and after pregnancy are safe, of high quality and focused on the needs of mothers, babies and families [(18)]. Information is collected about all mothers and babies who die either during pregnancy or soon after birth. This information is submitted directly from hospitals using a secure electronic data collection system.

Data Analysis

Both descriptive and statistical data analyses were used to answer the overall aim of this review. This review used publicly available analysis from PHS, MBRRACE-UK and NRS, as well as data analysis specifically for this review. Data analysis specifically for this review was carried out by Healthcare Improvement Scotland. In order to ensure the analysis carried out was valid and robust, independent statistical advice and analysis was obtained.

The main objectives for the data analysis were to:

- assess whether there was an increase in the crude neonatal mortality rate in 2021/22 compared with preceding years
- assess whether there were changes in the live birth population in 2021/22 compared with preceding years
- explore whether any changes had occurred in the balance between neonatal mortality and late pregnancy loss and / or stillbirth
- assess whether any change in the rate of neonatal mortality in 2021/22 related to a change in risk characteristics, and
- explore whether there were any changes in the rate of specific causes of neonatal death in 2021/22 compared with preceding years.

For this, we accessed publicly available data from NRS, PHS, the Office for National Statistics (ONS) and MBRRACE-UK. At the request of this review, PHS created a new dataset (the Neonatal Mortality Review Linked Dataset) which combined birth and death data from NRS, hospital maternity data from PHS and MBRRACE-UK data. From this dataset, PHS provided this review with fully anonymised counts of live births and neonatal deaths in the years 2017/18 to 2021/22 for NHS board of birth, deprivation, multiple births, gestation age and cause of death.

Findings from this analysis can be found on page 17. More information on definitions, data sources and statistical methods used, can be found in the Data Analysis Supporting Document.

In the following sections, we have described gestational age by completed weeks e.g. 24-27 weeks' gestation covers the period of 24 weeks and 0 days to 27 weeks and 6 days.

In this report, we use the term 'expected' to describe the number of neonatal deaths that would have occurred if the mortality rate for the preceding years had continued in 2021/22.

NHS board submissions

Following an initial assessment of the data provided by NRS and MBRRACE-UK, it was determined that seeking further information regarding 33 of the 135 neonatal deaths would not be appropriate for the purpose of this review, as it was extremely unlikely that these deaths would be impacted by the provision of neonatal care in Scotland in 2021/22.

These accounted for:

- Nine babies born before 22 weeks' gestation following spontaneous onset of labour (none of these cases would have been expected to survive). As noted above, the PMRT is not intended for use when the baby is born before 22 weeks' gestation.
- Ten babies, including six born before 22 weeks' gestation, born alive after termination of pregnancy. As noted above, the PMRT is not intended for use after termination of pregnancy.
- Eight cases where the information provided in the death certificate allowed certainty that the baby had a major congenital condition incompatible with survival (for seven of these babies there was a well-documented anticipatory care plan in place at the time of birth).
- One pregnancy for which there had been no antenatal care (unbooked pregnancy), where the baby died at home within the first hour of life.
- Five cases of SUDI which were subject to a SUDI review.

The neonatal mortality review team separated the remaining 102 cases by NHS board. NHS boards were asked to identify a key contact person for all communications relating to this review. The key contacts were asked to provide further details for each case. Further information included the cause of death and information on the type of local review being carried out into the death.

As well as providing more detail on each case, key contacts were asked to provide copies of relevant local review reports (including PMRT or equivalent and / or SAERs, as applicable) for each case. The cases were redacted to remove person identifiable information and to protect patient confidentiality. A secure system (Egress) was set up to receive the redacted local review reports. Each NHS board had its own secure zone for submitting the reports.

Once the required information was returned, and local review reports were submitted to Egress, the process of analysing the reports could begin. In order for the reports to be analysed, a separate zone was set up on Egress to allow access for a small group of selected clinical experts, who would form the Clinical Expert Review Panel.

In light of the varying time taken to complete the local reviews, the PMRT and SAER reports were uploaded to Egress over a period of time during which this review was carried out. A small number of local review reports were received late in the process. This required some adjustment to the process by the neonatal mortality review team, and an extension of the timeline initially planned for completion of this review.

Clinical Expert Review Panel

The local review reports received from the NHS boards were distributed between three external clinical experts (the Review Panel) from our Expert Review Group, as well as the review Chair, for analysis; in total two consultant neonatologists and two consultant obstetricians. Each report was considered by at least one consultant neonatologist and one consultant obstetrician. To ensure consistency, all reports were reviewed by the review Chair. The purpose of analysing the local review reports was to determine whether there were any themes, underlying causes or safety factors, from either a clinical and / or system perspective, which may have contributed to the baby's death.

One of the three external clinical experts (a consultant obstetrician), as well as the review Chair, had previously been employed by NHS Greater Glasgow and Clyde. The consultant obstetrician did not conduct analysis of local review reports from this NHS board and all the NHS Greater Glasgow and Clyde cases were reviewed by the other (independent) consultant neonatologist as well as the review Chair. Further information on the Review Panel members can be found in Appendix 4.

Each local review report submitted had been given an outcome grading (between 1 and 4) by the NHS board (outcome grading definitions are outlined on page 11). The Review Panel were asked to identify common themes and / or factors which may have contributed to the neonatal death, and to consider whether they agreed that the outcome grading provided by the NHS board was in line with the contents of each local review report.

While the neonatal mortality review team fully acknowledge the importance of providing appropriate and compassionate care following the death of a baby, the remit of this review was to identify factors potentially contributing to neonatal mortality and so only the care provided to the mother and baby up to the point of the birth of the baby, and care provided to the baby from birth up to their death was considered.

Following individual analysis, the Review Panel met virtually to discuss all 102 cases. During the meetings, agreement was reached on the outcome grading for the majority of cases, based on the content of the local review reports. Where there was initially a difference of opinion between Review Panellists, this was resolved either by immediate discussion or by additional assessment by a third Review Panellist and subsequent discussion. The outcome grading considered appropriate by the Review Panel was compared to the outcome grading allocated by the NHS board:

- **Agreement of outcome grading by NHS board (1 or 2)** - the Review Panellists agreed with the NHS board that an outcome grading of 1 or 2 was appropriate (either no issues identified or minor failings in care or service delivery, unlikely to have impacted upon the outcome).

- **Agreement of outcome grading by NHS board (3 or 4)** - if the Review Panellists considered that an outcome grading of 3 or 4 (indicating that improvements could have been made to the care provided) may be appropriate, these were discussed in further detail to ensure consensus. A note was taken of the factor(s) which may have contributed to the neonatal death.
- **Disagreement with outcome grading allocated by NHS board** - in instances where the Review Panellists were agreed that the content of the local review report indicated an outcome grading of 3 or 4 but where a grading of 1 or 2 had been recorded by the NHS board, this was noted. Similarly, the Review Panel sought to identify any cases where it considered that the outcome grading recorded by the NHS board was higher than indicated by the content of the local review report.
- **Insufficient information available** - where there was insufficient (or no) information available to make a judgement additional information was requested from the relevant board.

Findings from this analysis can be found on page 30.

Qualitative Analysis

As part of this review, a qualitative analysis (which involves analysing non-numerical data) was carried out on relevant free text content from the local review reports submitted by the NHS boards which were available at the time of the analysis. All selected perinatal mortality reviews were imported into the qualitative data analysis software, NVivo 11®. A form of Qualitative Content Analysis was used to analyse the data.

A coding frame was developed based on key headings from the PMRT and then inductive coding was applied to the text under those headings. In cases where both a SAER and a review using the PMRT were submitted, the conclusions of the SAER on the grading of care and contributory factors were given precedence in the event of any discrepancies. As NHS Greater Glasgow and Clyde does not use the PMRT, additional codes were added to the framework (as required) to code their local review reports.

A primary researcher with substantial experience of qualitative analysis carried out the analysis and a second researcher who is a qualified midwife analysed a subset of the data. The results were compared, and consensus was reached on any disagreements. In cases where the death took place in a different NHS board to the place of residence, the local review report was classified under the NHS board in which the baby died. Findings from the qualitative analysis can be found on page 33.

Approach to reporting of data in this report

Much of the data considered in this review are in the public domain and appropriate reference sources are cited. Other data were provided specifically for the purpose of the review, for example the local review reports, and are not in the public domain. In reporting findings relating to these other data, the neonatal mortality review team has been mindful of the need to be sensitive to the recognised impact on bereaved parents and families and avoid the release of person identifiable data. The team has also carefully considered other factors, including the quality, reliability and interpretation of the data.

Review Findings

Data Analysis Findings

This review used descriptive and statistical analyses to answer the overall aims. For this, a mixture of publicly available and bespoke data analysis, carried out by Healthcare Improvement Scotland, was used. The following areas were considered as part of the data analysis.

What was the change in crude neonatal mortality rate in 2021/22, and how significant is this?

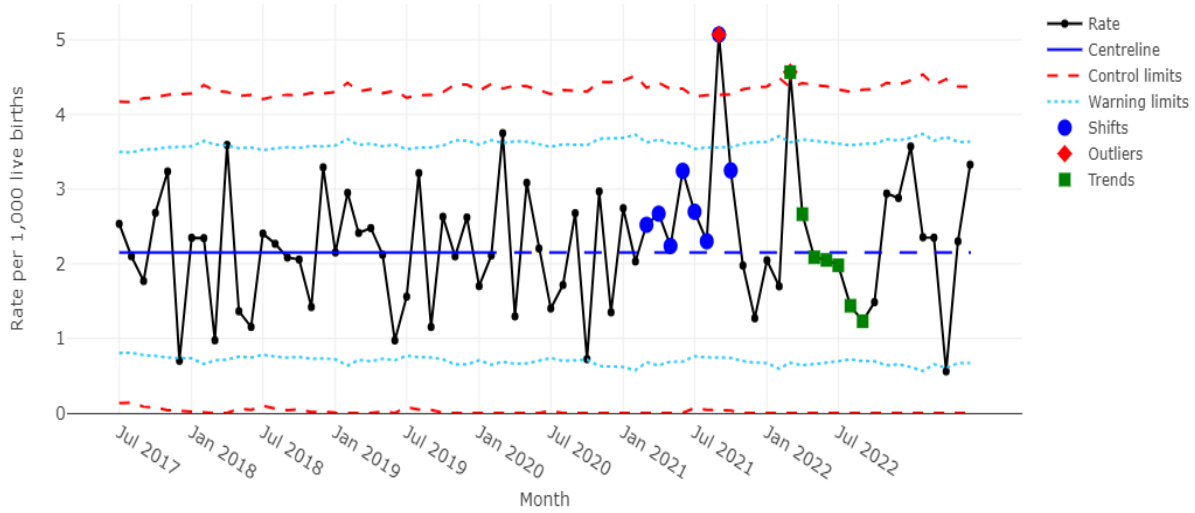
This review was initiated by signals in a Statistical Process Control (SPC) chart of the monthly rate of neonatal deaths per 1,000 live births in Scotland [19] (Figure 1) which was published by PHS. These signals were:

- two individual months being higher than the control limits (September 2021 and March 2022)
- eight consecutive months above a pre-COVID mean (from March 2021 to October 2021).

SPC charts use control limits to highlight when observations are unlikely to have occurred by chance. Eight or more consecutive data points above or below a mean is known as a 'shift' and is, again, unlikely to have occurred by chance. While it is never possible to eliminate the possibility of these observations occurring by chance, multiple signals are stronger indicators of something being different about the system rather than single isolated signals.

It should also be noted that from April 2022 to July 2023, there were no further breaches of control limits or shifts in the monthly data presented by PHS. The PHS analysis of monthly neonatal death rates, which was introduced to monitor the impact of COVID-19, has not been updated beyond July 2023, as it has been replaced by the Scottish Pregnancy, Births and Neonatal Data (SPBAND) Dashboard, which reports quarterly data.

Figure 1: Monthly rate of neonatal deaths per 1,000 live births in Scotland

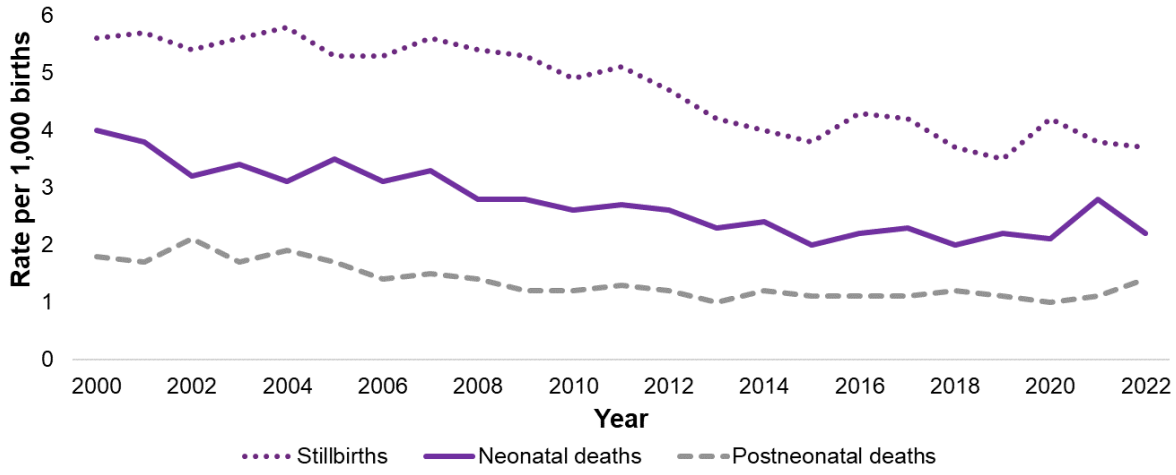


Source: Public Health Scotland COVID-19 Wider Impact Dashboard (September 2023)

NRS report annual neonatal death rates based on calendar year. These published data show a steady reduction in neonatal death rates until around 2015, when rates remained around 2.1 per 1,000 live births, up to 2021, when the neonatal death rate increased to 2.8 per 1,000 live births. This is the highest neonatal death rate since 2009 [20] (Figure 2).

The annual neonatal mortality rate for 2022, published by NRS, was 2.2 per 1,000, consistent with the rates observed in 2015-2020. However, at the time of writing this report, provisional data for January to September 2023 suggest the return to higher neonatal mortality rates in 2023 [21].

Figure 2: Annual rate of stillbirth, neonatal and post-neonatal deaths per 1,000 live births in Scotland



Source: National Records for Scotland, Vital Events Reference Tables

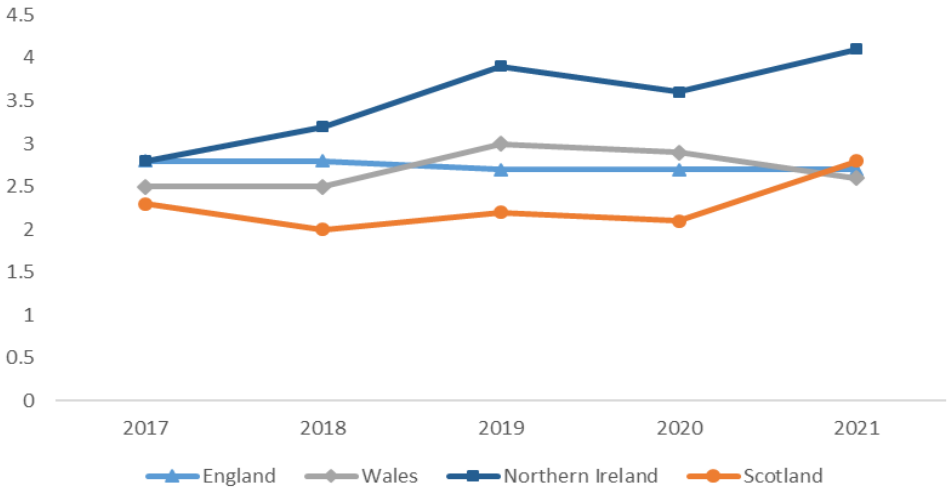
To assess the significance and scale of the increase in 2021/22, we estimated the number of neonatal deaths expected in 2021/22, if the mortality rate for the preceding four years had continued in 2021/22. Using this methodology, the expected number of neonatal deaths would have been 105. The actual number of neonatal deaths in 2021/22 was 135. Although this equals 30 (or 29%) more deaths than expected, uncertainty in the estimate puts the true value at between 8 and 55 neonatal deaths in 2021/22, higher than previous years. With a minimum value of 8, this range also confirms that a significantly higher number of deaths was observed in 2021/22.

Later in this report, we describe the estimated number of additional deaths for specific groups. We provide these estimates to indicate the relative contribution of different risk factors. As there is uncertainty in these estimates, and because babies can be included in more than one group (e.g. multiple births and under 24 weeks' gestation), the estimate cannot be used to provide a detailed breakdown of the total estimated additional deaths.

Was there a change in neonatal mortality across the rest of the UK?

The ONS reports infant mortality rates for all UK nations. As ONS publish data based on calendar years, the latest data for births in 2021 cover only the first three quarters of the period of this review. They report that neonatal mortality in 2021 was similar to mortality during the previous four years for England and Wales but increased in both Northern Ireland and Scotland [22]. Only the increase in neonatal mortality in Scotland was statistically significant.

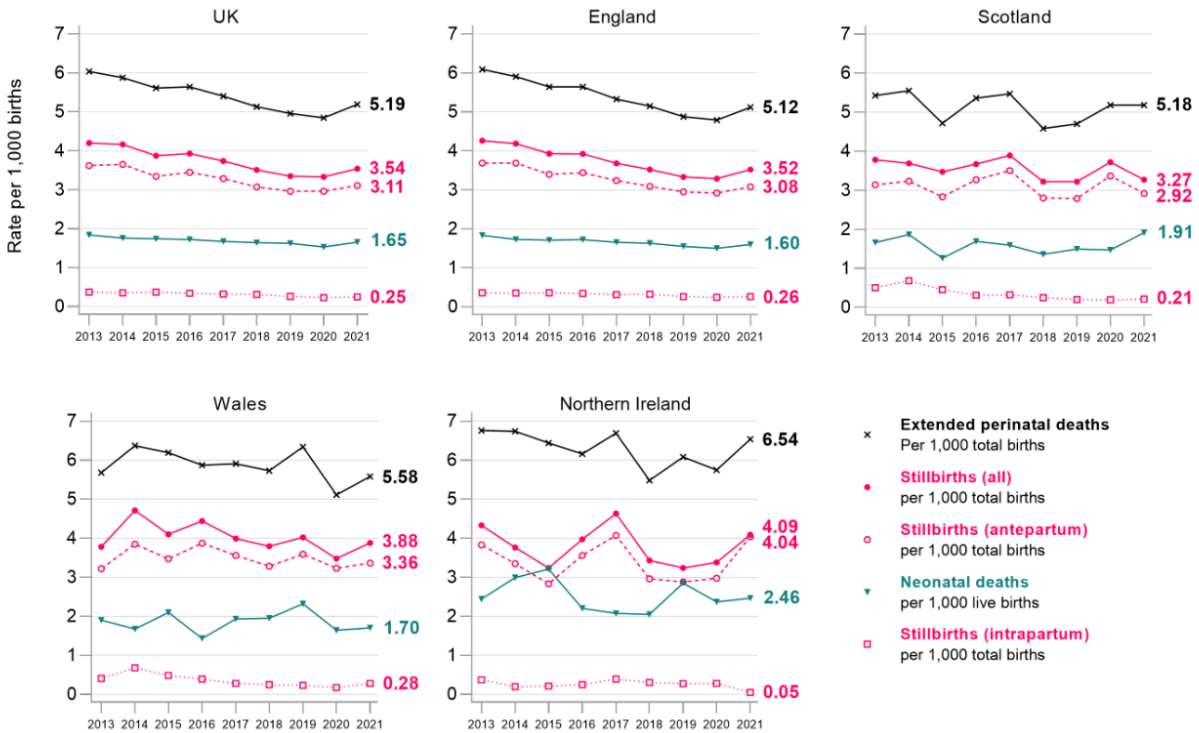
Figure 3: Rate of neonatal mortality per 1,000 live births across the United Kingdom



Source: Office for National Statistics, Child and infant mortality in England and Wales

MBRRACE-UK also publishes perinatal mortality rates for the whole of the UK based on calendar years [23]. The latest published rates are for the year 2021. MBRRACE-UK data differ from the PHS, NRS and ONS publications as they do not routinely report births where the gestation period was less than 24 weeks. In September 2023, MBRRACE-UK published a Perinatal Mortality Surveillance report for births from 1 January 2021 to 31 December 2021. The report highlighted an increase in extended perinatal mortality across the UK for the first time in seven years, following a period of year-on-year reductions. For England, Wales and Northern Ireland, this reflected an increase in both stillbirths and neonatal deaths, but for Scotland the increase was confined to neonatal deaths. Scotland had the lowest stillbirth rate in the UK.

Figure 4: Stillbirth, neonatal and extended perinatal mortality rates for the UK and by country of residence



Source: MBRRACE-UK Perinatal Mortality Surveillance

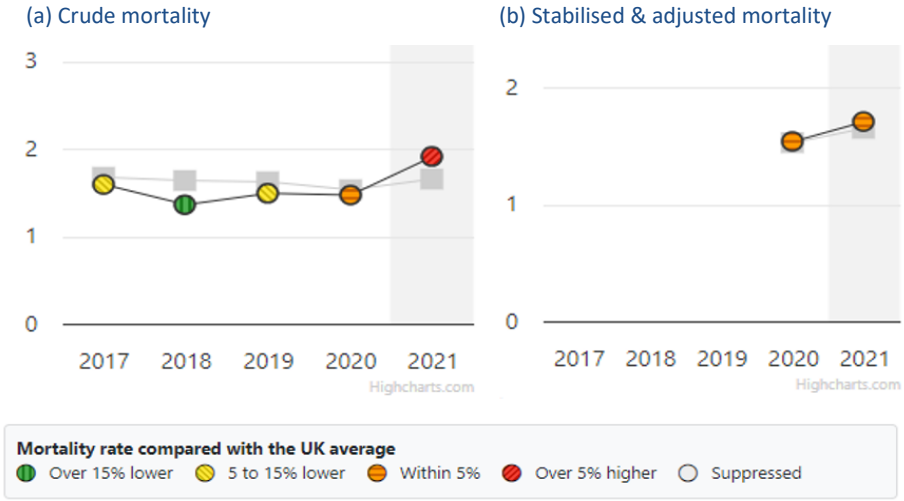
MBRRACE-UK data are important to this review because, as well as reporting crude rates, they report rates which are *stabilised,* to allow for the effects of chance variation due to small numbers, and *adjusted,* to account for key factors which are known to increase the risk of perinatal mortality. Stabilised and adjusted data allow better comparison of units of healthcare provision, such as NHS boards, taking account of the size of the unit as well as the mix of patients that they are caring for.

The key factors that MBRRACE-UK use to adjust rates are [24]:

- mother's age
- socio-economic deprivation based on the mother's residence
- baby's ethnicity
- baby's sex
- whether they are from a multiple birth, and
- gestational age.

In 2021, MBRRACE-UK reported the Scotland crude neonatal mortality rate to have been more than 5% higher than the UK rate, following four years below the UK rate. However, when stabilised and adjusted, the Scotland neonatal mortality rate for 2021 was within a similar range to the UK overall. This contrasts with 2020, when stabilising and adjusting the data made little difference to Scotland in relation to the UK. This indicates an increase in high-risk deliveries in Scotland in 2021.

Figure 5: MBRRACE-UK crude and stabilised & adjusted neonatal mortality rates per 1,000 live births, for Scotland compared to the UK average



Source: MBRRACE-UK perinatal mortality surveillance report data viewer

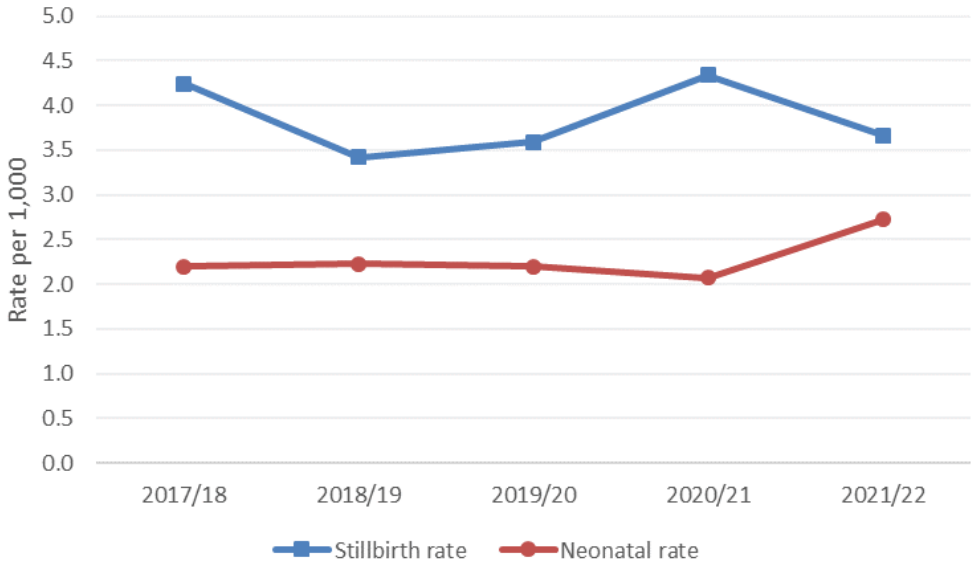
Was there a change in the balance between neonatal mortality and late pregnancy loss (at 22-23 weeks' gestation) and / or stillbirth (at 24 or more weeks' gestation)?

Perinatal mortality at 24 or more weeks' gestation

Recognising that the baby is at risk in the womb, and expediting delivery, will reduce the risk of stillbirth, but the baby may die later from the complications of preterm birth or other neonatal illness consequent upon an adverse *in utero* environment. It is therefore important to consider the overall perinatal mortality.

When rates for stillbirth and all neonatal deaths, regardless of gestation, are plotted for five financial years up to 2021/22 (Figure 6) the pattern is similar to MBRRACE-UK rates for calendar years and births from 24 weeks' gestational age (Figure 4). In Scotland, there was an increase in neonatal mortality in 2021/22 but, while the stillbirth rate varied across the five years, there was no overall trend in the stillbirth rate between 2017/18 - 2021/22.

Figure 6: Stillbirth, and neonatal mortality rates for Scotland



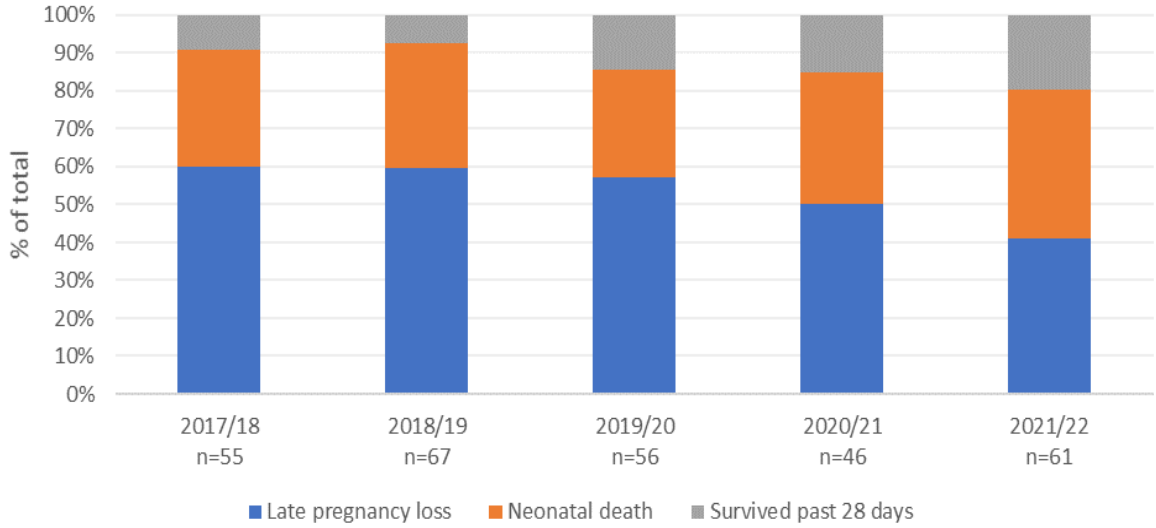
Source: National Records for Scotland, Vital Events Reference Tables

Perinatal mortality at 22 and 23 weeks' gestation

Changes in the management and / or classification of babies born before 24 weeks' gestation may have an impact on neonatal mortality rates. We noted both the revised BAPM guidance around perinatal management before 27 weeks' gestation, published in October 2019 [25], (specifically the recommendation to consider resuscitation from 22 weeks' gestation) and MBRRACE-UK guidance regarding the identification of signs of life before 24 weeks' gestation, published in November 2020 [26].

Since 2018/19, a decreasing proportion of pregnancies ending at 22-23 weeks' gestation has been classified as late pregnancy loss; coincident with this has been an increase in both the proportion of babies who are born at 22-23 weeks but die within 28 days (neonatal deaths) and the proportion of babies born at 22-23 weeks who survive beyond 28 days (Figure 7). This means an increased number of babies surviving after pregnancies ending at 22-23 weeks but also an increase in the number of neonatal deaths. This trend began prior to 2021/22 and made only a partial contribution to the increase in neonatal mortality in 2021/22.

Figure 1: Outcomes of pregnancies ending at 22 and 23 weeks' gestation



Source: Neonatal Mortality Review Linked Dataset

Were there differences in the characteristics of the entire birth population in 2021/22, compared to previous years?

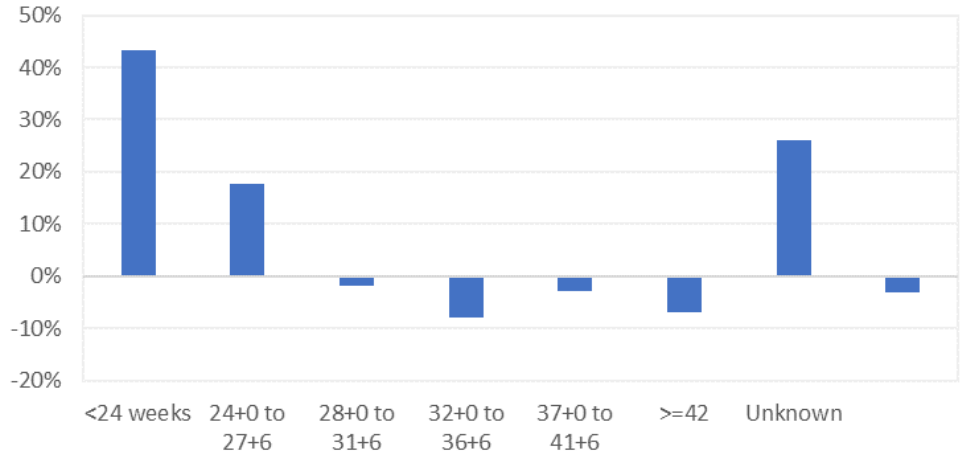
This review considered whether changes in the entire birth population could have contributed to an increase in neonatal mortality in 2021/22. PHS report birth statistics in their 'Births in Scotland' publication. Both maternal age and obesity have been steadily increasing over many years, as have the rates of caesarean section, but compared to the preceding year there was no significant change in any factor in either 2021 or 2022 to account for a change in neonatal mortality in 2021/22. Nor was there any change in the proportion of male births (generally associated with higher neonatal mortality) in NRS reported birth data.

Gestational age

The risk of babies dying in the neonatal period increases as the gestational age becomes more premature, particularly at the extremes of preterm gestation. We explored whether the distribution of births changed in 2021/22 with respect to gestation age, by assessing if there had been a change in the proportion of births from each gestational age band. We found a significant increase in the proportion of those babies born alive before 28 weeks' gestation with a corresponding decrease in all other gestational age groups.

In 2021/22 around 47 more babies were born alive before 28 weeks' gestation compared to the previous four years, with the largest proportional increase in those babies born before 24 weeks' gestation (Figure 8).

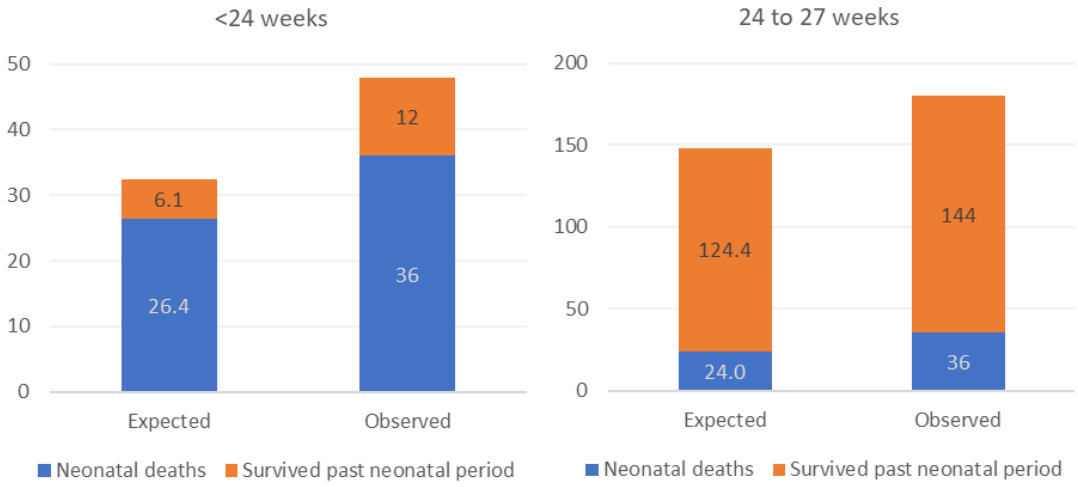
Figure 8: Percentage change in number of live births from 2017/18 - 2020/21 (average) to 2021/22



Source: Neonatal Mortality Review Linked Dataset

As a result of an increase in the absolute number of babies born before 28 weeks' gestation, and assuming that the mortality rate remained constant, we estimate around 22 more extremely preterm neonatal deaths occurred in 2021/22 than in the previous four years (Figure 9), 10 for babies born before 24 weeks' gestation and 12 for babies born between 24-27 weeks' gestation. Deaths of extremely preterm infants contributed to the overall increase in neonatal deaths in Scotland in 2021/22.

Figure 9: Expected and observed neonatal outcomes in 2021/22 for babies born before 28 weeks' gestation.



Source: Neonatal Mortality Review Linked Dataset

Ethnicity

Significant ethnic inequalities in neonatal mortality in the UK are widely acknowledged [27]. MBRRACE-UK reported that neonatal mortality rates for 2021 continued to be higher for babies of Black ethnicity (2.94 per 1,000 total births) and babies of Asian ethnicity (2.22 per 1,000 total births) compared with babies of White ethnicity (1.68 per 1,000 total births). In Scotland, recording of maternal ethnicity on the SMR02 dataset has historically been around 80% with the remaining 20% being 'not known / refused / not provided'.

Although levels of recording improved in 2021 and 2022 (82% and 86% respectively) with an increase in the recorded percentage of births to mothers of Asian, Scottish Asian or Asian British ethnicity, there remain difficulties interpreting these data. It is therefore not possible to draw any conclusions regarding the impact of ethnicity, and / or any changes associated with ethnicity in Scotland on neonatal mortality in 2021/22.

Multiple births

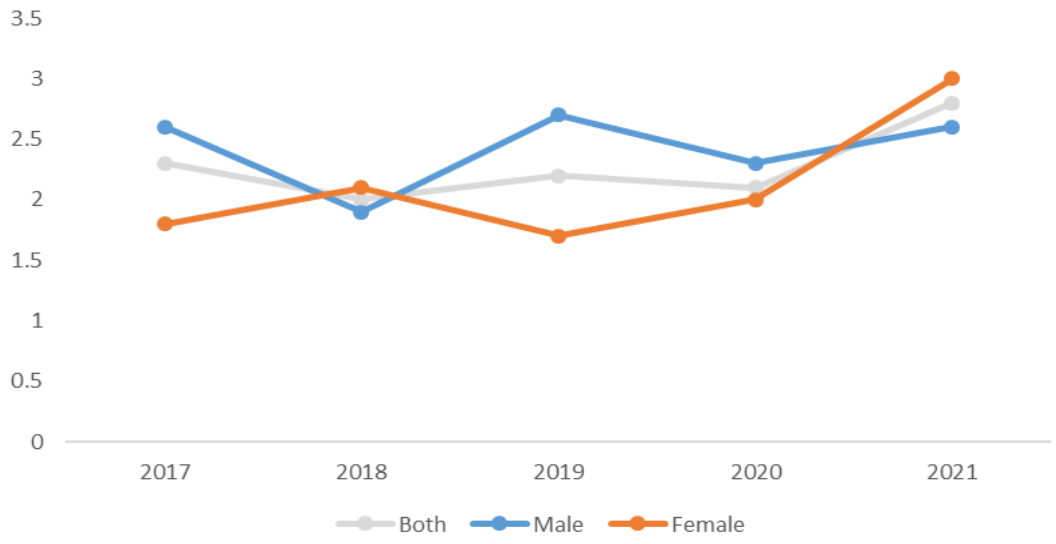
The percentage of live births that came from multiple births was lower in 2021/22 (2.6%) compared to preceding years (2.9%). A relatively higher proportion of these multiple births (4.8%) was before 28 weeks' gestation compared to the previous four years (2.4%) [28].

Were there differences in characteristics of babies who died in 2021/22 compared with previous years?

Sex specific mortality

Although males typically have a higher neonatal mortality rate than females, sex-specific birth rates published by NRS show higher neonatal mortality among females (3.0 per 1,000 births) compared to males (2.6 per 1,000 births) in 2021. (Figure 10). This finding is not repeated in other UK nations and in the absence of any plausible explanation, we believe this to be the result of chance variation.

Figure 10: Rate of neonatal death per 1,000 live births for males and females



Source: National Records for Scotland, Vital Events Reference Tables and Births Time Series Data

Socio-economic deprivation related mortality

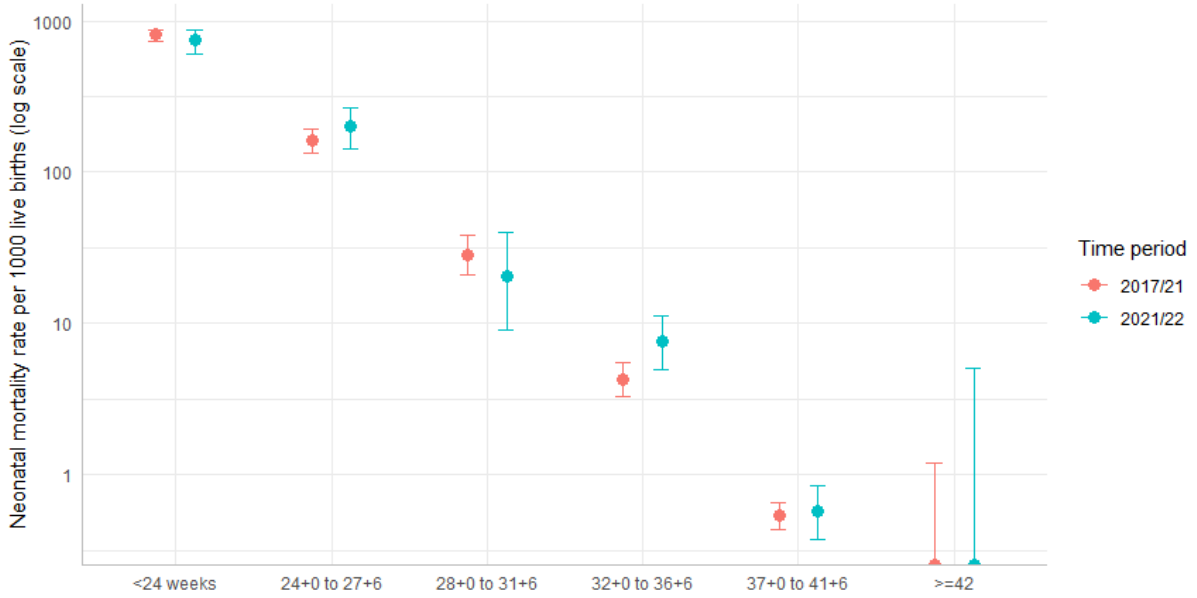
The Scottish Index of Multiple Deprivation (SIMD) is an area-based measure of relative deprivation, based on deprivation across seven domains: income, employment, education, health, access to services, crime and housing. Not every person in a highly deprived area will themselves be experiencing high levels of deprivation and vice-versa. We assessed changes in neonatal mortality rates for births within each SIMD quintile, based on the mother's residence. An SIMD quintile represents 20% of the population; the first quintile comprises the most deprived areas and the fifth quintile comprises the least deprived areas.

The number of births is not evenly distributed across the quintiles, as the birth rate is higher in the most deprived areas. Babies born to families living in more deprived areas also have a higher risk of neonatal death. Using the absolute difference between the neonatal mortality rate of the most and least deprived groups to describe deprivation gradient, there was no change in the neonatal mortality rate deprivation gradient between 2017/18 and 2021/22. Comparing observed with expected neonatal deaths in 2021/22 for each SIMD quintile, only the middle quintile had significantly more neonatal deaths than expected. This result indicates no change in socio-economic deprivation in 2021/22 that would account for the increase in neonatal mortality.

Gestational age specific mortality

The risk of babies dying in the neonatal period increases exponentially as the gestational age becomes more premature, and this was the case in 2021/22 (Figure 11).

Figure 2: Neonatal mortality rates in 2021/22 compared to the previous four years with 95% confidence intervals, by gestational age (logarithmic scale)



Source: Neonatal Mortality Review Linked Dataset

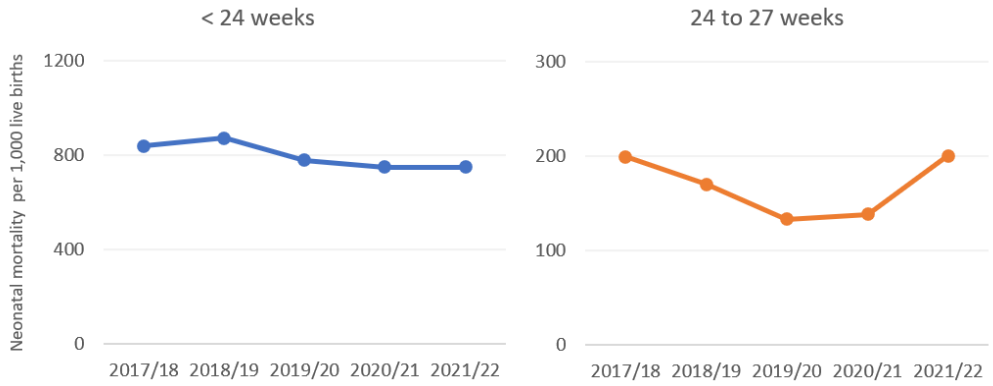
Extremely preterm babies (< 28 weeks' gestation)

We did not find a significant increase in the neonatal mortality rate (i.e. the number of babies dying as a proportion of the number of live births) for babies born before 28 weeks' gestation in Scotland in 2021/22 compared to the rate for the previous four years.

However, ongoing improvements in clinical management of extremely preterm babies was reflected in changes to the neonatal mortality rate across these four years, particularly for those babies born between 24-27 weeks' gestation (Figure 12). When we compared the neonatal mortality rate for extremely preterm babies born in Scotland in 2021/22 compared to the previous two years, we found a significant increase in neonatal mortality for babies born between 24-27 weeks' gestation, but not for babies born before 24 weeks' gestation.

This finding mirrors changes in the UK as a whole; in 2021, MBRRACE-UK reported the largest increase in neonatal deaths rates to be in babies born between 24-27 weeks' gestation for whom neonatal mortality rates increased by 18% [29].

Figure 3: Neonatal mortality rates for babies born before 28 weeks' gestation



Source: Neonatal Mortality Review Linked Dataset

Moderately preterm babies (32-36 weeks' gestation)

For babies born moderately preterm, between 32-36 weeks' gestation, there was an increase in the number of neonatal deaths compared to the previous four years, but this was not matched by an increase in births at 32-36 weeks' gestation. This led to a significant increase in the neonatal mortality rate for babies born between 32-36 weeks' gestation in 2021/22. The difference between observed and expected is estimated at 11 neonatal deaths.

Multiple births

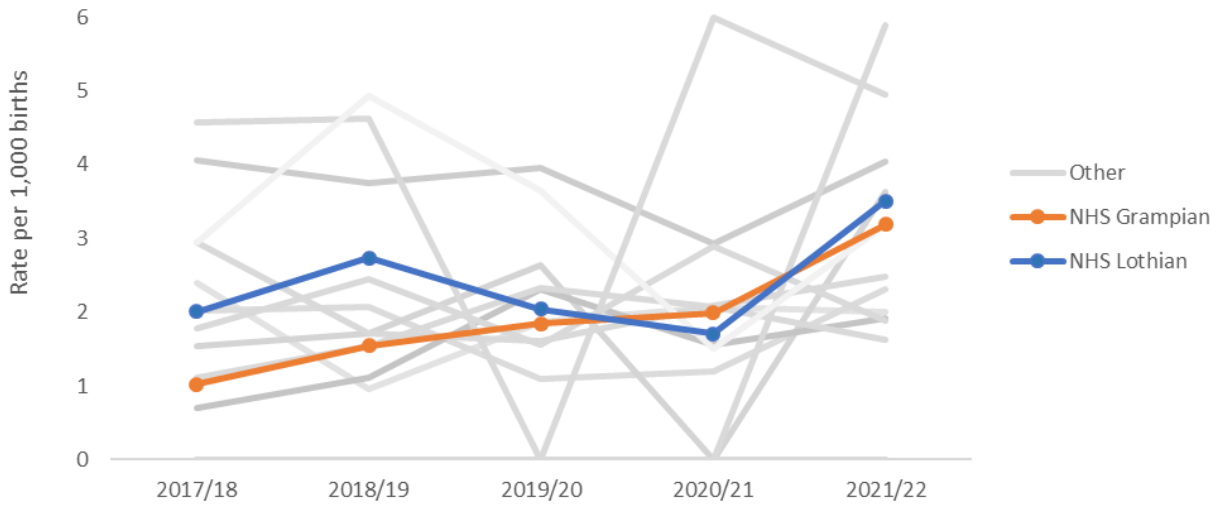
The significant increase in neonatal death rates in 2021/22 applied to both singleton and multiple births. However, for multiple births there was almost twice the number of deaths than would have been expected had rates been the same as in the previous four years (expected 12; observed 22). For singleton births there were 23% more deaths than expected (expected 92; observed 113). We conclude that neonatal deaths from multiple births made a disproportionately higher contribution to the increased mortality rates in 2021/22, likely associated with the higher proportion of multiple births that were very preterm (less than 28 weeks' gestation). This increase in neonatal deaths of babies born from multiple pregnancy does not explain in full the increase in neonatal mortality in 2021/22.

Were particular areas associated with a higher rate of neonatal death in 2021/22?

Unadjusted neonatal mortality rates by NHS board of birth

Analysis of unadjusted neonatal mortality rates by NHS board of birth in 2021/22 compared to the previous four years found a significant increase in two NHS boards (NHS Lothian and NHS Grampian). Combined, there were 20 more neonatal deaths than expected in these NHS board areas. It is important to note that both NHS boards include regional combined neonatal medical and surgical intensive care units which would admit more high-risk babies, including those transferred from other NHS boards in the region. A change in the proportion of high-risk pregnancies with no change in the safety and quality of care could explain a change in crude rates. It is therefore necessary to consider mortality rates adjusted for higher risk groups.

Figure 13: Neonatal mortality rates per 1,000 live births by NHS board of birth



Source: Neonatal Mortality Review Linked Dataset

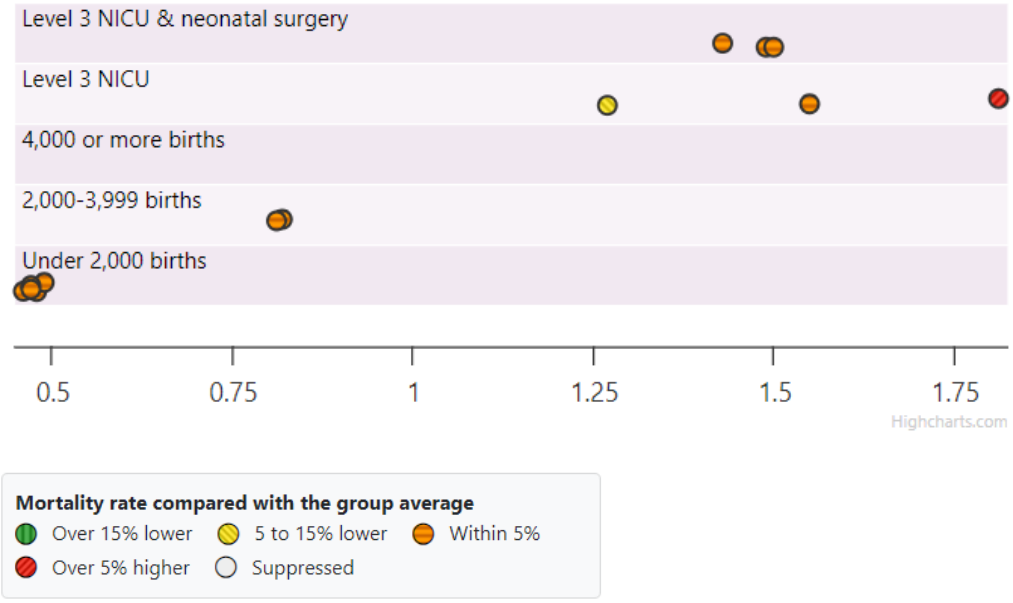
MBRRACE-UK adjusted rates by NHS board of birth

MBRRACE-UK report NHS board neonatal mortality rates adjusted for a number of risk factors. In order to compare them more fairly, MBRRACE-UK classify Trusts and Health Boards into five comparator groups, based on their level of service provision. These comparator groups are hierarchical, meaning an LNU caring for less vulnerable babies would be expected to have a lower overall neonatal mortality rate compared to a NICU. Stabilised and adjusted mortality rates are assessed according to variation from their respective comparator group UK average, so it is important that the neonatal units' designations are correctly reported to MBRRACE-UK. A complete explanation of the MBRRACE-UK methodology, including statistical methods, can be found in the Data Analysis Supporting Document.

In 2021, MBRRACE-UK crude neonatal mortality rates in NHS Ayrshire & Arran, NHS Forth Valley, NHS Lanarkshire and NHS Fife were more than 5% higher than the UK average for their comparator group but after adjustment for risk factors (stabilised and adjusted rates) and exclusion of congenital conditions, only NHS Fife was more than 5% higher than their comparator group.

The stabilised and adjusted rates versus unadjusted rates imply that the high crude neonatal mortality rates observed in NHS Ayrshire & Arran, NHS Forth Valley and NHS Lanarkshire, but not NHS Fife, can be explained by higher risk populations and / or variation due to small numbers. This finding does not imply that neonatal deaths in NHS Fife made a significant contribution to the overall increase in neonatal deaths in 2021/22; in our analysis of unadjusted neonatal mortality rates, we estimated one more death in NHS Fife, which was not statistically significant. The stabilised and adjusted rates also provide some evidence that the increase in NHS Grampian and NHS Lothian's unadjusted neonatal mortality rates reflected more high-risk populations.

Figure 14: MBRRACE-UK Stabilised & adjusted neonatal mortality rates excluding congenital anomalies for NHS board of birth relative to other neonatal units of comparable designation



**MBRRACE adjusted data should be interpreted in the knowledge that during the period under review, there was an agreement that mothers booked into NHS Fife, but who were expected to deliver before 27 weeks' gestation (28 weeks' gestation for multiple pregnancies), were transferred whenever possible to NHS Lothian.*

Were there differences in the causes of death among babies who died in 2021/22, compared with previous years?

In examining this question, we considered whether there were unusual cause(s) of neonatal death and whether there were changes in the rates of expected causes of neonatal deaths in 2021/22.

Details around cause(s) of death were derived from the ICD-10 (International Classification of Diseases 10th revision) and CODAC (cause of death and associated conditions). ICD-10 classification is coded by NRS from information available on the death certificate and CODAC classification is generated by MBRRACE-UK from information selected by the clinician reporting the neonatal death.

ICD-10 classifications relating to 'perinatal conditions' (which would include prematurity and babies affected by complications of labour and delivery) accounted for three out of four neonatal deaths in 2021/22. Congenital conditions contributed to around two thirds of the remaining deaths, with sudden infant death, external cause and all other causes accounting for the rest. These causes of death were broadly similar to previous years, with the exception of a small, but statistically significant, increase in the descriptor 'fetus and newborns affected by complications of placenta, cord and membranes; and other complications of labour and delivery'. This latter cause of death would account for around seven additional neonatal deaths in 2021/22. Further information can be found in the Data Analysis Supporting Document.

According to CODAC, just under half of deaths were caused by neonatal factors; of which extreme prematurity was the most common, followed by neurological and cardio-respiratory conditions. Congenital conditions were reported as the cause in around one in eight neonatal deaths. We also noted a significant increase in the likelihood of the death being ascribed to 'multiorgan failure' or

'neurological'. While 'multiorgan failure' could account for three or four additional neonatal deaths in 2021/22, it may simply reflect changes in practice in ascribing the main cause of death. Further information can be found in the Data Analysis Supporting Document. There were no deaths for which maternal COVID-19 infection or vaccination was registered as the underlying cause of death.

Summary of conclusions and recommendations

A number of observations may be made from an assessment of the available data.

- There was a significant increase in neonatal mortality in Scotland in 2021/22. The number of additional neonatal deaths in Scotland in 2021/22 compared to the previous four years is estimated at 30. UK-wide data describe an increase in neonatal mortality across all four devolved nations for those babies born after 24 weeks' gestation in 2021. In 2022/23, the neonatal mortality rate in Scotland returned to that observed between 2015 and 2020. However, at the time of writing this report, provisional data from January to September 2023 suggest a return to higher neonatal mortality rates in 2023.
- More babies than expected were born before 28 weeks' gestation in Scotland in 2021/22. Since babies born before 28 weeks' gestation have a higher neonatal mortality rate than babies born later in pregnancy, babies born before 28 weeks' gestation contributed to the overall increase in neonatal deaths in Scotland in 2021/22.
- There was a significant increase in the neonatal mortality rate for babies born at 32-36 weeks' gestation in Scotland in 2021/22. Ten of the 25 babies born at 32-36 weeks' gestation had a congenital condition incompatible with survival and a further three had either a major congenital or genetic condition which contributed to their death. From the data available to us, we were unable to determine if this reflected a change in the incidence of congenital conditions, or a change in the management of babies affected by major congenital conditions, and / or how much of the increase in neonatal mortality for babies born at 32-36 weeks' gestation in 2021/22 could be attributed to congenital conditions. Changes in neonatal mortality for this gestation group (32-36 weeks) should be a focus in the implementation of the recommendations in this report.
- The registered causes of neonatal deaths in Scotland in 2021/22 were broadly similar to those in previous years, with no new or unusual causes of death identified. Data suggest a possible higher rate of labour and delivery problems, but this does not explain in full the increase in neonatal mortality in 2021/22.
- Only one NHS board had a stabilised and adjusted neonatal mortality rate 5% or more higher than similar neonatal units across the UK. In 2021/22, there were 13 neonatal deaths in this NHS board, which equates to one death more than would have been anticipated.
- There was almost twice the number of neonatal deaths in babies born of multiple births than would have been anticipated. This increase would have contributed to the increased neonatal mortality rate in 2021/22 and is likely associated with the higher proportion of multiple births that were very preterm.
- It was not possible to draw any conclusions regarding the impact of ethnicity on neonatal mortality in 2021/22, due to insufficient recording of maternal ethnicity.

These findings accord with UK data for 2021, which identified increases in perinatal mortality across all four devolved nations, particularly for those babies born extremely preterm, between 24-27 weeks' gestation. Neither this review, nor the UK data, identified a single causative factor.

Neonatal mortality data require to be assessed regularly by those with responsibility for providing maternity and neonatal services. It is essential that the data are considered in the context of other available knowledge and experience of how services are operating in practice. This is a key component in any learning system for ensuring and continuously improving the safety and quality of services.

Whilst there are currently systems in place to achieve this in Scotland, and it was not the role of this review to assess the existing arrangements, it would be prudent to reflect on whether these might be improved, taking account of this review, and of relevant developments in other parts of the UK. It is important that all relevant organisations work collaboratively with a shared objective of understanding the reducing neonatal mortality.

Recommendation 1
NHS boards should work together, and with relevant national organisations, to consider the findings of this review and to identify any improvements that can be made to the existing systems for responding to early signals in the data indicating an increase in neonatal deaths at a local and national level. This should help to improve understanding of any emerging contributory factors and ensure timely response. This work should include learning from relevant developments in other parts of the UK.

Recommendation 2
NHS boards should work together, and with relevant national organisations, to improve the recording of ethnicity data in maternity services, given the significant gaps in this data and the importance of understanding and addressing potential health inequalities.

Clinical Expert Review Panel Analysis Findings

While a relatively small number of babies die in the first four weeks of life, each death is a tragedy for the family. Every family needs to understand why their baby died, and if the death might have been preventable. This is one reason why reviewing neonatal deaths is important, in addition to ensuring that any learning for services is identified.

The primary purpose for the Review Panel in examining the local review reports was to look for evidence of systematic failings in maternity and / or neonatal care in Scotland which might explain, either in part or in full, the increase in neonatal mortality in 2021/22. Specifically, the remit of the Review Panel was not to re-examine care in individual cases.

The Review Panel anticipated there were likely to be some cases where the local reviews had identified issues with the care provided to either or both the mother or baby that might have, or likely did, impact upon the outcome. Perinatal mortality review is intended to highlight such issues, acknowledge

these to the family, seek their views and facilitate learning, both locally and nationally to ensure ongoing improvements in care. It is therefore important, both for families and for learning for staff and the service, that these local reviews are adequately resourced and completed to the required standard and that appropriate outcome gradings are recorded in local review reports.

Review Panel Findings and Observations

Quality of local review reports

There was significant variation in the quality of local review reports into neonatal deaths in Scotland submitted by NHS boards for the purpose of this review. The Review Panel found evidence of poor quality, inconsistent and incomplete local reviews across NHS boards, and this limited the conclusions which could be reached by the Review Panel. As only local review reports for 2021/22 were considered, it is not possible to comment on how these reports compared with preceding years.

NHS boards were requested to remove person identifiable information prior to submitting local review reports. As a result of these redactions, the Review Panel were unable to ascertain, for the majority of cases, if external input to the local review had occurred.

In four cases (all babies unexpectedly born out of hospital with no professional attendant present), it was not clear to the Review Panel if the baby had shown definite signs of life or had been stillborn.

For several cases, it was not possible for the Review Panel to reach a conclusion based on the evidence available. Further information (largely regarding neonatal care) was requested from the relevant NHS boards. Missing neonatal data was a particular issue for one NHS board (NHS Grampian) in which four cases had insufficient information. The neonatal mortality review team contacted NHS Grampian to request further detail and the cases were reassessed following receipt of the information.

Grading of outcomes

For most neonatal deaths reviewed, the Review Panel agreed with the NHS board findings, that the care provided to both the mother and her baby was either optimal or included minor issues in care or service delivery, which were unlikely to have impacted upon the outcome.

In the remaining cases, the Review Panel generally agreed with the local NHS board findings, that factors in care of either or both the mother and the baby may have, or almost certainly did contribute to the baby's death. The majority of these factors related to antenatal or intrapartum care, for example, delay in delivery by caesarean section, undiagnosed breech presentation, delay in administration of antibiotics, or difficulties in resuscitating the baby. These factors reflect the types of issues which can occur in maternity and neonatal care; without comparative data it is not possible to comment on whether the incidence of these factors was different to preceding years.

Review Panel disagreement with recorded outcomes

In a small number of cases, either the rationale for the outcome grading was not sufficiently clear in the perinatal mortality review or SAER reports, or the outcome grading allocated by the NHS board did not seem to the Review Panel to accord with the information provided in the local review reports. Further information on outcome grading definitions is outlined on page 11.

For some of these cases, the NHS board's outcome grading was lower than the Review Panel expected. This was a particular issue for one NHS board (NHS Fife). Following notification of this to the NHS board, the Review Panel met with clinical representatives from NHS Fife to discuss the cases further. This meeting allowed NHS Fife representatives and the Review Panel to achieve consensus on the appropriate outcome gradings for each case.

Conclusion from Review Panel analysis

The Review Panel were aware of higher than expected mortality for babies born moderately or late preterm (between 32-36 weeks' gestation) in 2021/22 but from the information available to the Review Panel, this could not be explained. The Review Panel were also aware of the increased incidence of extremely preterm birth and increased mortality for those babies born 24-27 weeks' gestation; neither of these findings could be explained from the information available. With the exception of an increased incidence of extremely preterm birth, the Review Panel noted no unusual or unexplained contributing factors to the 135 neonatal deaths which occurred in Scotland in 2021/22.

Reflections and observations

An increasing number of extremely preterm babies are being offered active neonatal care in Scotland, consistent with practice across the wider UK and internationally. This ongoing trend towards more active management of pregnancies ending at 22-23 weeks' gestation was reflected in 2021/22 in fewer reported late pregnancy losses and more neonatal deaths compared to previous years and made a partial contribution to the increase in neonatal mortality in 2021/22.

While steadily improving, current survival for babies born between 22-23 weeks' gestation is around 30% [(30)], meaning that many neonatal deaths of those extremely preterm babies are not preventable. However, this does not preclude learning, as survival rates are higher and longer-term outcomes are better if appropriate steps to optimise outcomes are taken [(31)] and birth in a maternity facility, co-located with a NICU, can be facilitated.

Ten of the 25 babies born at 32-36 weeks' gestation had a congenital condition incompatible with survival and a further three had a major congenital or genetic condition which contributed to their death. From the data available to us, we were unable to determine if this reflected a change in the incidence of congenital conditions, or a change in the management of babies affected by major congenital conditions, and / or how much of the increase in neonatal mortality for babies born at 32-36 weeks' gestation in 2021/22 could be attributed to congenital conditions. Changes in neonatal mortality rates for moderate to late preterm babies should be closely monitored, and any trends in conditions contributing to the death should be investigated.

In the context of all preterm birth, maternity and neonatal teams should jointly explore factors which may have contributed to the preterm birth, as well as compliance with interventions known to improve outcomes.

Neonatal deaths recorded in 2021/22 included ten terminations of pregnancy, the majority of which were for major congenital conditions and were carried out before 22 weeks' gestation. It is important to note that, in the knowledge that their baby has an unsurvivable congenital condition, some families

choose to continue their pregnancy long enough to allow them to spend some time with their baby before the baby dies. This means that some cases which may previously have been recorded as a termination of pregnancy are now registered as a neonatal death.

Determining signs of life at the most preterm gestations can be very difficult, particularly if the birth occurs where no professional is present at delivery (also known as an unattended birth). The Review Panel noted four cases where the information available raised some doubt around whether the baby had been stillborn or had been born alive and subsequently passed away prior to professional assessment. The challenging nature of determining signs of life in such circumstances is a continuing issue and does not account for the increase in neonatal deaths seen in 2021/22.

Consideration was also given to healthcare staffing but, as explained in the Healthcare Staffing section below, there was little mention of staffing levels in the local review reports and reliable staffing data at the level of detail required were not available for the purpose of this review.

Qualitative Analysis Findings

A total of ninety-two local reviews were included in the qualitative analysis. These spanned ten NHS boards with the majority relating to three of the larger NHS boards, whose NICUs provide the full range of care for the smallest and sickest babies. Only local reviews with a submitted perinatal mortality or equivalent review report and / or SAER, available at the time of analysis, were included. If a short summary-style local review report was all that was submitted, the death was omitted from analysis.

Care issues identified as 'likely to have' or as 'may have' contributed to the outcome for the baby occurred in a minority of cases. These were largely related to maternity and / or obstetric care and accorded with care issues identified by the Review Panel when reviewing local reports.

Whilst there were some limitations to the qualitative analysis, it was useful in confirming the findings of the Review Panel; that the identified possible contributory factors to a minority of neonatal deaths in Scotland in 2021/22 reflected the issues which can occur in current UK maternity and neonatal care.

Summary of conclusions and recommendations

- There was significant variation in the quality of local review reports into neonatal deaths in Scotland submitted by NHS boards for the purpose of this review which is likely to have resulted in missed opportunities for learning. This limited the conclusions which could be reached by the Review Panel. As only local review reports for 2021/22 were considered, it is not possible to comment on how these reports compared with preceding years.
- From the information available in the local review reports, we did not find evidence of systemic failures of maternity or neonatal care, either across Scotland as a whole, or in any one NHS board, that would account for the significant increase in neonatal deaths in 2021/22. Nor did we identify either unusual factors or a cluster of any one factor to explain the increase in neonatal deaths in this period. Without comparative data from preceding years, we could not determine how many neonatal deaths in 2021/22 were potentially preventable.

Recommendation 3
NHS boards should work together and with relevant national organisations to ensure that local perinatal mortality reviews and Significant Adverse Event Reviews (SAER) are carried out consistently and in a timely manner, and are of appropriate quality, with findings and actions set out clearly in reports including the rationale for the outcome grading. Where more than one NHS board is involved in conducting a local review, it is essential that there is clarity about each board's responsibility, and that there is good communication between boards to ensure that there is no avoidable delay in completing the local review.

Other Considerations

COVID-19

This review intentionally did not undertake or commission additional specific analyses of the relationship between COVID and neonatal death, as the number of neonatal deaths which occurred during the review period in Scotland is too small to make such comparisons statistically valid. Much larger population studies, which cover the same time period as this review, have been published which outline findings from Scotland, the wider UK and internationally.

Existing published studies

Using data from the COVID-19 in Pregnancy in Scotland (COPS) database, a population-based matched cohort study in Scotland explored any link between SARS-CoV-2 infection (COVID) and / or COVID-19 vaccination in the six weeks prior to conception or during pregnancy, and adverse maternal and / or neonatal outcomes [32]. The COPS study database contained information on 81,441 singleton pregnancies, including 12,808 where the mother had received COVID-19 vaccination. Consistent with other studies, COPS reported that maternal SARS-CoV-2 infection was associated with the baby being 1.35 times more likely to be preterm and was also associated with the mother being 1.72 times more likely to be admitted to critical care or to die. Within the COPS cohort, there were 17 neonatal deaths; neonatal death tended to be more likely if the mother had COVID but this difference did not reach statistical significance.

There was no evidence of increased risk of any adverse maternal or neonatal outcome following vaccination either shortly before or during pregnancy. The data from Scotland are consistent with UK data [33] and support the UK-wide national recommendation, that all pregnant women should be vaccinated against COVID-19 [34]. Data from the COPS study also showed no association between mothers having a SARS-CoV-2 infection or COVID-19 vaccination during early pregnancy and either early pregnancy loss or the risk of the baby having a major congenital condition [35].

Recently published data from MBRRACE-UK [36] show a 53% increase in maternal deaths in 2020-22 compared to the previous three-year period; 2017-19 (13.41 versus 8.79 per 100,000 maternities). When maternal deaths directly attributed to COVID-19 are excluded, the maternal death rate for 2020-22 remains significantly higher (by 31%) than the rate in 2017-2019, implying a potential indirect effect of the pandemic.

Findings from this review

From the 102 cases analysed for this review, COVID was noted in only seven cases from four NHS boards. This included staff absences due to COVID, one case of long COVID and four mothers who tested positive around the time of delivery. Possible contributory factors to the baby's death included maternal illness, preterm birth and staffing shortage consequent upon the pandemic. Maternal COVID vaccination was not detailed in any of the local reviews analysed.

Possible wider impact of the pandemic

Whilst it is possible that the direct and indirect effects of the COVID-19 pandemic may have contributed, at least in part, to the increase in neonatal mortality in Scotland 2021/22, it is not possible to draw conclusions about this from the information available to this review.

Healthcare Staffing

The neonatal mortality review team contacted the Excellence in Care (EiC) team and the Healthcare Staffing Programme (HSP) team within Healthcare Improvement Scotland, to ascertain what information would be available on healthcare staffing during the review period. It was advised that the 17 NHS boards, with patient facing services (14 territorial NHS boards, the NHS National Waiting Times Centre, the State Hospital Boards for Scotland and the Scottish Ambulance Service), are expected to submit data for various EiC measures displayed on the Care Assurance and Improvement Resource (CAIR) dashboard, including workforce measures. These measures are:

- Funded Establishment (provided manually by NHS boards and not displayed on CAIR)
- Establishment Variance
- Supplementary Staffing Use
- Predictable Absence Allowance (including, sickness, annual leave, and maternity / paternity leave)

The workforce data are extracted centrally from the Scottish Standard Time System (SSTS) by PHS and processed for display on CAIR. Despite this, there are a number of challenges with data validity which have prevented its use for the purpose of this review. These challenges include:

- **COVID-19 pandemic** - at the start of the pandemic, the EiC and HSP was paused to focus on the COVID-related priorities, with staff involved in EiC and HSP redeployed to other areas. As a result, NHS boards were not required to submit data to CAIR during this period or undertake 'runs' of the HSP Staffing Level Tools. While some NHS boards continued with submission of data and tool runs, others were unable to maintain data collection, system updates and updates to a reference file. The reference file is a 'structural block' for the CAIR dashboard which maps the wards / team that data is expected to be collected. Due to the number of local changes to wards during the pandemic, the reference files became out of date and resulted in incomplete datasets being extracted.
- **Out of date Funded Establishment** - the Funded Establishment is a key component to the Establishment Variance and Supplementary Staffing measures. From the 17 NHS boards involved in EiC, 14 are expected to submit data for maternity and neonatal areas. This is for 93 teams and wards across 33 sites. At the time of this review, some of the data were incomplete or out of date.

- **Data frequency** - at the time of this review, the data submitted to CAIR are reported monthly, with data extractions usually running approximately 4-6 weeks in arrears. As a result, this would only provide the review with high level 'flags' within the data, rather than data for specific dates relating to the cases under review. There was a similar picture within HSP with staffing level tool frequency of biannual runs for a two-week period with the timescales for those tool runs not necessarily capturing the specific dates relating to the cases under review.

In conclusion, due to a lack of confidence in the quality and completeness of the data for the relevant time period, it was considered not appropriate to include the data held within HSP and EiC on healthcare staffing within maternity and neonatal services for the purpose of this review. It was also noted that data held for that period provided through monthly NHS board submissions would, in any event, not have provided the level of detail required for this review, for example, staffing on the specific dates, wards and shifts when neonatal deaths occurred.

Healthcare Improvement Scotland, through EiC and HSP, has been working with NHS boards and in partnership with NHS Education Scotland, since the period under consideration by this review, to improve healthcare staffing data collection and analysis, supported by the development of digital solutions. Systems are now in place to enable a consistent approach in recording patient numbers and acuity, together with the actual and required staffing for each shift. This will support implementation of the Health and Care Staffing (Scotland) Act 2019, which will be brought into effect in April 2024.

Next Steps

This review has provided an analysis of available data for neonatal deaths in 2021/22. There are some limitations noted in the data analysis and questions about the increase, which therefore remain unanswered. At the time of writing this report, provisional data for January - September 2023 shows an increase in neonatal mortality rates in 2023, which is out-with the period considered by this review. These issues require further exploration and will require all stakeholders including the Scottish Government, NHS boards and relevant national organisations to work together with the shared aim of improving the quality and safety of maternity and neonatal services.

Recommendation 4
Healthcare Improvement Scotland should engage with the Scottish Government, NHS boards, and relevant national organisations to consider the findings from this review, and agree the actions required to implement recommendations 1-3 above, together with any further actions necessary to improve the quality and safety of maternity and neonatal services. This should include sharing learning with relevant organisations across the UK.

Glossary

TERM	EXPLANATION
Adverse Event	An event that could have caused, or did result in, harm to people or groups of people.
Antenatal care	Care given to pregnant women before their babies are born
BAPM	British Association of Perinatal Medicine
Birth asphyxia	When the baby is deprived of oxygen either before, or around the period of birth
Caesarean section	Also known as C-section, is the surgical procedure by which one or more babies are delivered through an incision in the mother's abdomen
CAIR	Care Assurance and Improvement Resource
CODAC	Cause Of Death and Associated Conditions
COPS	COVID-19 in Pregnancy in Scotland
COVID / COVID-19	An illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
Egress	A cloud email security platform that uses adaptive security models to protect against advanced phishing, data loss prevention, and encryption threats
EiC	Excellence in Care
Gestation	The length of a pregnancy (measured in weeks and days), historically measured from the first day of the last menstrual period; now most commonly assessed by early ultrasound examination
HQIP	Healthcare Quality Improvement Partnership
HSP	Healthcare Staffing Programme
ICD-10	International Classification of Diseases 10th revision
Intrapartum care	The care of the mother and the baby during the birth process
Late fetal loss	A baby who completes at least 22 weeks' gestation and is born before 24 completed weeks' gestation, but who had died before birth
LNU	Local Neonatal Unit (formerly known as Level 2 units): these neonatal units provide special care and also more specialised high dependency care, including assisted ventilation

MBRRACE-UK	Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK
Neonatal Care	Care that is provided to any baby in the first 28 days of life
Neonatal ScotSTAR	Scottish Neonatal Transport Service, a division of the Scottish Ambulance Service
Neonatologist	A paediatrician who specialises in care of the newborn
NICU	Neonatal Intensive Care Unit (formerly known as Level 3 units): these neonatal units provide the full range of medical neonatal care for their local population as well as additional specialist care (which may include surgical and / or cardiac services) for babies and their families
NRS	National Records of Scotland
NVivo 11®	A desktop application which lets users organise, analyse and visualise information from documents
Obstetrician	A doctor who specialises in care during pregnancy, labour and after birth
ONS	Office for National Statistics
Perinatal death	The loss of a fetus or newborn baby, where 'perinatal' refers to the latter part of pregnancy and the first few days or weeks of life
PHS	Public Health Scotland
PMRT	Perinatal Mortality Review Tool
Preterm / premature	Babies born before 37 weeks of pregnancy are completed
Qualitative Analysis	The process of analysing non-numerical data
SAER	Significant Adverse Event Review
Sands	The stillbirth and neonatal death charity
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SCU	Special Care Units (formerly known as Level 1 units): provide special care (e.g. tube feeding and / or intravenous antibiotic therapy for babies who are born no more than eight weeks preterm)
SIMD	Scottish Index of Multiple Deprivation
SPC	Statistical Process Control
SSTS	Scottish Standard Time System
Stillbirth	A baby who is delivered after 24 completed weeks' gestation and does not show signs of life
SUDI	Sudden Unexpected Death in Infancy

Appendix 1

Recommendations

The recommendations outlined below should be considered in the context of the wider findings set out in this report. It is important that the recommendations are considered together rather than in isolation. Early signals in the data cannot be fully understood without timely and appropriate review of neonatal deaths.

Recommendation 1
NHS boards should work together, and with relevant national organisations, to consider the findings of this review and to identify any improvements that can be made to the existing systems for responding to early signals in the data indicating an increase in neonatal deaths at a local and national level. This should help to improve understanding of any emerging contributory factors and ensure timely response. This work should include learning from relevant developments in other parts of the UK.

Recommendation 2
NHS boards should work together, and with relevant national organisations, to improve the recording of ethnicity data in maternity services, given the significant gaps in this data and the importance of understanding and addressing potential health inequalities.

Recommendation 3
NHS boards should work together and with relevant national organisations to ensure that local perinatal mortality reviews and Significant Adverse Event Reviews (SAER) are carried out consistently and in a timely manner, and are of appropriate quality, with findings and actions set out clearly in reports including the rationale for the outcome grading. Where more than one NHS board is involved in conducting a local review, it is essential that there is clarity about each board's responsibility, and that there is good communication between boards to ensure that there is no avoidable delay in completing the local review.

Recommendation 4
Healthcare Improvement Scotland should engage with the Scottish Government, NHS boards, and relevant national organisations to consider the findings from this review, and agree the actions required to implement recommendations 1-3 above, together with any further actions necessary to improve the quality and safety of maternity and neonatal services. This should include sharing learning with relevant organisations across the UK.

Appendix 2

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Appendix 3

Terms of Reference: Healthcare Improvement Scotland: Review of systems, processes, and governance for the delivery of Neonatal Care

Introduction

1. Data published in the Public Health Scotland (PHS) COVID-19 wider impacts dashboard in May 2022 showed a significant increase in neonatal mortality in September 2021 and March 2022, which breached PHS statistical control limits. Data also suggested a sustained period in the middle of 2021 when neonatal and infant mortality rates were higher than pre-pandemic levels.
2. On 17 August 2022, the Minister for Public Health, Women's Health and Sport commissioned Healthcare Improvement Scotland to take forward a review in relation to the significant increase in neonatal mortality across Scotland in the year 2021-2022.
3. On 30 September 2022, the Minister for Public Health, Women's Health and Sport sent a letter to all NHS board chief executives in Scotland to confirm the commission and to ask boards for support in completing the Perinatal Mortality Review Tool (PMRT) and, where appropriate, the Maternity and neonatal (perinatal) adverse event review process for Scotland, in a timely manner, as data from the local reviews are an integral part of the national review.
4. The scope of this review will cover reported neonatal deaths across Scotland between 1 April 2021 and 31 March 2022. The review will be informed by relevant data and clinical expertise.
5. The review will assess and determine whether there are any themes, underlying causes or safety factors, from both a clinical and system perspective and, if there are, will identify key learning points and make recommendations for improvements in the quality of care. The review will consider the systems, processes and governance for the delivery of care, which are relevant to the review scope.
6. In carrying out this review, Healthcare Improvement Scotland will take account of any related formal complaints or inquiries that may be proceeding at the same time as the review and ensure appropriate separation of the review from these processes.
7. Sandra McDougall, Associate Director (Quality Assurance Directorate) is accountable for the overall delivery of this work and Nanisa Feilden, Senior Reviewer (Quality Assurance Directorate) is responsible for operational delivery within Healthcare Improvement Scotland.
8. The review will be conducted by an Expert Review Group. The group will be led by Dr Helen Mactier, a recently retired consultant neonatologist and honorary senior research fellow within medicine (University of Glasgow).
9. A programme team has been established within Healthcare Improvement Scotland to provide managerial and administrative support to all aspects of the review, including the internal reference group and expert review group. The team consists of the senior reviewer, a programme manager, a project officer and an administrative officer.
10. The review is expected to be completed 6-9 months from the establishment of the expert review group.

Role and Remit

11. The main aims of the review are as follows.

    a. To understand any contributing factors to the national increase in neonatal mortality during 2021-2022.

    b. To draw on relevant data and clinical expertise, including taking account of data and consideration of reports from NHS board reviews of neonatal deaths that have been carried out using the standardised PMRT or alternative local review tool and which may also be subject to a significant adverse event review.

    c. To assess and determine whether there are any themes, underlying causes or safety factors, from both a clinical and system perspective.

    d. To identify learning points and make recommendations for improvements.

    e. To ensure the review is sensitive to the impact already experienced by the affected families.

    f. To take account of any related formal complaints or inquiries that may be proceeding at the same time and ensure appropriate separation of the review from these processes.

    g. To engage appropriately with relevant stakeholders, including policy leads at Scottish Government and other relevant bodies such as the Internal Reference Group, PHS, NHS boards, the Scottish Perinatal Network and third sector organisations.

    h. To ensure Scottish Government are updated as the review progresses in order to provide assurances to the Minister for Public Health, Women's Health and Sport.

    i. To comply with appropriate confidentiality requirements regarding handling of any patient information.

    j. To carry out the review independently, make recommendations and publish findings.

Out of scope

12. The following areas are out with the scope of the review.

    a. The review will not cover reported neonatal deaths across Scotland before 1 April 2021 and after 31 March 2022.

    b. The review will not duplicate any matters which are, or have been, the subject of another review, investigation or audit process.

    c. The review will not duplicate or carry out further reviews of individual neonatal deaths.

    d. The review will not routinely seek further information following consideration of existing review reports. However, a process will be put in place to follow-up PMRTs, or other review data/reports if required, with reasonable questions and discussions with staff or teams to identify any issues with systems and processes around the time of the death(s).

    e. The review will not look at any individual point of care failures. However, if information provided suggests this might be the case, this will be escalated using the Healthcare Improvement Scotland's escalation process.

Methodology

13. The Expert Review Group, and the Healthcare Improvement Scotland programme team, will:

    f. be comprised of persons with relevant skills and experience to provide key findings and recommendations for improvement

    g. act as a consultative body and provide expert advice and knowledge to the review

    h. work within the scope of the review and provide support to reach review timescales (including providing comments and feedback, where necessary)

    i. ensure links with key stakeholders to gather information and data and disseminate relevant information to colleagues within organisations, where appropriate

    j. seek additional expert advice to complement the knowledge and skills of the review team, if required

    k. consider key documents and data submitted by stakeholders including data from NHS board reviews of neonatal deaths that have been carried out using the standardised PMRT or other local review tool, and which may also be subject to a significant adverse event review

    l. assess best practice guidelines, clinical standards and any other relevant protocols and guidance, and

    m. produce a report with key findings and recommendations to support improvement.

Expert Review Group

14. Membership is predominantly drawn from maternity, obstetric and neonatal services across Scotland, together with clinical experts from out with Scotland and representatives from third sector organisations. A full list of group members can be found in Appendix 4.

Appendix 4

Expert Review Group members

NAME	DESIGNATION	ORGANISTION
Dr Helen Mactier (Chair)	Consultant Neonatologist	*Retired*
Charlotte Bevan	Joint Head Saving Babies Lives	Sands (the stillbirth and neonatal death charity)
Dr Shetty Bhushan	Consultant Neonatologist	NHS Tayside
Professor Alan Cameron	Clinical Lead for Obstetrics	*Retired*
Cheryl Clark	Head of Midwifery	NHS Lanarkshire
Dr Lynda Fenton	Consultant in Public Health, Clinical and Public Health Intelligence (Child Health)	Public Health Scotland *
Clare Hargan	Head of Service	Scotstar (Neonatal Transport)
Dr Cath Harrison	Consultant Neonatologist	Leeds Teaching Hospitals NHS Trust
Dr Ewen Johnston	Consultant Neonatologist	NHS Lothian
Graham Latta	Senior Neonatal Transport Charge Nurse	Scotstar (Neonatal Transport)
Kate Mulley	Director of Research Education and Policy	Sands (the stillbirth and neonatal death charity)
Dr Hanan Mustafa	Consultant Obstetrician	NHS Lothian
Dr Tony Nicoll	Consultant Obstetrician	NHS Tayside
Dr Louise Page	Consultant Obstetrician and Gynaecologist	Chelsea & Westminster Hospital NHS Foundation Trust
Dr Colin Peters	Consultant Neonatologist	NHS Greater Glasgow and Clyde
Alison Wright	Advanced Neonatal Nurse Practitioner, Neonatal Services	NHS Tayside

** Independent statistical advice and analysis to support the review was provided by Clara Calvert, an Epidemiologist and Chancellor's Fellow at the University of Edinburgh and Honorary Researcher with Public Health Scotland.*

Appendix 5

Clinical Expert Review Panel biographies

Dr Helen Mactier, Consultant Neonatologist *(retired)*

Dr Mactier is a recently retired consultant neonatologist with over twenty years' experience at Princess Royal Maternity in Glasgow. She was President of the British Association of Perinatal Medicine (BAPM) 2019-22. Helen has significant experience studying the challenges facing maternity and neonatal services both within Scotland and across the wider UK and was a panel member of the Independent Investigation into East Kent Maternity Services, 2021-22. Helen also chaired the Neonatal Services subgroup of the Scottish Government's plan for maternity and neonatal care published in 2017.

Dr Cath Harrison, Consultant Neonatologist

Dr Harrison has been a consultant neonatologist in Leeds since 2004 and has training and experience from the UK, Australia and South Africa. She is also the Clinical Lead for Embrace, a combined neonatal and paediatric transfer service in the UK (carrying out over 2000 transfers per year) and the Chair of the UK Neonatal Transport Group. Cath is the UK training advisor for Royal College Subspecialty Advisory Committee (CSAC) for neonatology, having been the CSAC Chair for 6 years. She has a long-standing interest in global health and has worked in lower middle-income countries, developing education and training packages, for the last 25 years.

Dr Louise Page, Consultant Obstetrician and Gynaecologist

Dr Page works clinically at West Middlesex Hospital where she is the obstetric service lead and one of the maternity quality and safety leads. She was the founding president of the British Intrapartum Care Society (2018-2022) and is one of the co-organisers of the annual Royal College of Obstetricians and Gynaecologists (RCOG) / British Maternal and Fetal Medicine Society (BMFMS) Management of the Labour Ward course. Louise is the interim clinical director for the Maternity and Newborn Safety Investigations (MNSI) programme, which undertakes a significant number of independent investigations focusing on maternity services and perinatal care in England, specifically all cases of maternal death related to pregnancy and other cases meeting the MNSI referral criteria.

Professor Alan Cameron, Consultant Obstetrician *(retired)*

Professor Cameron was a Consultant Obstetrician in Glasgow for 28 years; he retired in 2019. He retained an active research profile and was awarded an Honorary Professorship from the University of Glasgow in 2007. He was the Scottish Members representative on the RCOG Council from 1996-2002, and President of the British Maternal and Fetal Medicine Society from 2005-08. From 2013-16, he was Vice President for Clinical Quality at the RCOG, and the co-principal investigator of the flagship RCOG project 'Each Baby Counts'. From 2019-22, he was the National Clinical Lead for Obstetrics with MCQIC and in 2019, the Welsh Health Secretary appointed him as the Obstetric Lead for an Independent Review of a Health Board's maternity and neonatal services. He has been a Specialty Maternity Advisor to the HSIB since 2019 and was appointed as a Clinical Advisor in 2020.

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Healthcare Improvement Scotland

Edinburgh Office	Glasgow Office
Gyle Square	Delta House
1 South Gyle Crescent	50 West Nile Street
Edinburgh	Glasgow
EH12 9EB	G1 2NP
0131 623 4300	0141 225 6999

www.healthcareimprovementscotland.org