HSIB

HEALTHCARE SAFETY INVESTIGATION BRANCH

WWW.HSIB.ORG.UK

National Learning Report

Intrapartum stillbirth: learning from maternity safety investigations that occurred during the COVID-19 pandemic, 1 April to 30 June 2020

Independent report by the
Healthcare Safety Investigation Branch I2020/024

September 2021

Providing feedback and comment on HSIB reports

At the Healthcare Safety Investigation Branch (HSIB) we welcome feedback on our investigation reports. The best way to share your views and comments is to email us at **enquiries@hsib.org.uk** or complete our online feedback form at **www.hsib.org.uk/tell-us-what-you-think**.

We aim to provide a response to all correspondence within five working days.

About HSIB

We conduct independent investigations of patient safety concerns in NHS-funded care across England. Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. Our investigations identify the contributory factors that have led to harm or the potential for harm to patients. The safety recommendations we make aim to improve healthcare systems and processes, to reduce risk and improve safety.

We work closely with patients, families and healthcare staff affected by patient safety incidents, and we never attribute blame or liability.

Considerations in light of coronavirus (COVID-19)

We have adapted some of our national investigations, reports and processes to reflect the impact that COVID-19 has had on our organisation as well as the healthcare system across England. For this report, the way we engaged with staff and families was revised.

A note of acknowledgement to families

We would like to thank the families whose experiences are described in this report. We are grateful to those who generously gave their time under such difficult circumstances.

To protect the anonymity of the women and pregnant people and their families, clinical details of the woman and pregnant person's care and their experiences have not been described in this report.

Also to preserve anonymity, individuals are referred to as the woman, pregnant person, parent, baby or family member.

A note of acknowledgement to members of staff

We would also like to thank the healthcare providers and staff who participated in the maternity investigations and shared their perceptions of the incidents and the healthcare service with us, as well as expressing their empathy for the families involved.

A note to those pregnant or planning pregnancy

We appreciate that reading this report may be concerning for people who are currently pregnant, those planning a pregnancy or their families. It is important to acknowledge that during the time period covered by the report thousands of women and pregnant people and babies experienced a safe pregnancy, labour and birth.

Our investigations

Our investigators and analysts have diverse experience of healthcare and other safety-critical industries and are trained in human factors and safety science. We consult widely in England and internationally to ensure that our work is informed by appropriate clinical and other relevant expertise.

We undertake patient safety investigations through two programmes:

National investigations

Concerns about patient safety in any area of NHS-funded healthcare in England can be referred to us by any person, group or organisation. We review these concerns against our investigation criteria to decide whether to conduct a national investigation. National investigation reports are published on our website and include safety recommendations for specific organisations. These organisations are requested to respond to our safety recommendations within 90 days, and we publish their responses on our **website**.

Maternity investigations

We investigate incidents in NHS maternity services that meet criteria set out within one of the following national maternity healthcare programmes:

- Royal College of Obstetricians and Gynaecologists' 'Each Baby Counts' report
- MBRRACE-UK 'Saving Lives, Improving Mothers' Care' report.

Incidents are referred to us by the NHS trust where the incident took place, and, where an incident meets the criteria, our investigation replaces the trust's own local investigation. Our investigation report is shared with the family and trust, and the trust is responsible for carrying out any safety recommendations made in the report.

In addition, we identify and examine recurring themes that arise from trust-level investigations in order to make safety recommendations to local and national organisations for system-level improvements in maternity services.

For full information on our national and maternity investigations please **visit our website**.

Terms used in this report

Abdominal transducers are the devices placed on a woman and pregnant person's abdomen to measure contractions and the baby's heart rate.

Anomaly scan is the mid-pregnancy anomaly ultrasound scan (USS) looks for some physical abnormalities in a baby. The USS only looks for these problems and can't find everything that might be wrong. It looks in detail at a baby's bones, heart, brain, spinal cord, face, kidneys and abdomen. It allows the sonographer or doctor to look specifically for 11 conditions, some of which are very rare.

Carbon monoxide test tests for carbon monoxide (CO), a poisonous gas that reduces the amount of oxygen to both woman and pregnant person and baby. The CO test is a simple non–invasive breath test which gives a woman and pregnant person an immediate indication of the CO level in their body.

Cardiotocography (CTG) is an electronic means of recording the unborn baby's heart rate pattern, to assess their well-being. This is used both during the antenatal period, and during labour. During labour, a woman and pregnant person's contractions are also monitored by this machine which produces a printed or electronic record referred to as the CTG. It is usually performed externally, using two devices (transducers) placed on a woman and pregnant person's abdomen.

Dating scan is an ultrasound scan completed around 10 – 14 weeks of pregnancy to check the duration of a pregnancy and the development of the baby.

Doppler device is the ultrasound equipment used during an ultrasound examination that measures blood flow in a baby and/or the placenta. It is used in a variety of situations to check on the health of a baby.

Established labour is when the woman and pregnant person's cervix is dilated to about 4 cms and they are having regular contractions.

Fetal and **fetus** is sometimes used in place of 'baby's' and 'baby'.

Fetal compromise refers to the restriction of blood flow to the baby during pregnancy.

Fetal scalp electrode (FSE) is a small clip placed on the unborn baby's head or bottom, if external monitoring produces an unreadable CTG. It is applied during a vaginal examination.

Growth scans is an ultrasound scan performed to check the overall wellbeing of a baby. It involves some combination of assessing a baby's size, the amount of fluid around a baby and the measurement of blood flow to the placenta and within a baby using Doppler ultrasound.

Histology is the study of human tissue using a microscope.

Histopathology is the study of changes in diseased human tissue using a microscope.

Intrapartum means the period of time from the onset of a woman and pregnant person's labour to when a baby is born.

Intrapartum stillbirth is when a baby was thought to be alive at the start of labour but was born, beyond 37 weeks of gestation, with no signs of life.

Intrauterine means within the woman and pregnant person's womb.

Latent phase of labour refers to the first part of labour, when there are painful contractions and there is some cervical change, including thinning out and opening of the cervix.

Meconium is a baby's first bowel motion, formed mainly of mucus and bile. It is usually passed after birth and can sometimes be found in the amniotic fluid ('waters') during labour.

Membrane sweeps where a midwife or doctor uses a single finger to sweep around the cervix in a circular motion to release hormones. This is designed to reduce the need for formal induction of labour.

Neonatal resuscitation the delivery of inflation breaths to a recently born baby with or without chest compressions.

Obstetric refers to care provided to a woman and pregnant person during labour and before and after a pregnancy.

Obstetric-led implies care will primarily be delivered by an obstetrician.

Perinatal refers to the period of time shortly before, during or after birth.

Placental pathologies refers to damage or insults to the placenta, the circulatory system between the woman and pregnant person and the fetus.

Resuscitaire is a medical device which is has the capability to provide warmth, oxygen and resuscitation equipment to enable an emergency response to the birth of a baby.

Symphysis-fundal height is a measurement of the size of the uterus which is used to assess a baby's growth during pregnancy. It is measured from the top of the uterus to a woman and pregnant person's pubic bone.

Third trimester refers to the last 3 months of a pregnancy.

About this report

This national learning report highlights the themes identified within 37 HSIB maternity investigations into intrapartum stillbirth which occurred between April and June 2020. The report describes the context of the COVID-19 pandemic and how existing and emerging risks associated with maternity care may have impacted on the rate of referrals relating to incidences of intrapartum stillbirth that were made to HSIB during this time. Robust family engagement took place for each of the 37 maternity investigations; this report relies on evidence from the individual investigation reports and therefore independent consultation with families was not undertaken for this report.

The report is colour coded to reflect six themes representing the factors contributing to the risks managed within maternity care:

1 **Guidance**

2 **Management of risk**

3 **Telephone triage**

4 **Interpretation services**

5 **Work demands and capacity to respond**

6 **Neonatal resuscitation** (resuscitation of the newborn baby).

The figure on page 12 highlights how some risks are well recognised as existing in maternity care, and how some risks may have been exacerbated and others created by the COVID-19 pandemic.

Readers can choose to read all sections of the report or focus on specific contributory factors based on the colour-coded theme.

Executive Summary

Introduction

This national learning report reviews the findings of HSIB maternity investigations into intrapartum stillbirths referred between 1 April and 30 June 2020 (the first peak of the COVID-19 pandemic in England). 'Intrapartum' means the period of time from the onset of a woman and pregnant person's labour to when a baby is born. 'Intrapartum stillbirth' is when a baby was thought to be alive at the start of labour but was born, beyond 37 weeks of gestation, with no signs of life (see below for more details). In this report 'fetal' and 'fetus' is sometimes used in place of 'baby's' and 'baby'.

This report aims to:

- inform understanding about the range of factors that may have contributed to the increased referral rate to HSIB of incidences of intrapartum stillbirth
- promote and support learning discussions within organisations
- influence the development of systems and processes to optimise patient safety, particularly during times of increased pressure on the healthcare service
- identify potential safety risks that merit further HSIB investigation.

Method

A review of HSIB's maternity investigation reports identified 37 reports concerning cases of intrapartum stillbirth referred in this time period, where completed and checked reports were available and where families gave consent for publication. The reports were coded and analysed using recognised methods and themes were identified.

Definition of terms and investigation criteria

HSIB uses the definition of intrapartum stillbirth from the Royal College of Obstetricians and Gynaecologists (RCOG) Each Baby Counts national quality improvement programme: 'when the baby was thought to be alive at the start of labour but was born with no signs of life'. The HSIB criteria to investigate stillbirths includes full-term deliveries (beyond 37 weeks of gestation) following labour that resulted in an intrapartum stillbirth. This excludes cases that include the death of the woman and pregnant person and includes cases in which:

- labour was diagnosed by a health professional; this includes the latent phase of labour (when the woman and pregnant person's cervix is less than 4cm dilated)

- the woman and pregnant person called the unit to report any concerns of being in labour, for example (but not limited to) abdominal pains, contractions, or suspected ruptured membranes (waters breaking)

- the baby was thought to be alive at induction of labour (that is, at the time when labour was started artificially)

- the baby was thought to be alive following suspected or confirmed pre-labour rupture of membranes (that is, after the woman and pregnant person's waters had, or were suspected to have, broken before they had gone into labour).

Findings

No direct effects of COVID-19 infection were seen in any of the reports reviewed. Five of the women and pregnant people had clinical symptoms consistent with COVID-19 infection and none of them tested positive. Testing for COVID-19 was limited in the period covered by the review and not all women and pregnant people were tested. Of the 37 cases, 27 (73%) of pregnancies were at or beyond 40 completed weeks of pregnancy. The majority of deaths occurred due to problems with the placenta and compromised blood flow to the baby.

Of the women and pregnant people in the 37 reports, 16 (43%) had a first language other than English, and women and pregnant people from ethnic minority or socio-economically deprived backgrounds were over-represented.

Six main themes emerged from the analysis of the reports:

1 **Guidance**

2 **Management of risk**

3 **Telephone triage**

4 **Interpretation services**

5 **Work demands and capacity to respond**

6 **Neonatal resuscitation** (resuscitation of the newborn baby).

The figure below represents these themes, which are colour coded within the report, and reflect issues identified within the delivery of maternity care that either pre-existed, were exacerbated by, or were specific to, the COVID-19 pandemic.

1 Guidance

2 Management of risk

3 Telephone triage

4 Interpretation services

5 Work demands and capacity to respond

6 Neonatal resuscitation

Pre-existing maternity care issues **irrespective** of COVID-19

Ring 1

Maternity care issues **exacerbated** during the COVID-19 pandemic

Ring 2

Maternity care issues **specific** to the COVID-19 pandemic

Ring 3

1 Guidance

In response to the changing situation and developing understanding of risks during the first wave of the COVID-19 pandemic, a large volume of rapidly changing guidance was produced. Despite best efforts to make this accessible to staff, investigations found variation in local implementation, difficulty in assimilating the changes and in one instance an important discrepancy between two sets of current national guidance on the management of reduced fetal movements.

2 Management of risk

Although the NHS identified continued provision of maternity services as a priority, operational changes were made to reflect the need to reduce the risk of transmission of infection. In all the cases reviewed, the women and pregnant people received the recommended number of appointments and scans, and appropriate bereavement care was provided. Some face-to-face antenatal (pre-birth) visits were replaced with remote consultations, resulting in fewer opportunities to perform physical examinations such as symphysis-fundal height measurement (measurement of the size of the uterus which is used to assess a baby's growth during pregnancy), and carbon monoxide testing (a simple non–invasive breath test which gives women an immediate indication of the carbon monoxide level in their body) was paused. Some hospital ultrasound scans were stopped or delayed during this period.

3 Telephone triage

Difficulties in communication were identified, relating to the availability and presentation of clinical records, documentation and communication of information from triage calls, and availability of interpretors particularly in urgent circumstances. The usual reliance on family members to provide translation support, which is not in line with national guidance, was emphasised when policies were introduced requiring women and pregnant people to attend antenatal appointments alone.

4 Interpretation services

The review identified that family members do provide translation support when interpretation services cannot be provided by the local maternity service, even though this is not in line with national guidance. However, during the first wave of the pandemic, when women and pregnant people were required to attend antenatal appointments alone, the provision of interpretation services was even more critical.

5 Work demands and capacity to respond

Changes were identified in work processes, staffing levels and physical layout of the space in which staff were working, resulting from the pandemic. Membrane sweeps (a midwife or doctor uses a single finger to sweep around the cervix), designed to reduce the need for formal induction of labour, were stopped in some centres, to reduce the infection risk associated with more prolonged contact between patients and staff. Some of the necessary changes made to the physical space, for example to enable staff to don and doff (put on and take off) personal protective equipment, had unintended and unforeseen consequences in terms of the usability of equipment in its new position.

6 Neonatal resuscitation

The review highlighted gaps between how neonatal resuscitation (delivery of inflation breaths with or without chest compressions) is expected or imagined to work and how it actually happens. This issue has been highlighted in other types of national reports. The review identified that existing systems, equipment and environments to support neonatal resuscitation do not appear to consistently enable all staff to act and respond as required by the guidance.

Conclusion

This HSIB national learning report has identified significant efforts to maintain good care for patients during an unprecedented pandemic and the resulting changes in healthcare systems. HSIB makes safety recommendations to reduce variation and improve safety regarding remote consultation, communication, monitoring of fetal wellbeing, triage, and availability of interpretation services. Further safety recommendations relate to taking a proactive approach to the assessment of patient safety risks and the use of an overall safety management system in maternity care, as used in other safety-critical industries.

HSIB makes the following safety recommendations

Safety recommendation R/2021/144:
HSIB recommends that NHS England and NHS Improvement leads work to develop a process to ensure consistency and clarity across national maternity clinical guidance.

Safety recommendation R/2021/145:
HSIB recommends that future iterations of the Royal College of Obstetricians and Gynaecologists' guidance clarify the management of a reported change in fetal movements during the third trimester of pregnancy with due regard to national policy.

Safety recommendation R/2021/146:
HSIB recommends that NHS England and NHS Improvement leads work to collate and act on the evidence on the risks and benefits associated with the use of remote consultations at critical points in the maternity care pathway.

Safety recommendation R/2021/147:
HSIB recommends that NHSX develops specifications for electronic patient record (EPR) systems that require adherence to national interconnectivity standards for the exchange of core maternity healthcare information. The specifications should include functionality to enable both women and pregnant people and professionals to add to the record, and also support alerting functionality.

Safety recommendation R/2021/148:
HSIB recommends that the Department of Health and Social Care commission a review to improve the reliability of existing assessment tools for fetal growth and fetal heart rate to minimise the risk for babies.

Safety recommendation R/2021/149:
HSIB recommends that NHS England and NHS Improvement leads the development of minimum operating standards for pre assessment maternity telephone triage services to support safe and consistent telephone triage to ensure reliable identification of risks.

Safety recommendation R/2021/150:
HSIB recommends that NHS England and NHS Improvement develop minimum operating standards for interpretation services in maternity care which will include a communication risk assessment.

Safety recommendation R/2021/151:
HSIB recommends that NHS England and NHS Improvement develop a framework to support Trusts to anticipate operational risk in maternity services when delivering neonatal resuscitation.

HSIB makes the following safety observations

Safety observation O/2021/126:
It may be beneficial if further work is done to understand the specific aspects of the healthcare system which could explain the disparity in the experience and risk for women and pregnant people from Black, Asian and minority ethnic backgrounds and those with higher socio-economic deprivation.

Safety observation O/2021/127:
It may be beneficial if multidisciplinary simulation is considered as a tool to support prospective risk analysis for neonatal resuscitation.

Safety observation O/2021/128:
It may be beneficial if expertise applied within other safety critical industries is integrated into the development and implementation of a maternity-focused proactive safety management system.

Contents

1 Background and context

1.1 Intrapartum stillbirth

1.1.1 As with any instance of the death of a baby or child, stillbirths have long-lasting effects on parents, their families and healthcare professionals. The unexpected death of a baby, where parents have no time to prepare, as in the case of intrapartum stillbirth, has a considerable impact on all concerned (Nuzum, 2018). Stillbirths have been associated with significant negative emotional, psychological, social and financial consequences for families who endure this experience (Heazell et al, 2016).

1.1.2 The term 'intrapartum' refers to the period of time from the onset of a woman and pregnant person's labour to when a baby is born. HSIB uses the definition of an intrapartum stillbirth from the Royal College of Obstetricians and Gynaecologists (RCOG) Each Baby Counts national quality improvement programme: 'when the baby was thought to be alive at the start of labour but was born with no signs of life' (Royal College of Obstetricians and Gynaecologists, 2015a). The HSIB criteria to investigate stillbirths includes full-term deliveries (beyond 37 weeks of gestation) following labour that resulted in an intrapartum stillbirth (**Healthcare Safety Investigation Branch, 2021a**). This excludes cases that include the death of the woman and pregnant person and includes cases in which:

- labour was diagnosed by a health professional; this includes the latent phase of labour (when the woman and pregnant person's cervix is less than 4cm dilated)
- the woman and pregnant person called the unit to report any concerns of being in labour, for example (but not limited to) abdominal pains, contractions, or suspected ruptured membranes (waters breaking)
- the baby was thought to be alive at induction of labour (that is, at the time when labour was started artificially)
- the baby was thought to be alive following suspected or confirmed pre-labour rupture of membranes (that is, after the woman and pregnant person's waters had, or were suspected to have, broken before they had gone into labour).

1.1.3 The Office for National Statistics (ONS) publishes data on all stillbirths of babies born after 24 weeks' gestation where the baby shows no signs of life at birth (Office for National Statistics, n.d.). MBRRACE-UK also

defines stillbirth as occurring 'before or during birth once a pregnancy has reached 24 weeks' (MBRRACE-UK, 2020a). The RCOG Each Baby Counts improvement programme distinguishes between antepartum (pre-labour) and intrapartum (during labour) stillbirths.

1.1.4 This national learning report focuses on intrapartum stillbirths, based on HSIB's criteria for investigation (which is different from those of other national organisations), which occurred during the early part of the COVID-19 pandemic, between 1 April and 30 June 2020.

1.2 Rate of stillbirths in the early part of the COVID-19 pandemic

1.2.1 This review of HSIB's maternity investigations into intrapartum stillbirths was prompted by a reported increase in stillbirths in the early part of the COVID-19 pandemic (Khalil et al, 2020) and an increase in such referrals to HSIB.

1.2.2 In 2015 (when international comparison was last made), the UK stillbirth rate was 24th out of 49 high-income countries and an estimated 4.2 million women and pregnant people globally lived with depression associated with having a stillbirth (Heazell et al, 2016).

1.2.3 The stillbirth rate in the UK in 2018 was 3.51 per 1,000 births. Of 735,745 births, 2,579 babies were stillborn. Stillbirth rates have reduced by just over 16% (from 4.2 per 1,000 total births in 2013 to 3.51 per 1,000 total births in 2018) representing approximately 500 fewer stillbirths in 2018 (MBRRACE-UK, 2020a). One third of this reduction is thought to be associated with the introduction of national initiatives since 2015 (MBRRACE-UK, 2020a).

1.2.4 The ONS (2020) reported that the stillbirth rate in April 2020 was the highest seen in the months examined so far in 2020 and the highest recorded since September 2018.

1.2.5 A subsequent review of the ONS data (Stowe et al, 2021) did not find an overall increase in all stillbirths in England during the period of the pandemic considered within this review. International studies vary (Kumar et al, 2020; Mor et al, 2020; Ashish, 2020; De Curtis et al, 2020) but a systematic review showed an overall increase in international stillbirth rates (Chmielewska et al, 2021). There remains uncertainty among experts whether the rate of stillbirths has increased during the COVID-19 pandemic.

1.2.6 Between 1 April and 30 June 2019 there were 24 referrals to HSIB maternity investigation programme that fitted the specified criteria for intrapartum stillbirth (Healthcare Safety Investigation Branch, 2021a). HSIB noted there were 45 referrals for the same time period in 2020.

1.3 Changes in healthcare guidance and service delivery in the early stages of the COVID-19 pandemic

1.3.1 Women and pregnant people were added to the 'clinically vulnerable' group on 16 March 2020 (Public Health England, 2020a). Maternity services rapidly adjusted the way they delivered care throughout the pregnancy pathway. A series of national guidance was issued in subsequent weeks to balance the potential risk of COVID-19 infection in women and pregnant people and their babies while continuing to provide effective maternity care. This national guidance was locally interpreted by maternity service providers. From 29 April, it was recommended that maternity services make regular contact with women and pregnant people under their care to explain access to services (NHS England and NHS Improvement, 2020b).

1.3.2 On 17 March 2020, the NHS Chief Executive and NHS Chief Operating Officer mandated change in NHS services to prepare for large numbers of patients with COVID-19 (NHS England and NHS Improvement, 2020c). All non-urgent elective (planned) work was postponed from 15 April 2020. Maternity services remained operational.

1.3.3 On 23 March, the UK Prime Minister announced that the public should only leave their homes for essential reasons (Prime Minister's Office, 2020). These 'stay at home' restrictions started to be eased from 13 May 2020.

2 Maternity care during COVID-19

This section considers maternity care and the management of identified risks associated with pregnancy during the COVID-19 pandemic, between April and June 2020. These topics are expanded upon further within the supplementary information provided with this report.

2.1 Changes in guidance for maternity care during the COVID-19 pandemic

2.1.1 National Institute for Health and Care Excellence (NICE) antenatal care guidance (National Institute for Health and Care Excellence, 2019a) sets out the requirements for antenatal care, **see appendix 1**. The following sections describe key modifications published in guidance during the COVID-19 pandemic.

2.1.2 In March 2020 guidance on accessing maternity services during pregnancy was published by the Royal College of Obstetricians and Gynaecologists (RCOG) with the Royal College of Midwives, Royal College of Paediatric and Child Health, Royal College of Anaesthetists and the Obstetric Anaesthetists Association based on advice from Public Health England and a range of other sources (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020a; 2020b). This is described in the HSIB report, '**Maternal death: learning from maternal death investigations during the first wave of the COVID-19 pandemic**' (Healthcare Safety Investigation Branch, 2021).

2.1.3 Specific advice on social distancing for women and pregnant people above 28 weeks' gestation was added on 21 March 2020 (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020c). General changes in practice included the following (see figure 1):

Figure 1 Summary of COVID-19 national guidance

- Increased use of personal protective equipment (Public Health England, 2020b, Royal College of Anaesthetists, Association of Anaesthetists, Faculty of Intensive Care Medicine, Intensive Care Society, Obstetric Anaesthetists Association, 2021).

- Increased use of remote consultations (NHS England and NHS Improvement, 2020d).

- Restricting family visits to reduce the risk of transmission of the virus (NHS England and NHS Improvement, 2020e).

- Access to some services were reduced, such as ultrasound scans (NHS England and NHS Improvement, 2020f).

- Services and patient pathways were reconfigured to separate patients with and without symptoms suggesting COVID-19.

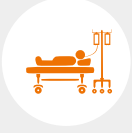
- Staff were redeployed to other areas of hospitals (NHS England and NHS Improvement, 2020b).

- Critical care services were expanded, and additional equipment sourced (NHS England and NHS Improvement, 2020g).

- Staff who developed symptoms of COVID-19 were asked to self-isolate, which meant being absent from work for 14 days (Public Health England, 2020c).

- Staff received risk-assessments, and some were redeployed to non-patient-facing roles (Health and Safety Executive, 2020).

- Temporary reorganisation guidance for intrapartum maternity care was published on 9 April 2020 (NHS England and NHS Improvement, 2020h).



- Guidance for coroners allowed for increased use of other sources of evidence to reduce post-mortem examination numbers (Lucraft, 2020).

2.1.4 Guidance across maternity services in England changed in relation to women and pregnant people having their partner, relative or friend with them when receiving care during the COVID-19 pandemic. An NHS framework (NHS England and NHS Improvement, 2020a) was first published in September 2020, to assist NHS trusts to reintroduce access for partners, visitors and other support people for a woman and pregnant person using maternity services in England. This guidance has continued to be updated to increase the attendance of partners at antenatal and ultrasound scan appointments (NHS England and NHS Improvement, 2021).

2.1.5 The RCOG published version 1 of 'Coronavirus (COVID-19) infection in pregnancy' on 9 March 2020 (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020a). This highlighted that pregnancy care during the COVID-19 pandemic was an essential service and that women and pregnant people should be advised to attend routine antenatal care appointments unless advised to do otherwise. Maternity units were urged to adopt teleconferencing and videoconferencing capability and to consider what appointments may be conducted remotely.

2.1.6 On 30 March 2020 the RCOG recommended that if capacity for scanning was compromised, ultrasound scans should be prioritised in the following order: an anomaly scan between 18 and 23 weeks' gestation, then a dating (with or without screening scan) at 11 weeks and 2 days (11+2) to 14 weeks +1 day (14+1) gestation and then growth scans (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020i).

2.1.7 In version 5 of 'Coronavirus (COVID-19) infection in pregnancy', published on 28 March 2020, the RCOG highlighted the importance of antenatal care continuing, stating that 'if women do not attend antenatal services they are at an increased risk of maternal death, stillbirth and other adverse perinatal outcome'. This guidance acknowledged increasing pressure on the NHS and maternity services, which may require changes to service provision (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020d).

2.1.8 In version 5 of 'Coronavirus (COVID-19) infection in pregnancy', maternity units were advised to maximise the use of remote consultations to provide additional antenatal consultations and consider areas in which services could be rationalised. This included:

- The suspension of carbon monoxide (CO) monitoring as a precautionary measure over concerns of coronavirus transmission (as women and pregnant people have to exhale during the procedure). Smoking is associated with an increased risk of poor perinatal outcome, including stillbirth. To aid smoking

reduction a care bundle for reducing perinatal mortality' advised CO testing for all women and pregnant people at booking and 36 weeks' gestation (NHS England and NHS Improvement, 2019).

- Reducing inductions of labour (IOL) where this was not deemed strictly necessary for clinical reasons.

- Reducing growth scans not strictly included within current guidance.

2.1.9 Further guidance for antenatal and postnatal services in the evolving coronavirus (COVID-19) pandemic was produced 2 days later on 30 March 2020 (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020i). Key elements were to maintain essential monitoring and that 'many elements of antenatal care may require in-person assessment in particular blood pressure and urine checks, measurement of fetal growth and blood tests'. The guidance acknowledged the shortage of evidence about rationalising visit numbers and advised 'a minimum of 6 face-to-face antenatal consultations' and suggested a modified schedule (**see appendix 1**). This included the consideration for appointments from 41+0 weeks' gestation to be followed immediately by either an outpatient or inpatient IOL to avoid a further attendance.

2.1.10 Advice on intrapartum services for all women and pregnant people was contained in version 6 of the general COVID-19 infection in pregnancy guidance, issued on 3 April 2020, which highlighted that 'intrapartum services should be provided in a way that is safe, with reference to minimum staffing requirements with a maintained ability to provide emergency multidisciplinary care'. This guidance also stated that 'women should be permitted and encouraged to have a birth partner present with them in labour and during the birth' (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020e). It acknowledged that there would be an expectation to restrict the number or swapping of birth partners, and that some/all visitors may be restricted in the antenatal and postnatal settings, in line with individual hospital policies.

2.1.11 The International Confederation of Midwives released a statement in March 2020 suggesting 'where the health systems can support homebirth, healthy women experiencing a normal pregnancy and with support from qualified midwives, with appropriate emergency equipment, may be safer birthing at home or in a primary maternity unit/birth centre than in a hospital where there may be many patients (even non-maternity patients) with COVID-19' (International Confederation of Midwives, 2020).

2.1.12 The need for temporary reorganisation of intrapartum maternity care was recognised in NHS general guidance issued on 9 April 2020 (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020e). This guidance outlined that providing safe services meant balancing the response to the COVID-19 pandemic with the continuing need to manage obstetric risk. The need to suspend some services was acknowledged, with a potential consequence on place of birth choice. Secondary considerations for place of birth, away from an obstetric-led maternity unit, included the potential impact on transfer times, with the increased burden placed on ambulance services. Further guidance was provided on 9 April 2020 in 'Guidance for the provision of midwife-led settings and homebirth in the evolving coronavirus (COVID-19) pandemic' (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020f). Different phases of response escalation were suggested dependent on midwifery shortages and ambulance service provision in an attempt to keep all place of birth options available for as long as possible.

2.1.13 Increasing anxiety around COVID-19 transmission in hospital was addressed in version 7 of the general guidance, issued on 9 April 2020, which 'recognised that attending maternity services, particularly when located in hospitals, may cause significant anxiety about the possibility of contracting COVID-19' (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020g). Further guidance was published on 22 May 2020, which highlighted the need to ensure wider dissemination of this information to all user groups: 'such information should be available in community languages other than in English and in visual or easy to understand formats as far as possible – where such interpretation services are not available consideration should be given to providing local community online groups and radio stations with information about any service changes to enable them to share key information with the local communities' (Royal College of Obstetricians and Gynaecologists, 2020h). Accessing more vulnerable groups of women and pregnant people was also addressed in this guidance, with advice to prioritise face-to-face contacts for women and pregnant people with an increased risk of complications due to COVID-19, including women and pregnant people from all ethnic minorities (excluding White minorities) or 'Black, Asian and ethnic minority backgrounds (excluding White minorities)' and women and pregnant people living in socio-economic deprivation.

2.2 Association of COVID-19 and intrapartum stillbirth

The COVID-19 pandemic has brought in an unprecedented change in daily wellbeing and maternity care across the world. Many maternity services are responding to restrictions and disruptions through national or local

lockdowns. As described in **section 1.2**, some studies suggest there was an increase in stillbirths during the first peak of the COVID-19 pandemic. The reason(s) for this remains unclear, but could plausibly be separated into direct and indirect effects of COVID-19.

Direct effect of the COVID-19 pandemic

2.2.1 A single centre study with a large US cohort (group) of 82 infants born to women and pregnant people who had tested positive for COVID-19 demonstrated no cases of virus transmission to unborn babies (Salvatore et al, 2020). A UK cohort study demonstrated that 12 of 265 (5%) infants born to women and pregnant people with confirmed COVID-19 tested positive, 6 of them within the first 12 hours after birth (Knight et al, 2020). There have been reports of fetal death directly related to intrauterine transmission of COVID-19 in conjunction with findings in the placental and/or fetal tissue (Linehan et al, 2021). However, the majority of stillbirth data has not demonstrated a risk of vertical transmission (direct transfer from the woman and pregnant person to the baby) (Di Mascio, 2020).

2.2.2 It is rare for respiratory viruses to result in intrauterine transmission of infection to the fetus as the placenta acts as a barrier to infection. As the pandemic progressed there were single case reports of COVID-19 infection being isolated from amniotic fluid (Zamaniyan et al, 2020) and placental tissue (Kirtsman et al, 2020). These appear to be rare events, with most reports showing no evidence of direct transfer from the woman and pregnant person to the baby, but appeared to be associated with a range of different placental pathologies which have been associated with stillbirth (Walker et al, 2020; Sharps et al, 2020).

Indirect effects of the COVID-19 pandemic

2.2.3 Many studies reporting an excess in stillbirth rates have raised concerns about the indirect effects of the pandemic. Emerging data about disrupted pregnancy services was highlighted in a news article in Nature in September 2020 (Watson, 2020). These disruptions included reduced face-to-face contacts or cancellation of proposed ultrasound scan surveillance or screening tests, or women and pregnant people being reluctant to attend hospital due to perceived high risk of infection (**Healthcare Safety Investigation Branch, 2021b**; Khalil et al, 2020; De Curtis et al, 2020).

2.3 Management of risk in maternity care

Staff work across teams and various healthcare settings to exchange, interpret, and synthesise information to identify concerns or potential risks associated with the wellbeing of the woman and pregnant person or fetus.

This will determine the clinical care pathway, at the start of a person's pregnancy, to reflect the level of associated risk. Effective interaction between parents and maternity services supports the exchange and sharing of critical information. Women and pregnant people provide their medical history, the symptoms they are experiencing and the beliefs or concerns they may have. Clinical staff, within hospital or community settings, gather this information, in paper or electronic records.

2.3.1 A 'thorough risk assessment' is recommended at each healthcare contact during pregnancy (House of Commons, 2020). Figure 2 summarises the main opportunities for risks to be identified and where critical decisions may be made to manage these risks. The results of medical tests, ultrasound scans or measurements of physical signs will provide cues to clinicians of the health and wellbeing of the woman and pregnant person and their baby/babies and the likelihood of a healthy pregnancy and birth. The reliability, timing and presentation of information may affect clinicians' ability to assess a situation, make judgements and make decisions with the parents. The **supplementary information** provided with this report expands upon the evidence for the use and reliability of the tools and technology relied upon to provide maternity care. Equally, the knowledge and expertise of clinicians determines their ability to interpret the information available.

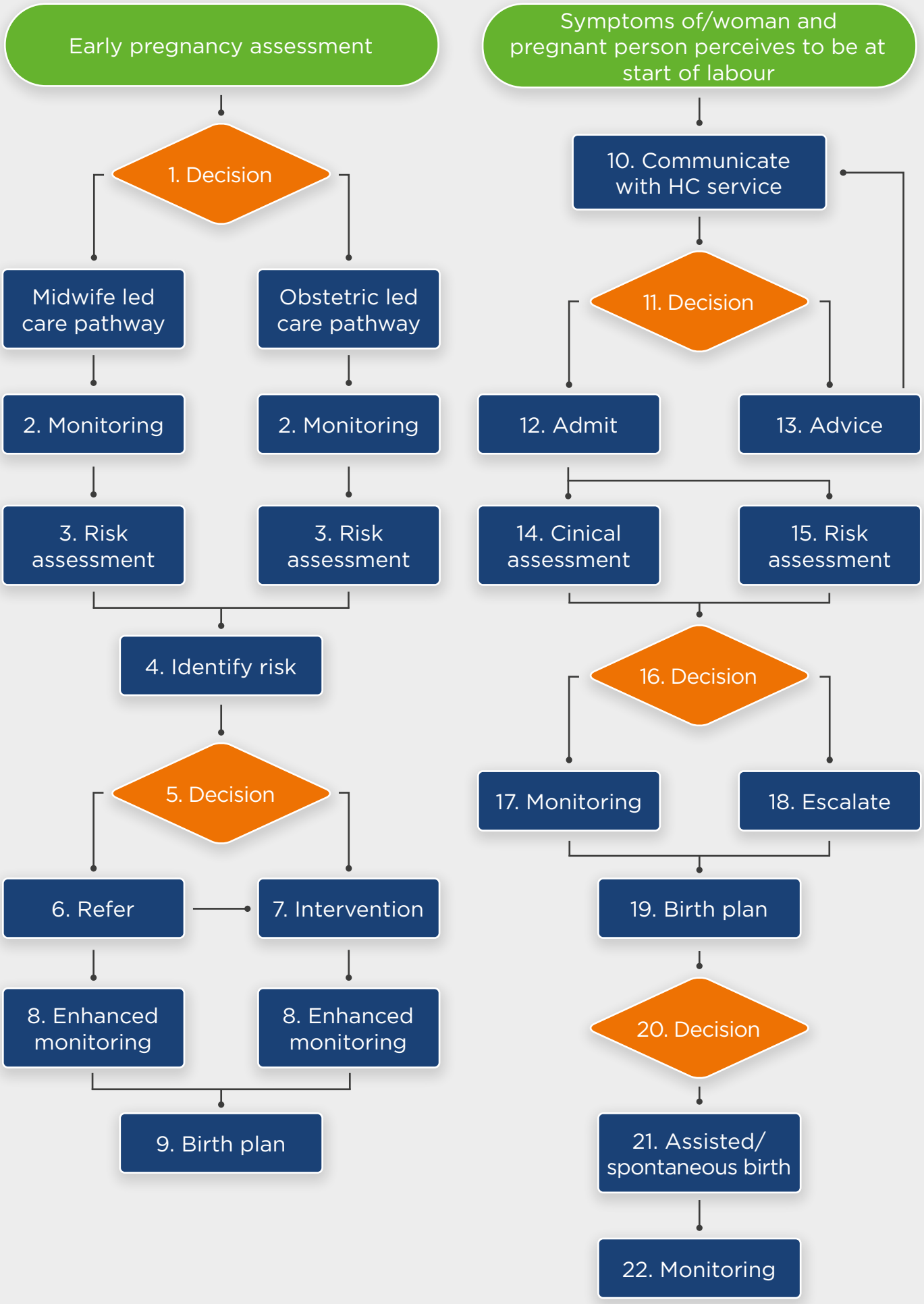
2.3.2 Midwives provide the clinical lead for women and pregnant people assessed as suitable for a low risk care pathway. They provide individualised care and continuity of care within various settings, while co-ordinating with other relevant health professionals and services (Royal College of Midwives, 2016).

Management of risk

2.3.3 The concept of risk management may be considered from different perspectives; firstly, in terms of the ability of clinical staff to manage clinical risks and secondly, how organisations identify and manage risks within the context (or emerging situations such as the COVID-19 pandemic) or environment where care is delivered.

2.3.4 Traditionally, risk management is used to identify threats to life or wellbeing and proactively develop controls to minimise harm. There is a legal requirement for organisations within the UK to ensure they reduce known risks to 'as low as reasonably practicable' (ALARP) (Health and Safety Executive, n.d.). Risk management in healthcare does not currently reflect this approach, which is adopted by other industries (Sujan et al, 2017). A proactive risk assessment enables an organisation to present calculations and qualitative evaluations of the level of risk and associated cost to manage the risk. This provides evidence to any clinical judgement made that the principle of ALARP has

Figure 2 Critical points at which risks to the woman and pregnant person and baby are evaluated



been met, with the understanding that 'the greater the risk, no doubt, the less will be the weight to be given to the factor of cost' (Health and Safety Executive, n.d.). Societal concerns may also inform the perception of the associated cost appropriate to manage a risk, for example if a decision not to implement a control to manage a risk may cause loss of trust among the public (NHS Providers, 2021).

2.3.5 Organisations have a duty to identify hazards relevant to a working environment and understand the associated risks in order to evaluate whether existing controls are sufficient. In some instances, organisational measures to control a known hazard may transfer the risk to other individuals or employees. Equipment procured to help recognise clinical risks may not support clinicians to easily identify, interpret and trust information or make decisions. Limitations in equipment design may create issues with usability, reliability, or suitability for use in a specific environment or in the context of other activities. Any such equipment issues may increase risks relating to the identification of critical information. Clinical staff may be required to manage this risk to minimise potential harm.

Dynamic risk assessment

2.3.6 The concept of a dynamic risk assessment is recommended as a key component of antenatal and intrapartum care (National Institute for Health and Care Excellence, 2019a; n.d.). This requires a continual need to interpret clinical risks to inform clinical decision making. To achieve this, reliable information is required which can identify factors known to influence stillbirth or cause harm to the woman and pregnant person or their baby.

2.3.7 Clinicians' ability to recognise and identify cues that indicate significant and cumulative risks to the wellbeing of the woman and pregnant person or their baby depends upon the quality of the tools available to them. The supplement to this report (**see supplementary information**) highlights the evidence for, and efficacy of, certain assessment tools that are currently recommended and relied on during maternity care, which will be referred to later within this report.

2.3.8 The judgements and decision making required in the context of maternity care may be distributed across several healthcare settings; for example information may be shared across community and inpatient settings, which can create uncertainty around the availability of information required in time-critical situations. Maternity care systems are complex

systems. Decisions are not made in a vacuum and variability in the quality of information, environment, staff and conflicting goals may all influence decision making in the real world (Zsambok and Klein, 1997).

2.3.9 The following sections of this report will consider how maternity systems influence the risk associated with identification of critical cues, which may assist in understanding risks emerging during a pregnancy and the decisions made relevant to intrapartum care.

3 Methods used in this review

This review aimed to provide a comprehensive understanding of the content of HSIB maternity investigation reports relating to intrapartum stillbirth cases, which were referred to HSIB between 1 April and 30 June 2020. This section sets out the approach taken to the identification and analysis of themes across all the reports.

3.1 Inclusion criteria

3.1.1 Maternity reports on intrapartum stillbirth were included within the review if:

- they were referred to HSIB between April and June 2020
- the report had been completed by 30 November 2020, and
- family feedback and consent had been obtained.

This included 37 reports, which had also received a factual accuracy check by the trust and families involved. The criteria for inclusion as an intrapartum stillbirth was based on the definition from the Royal College of Obstetricians and Gynaecologists' Each Baby Counts programme (Royal College of Obstetricians and Gynaecologists, 2015a) (**see section 1.1.2**).

3.2 Approach

3.2.1 The reports were appropriately managed in line with HSIB data handling policies. Data analysis software was used to interrogate the text within the report.

3.2.2 The intrapartum stillbirths were classified by cause of death based on the recognised Cause of Death and Associated Conditions (CODAC) classification system (Frøen et al, 2009). The CODAC system uses a three-level hierarchical tree of coded causes of death; a full description can be found in Frøen et al (2009). The classification categories were discussed and agreed by a multidisciplinary team of three investigators.

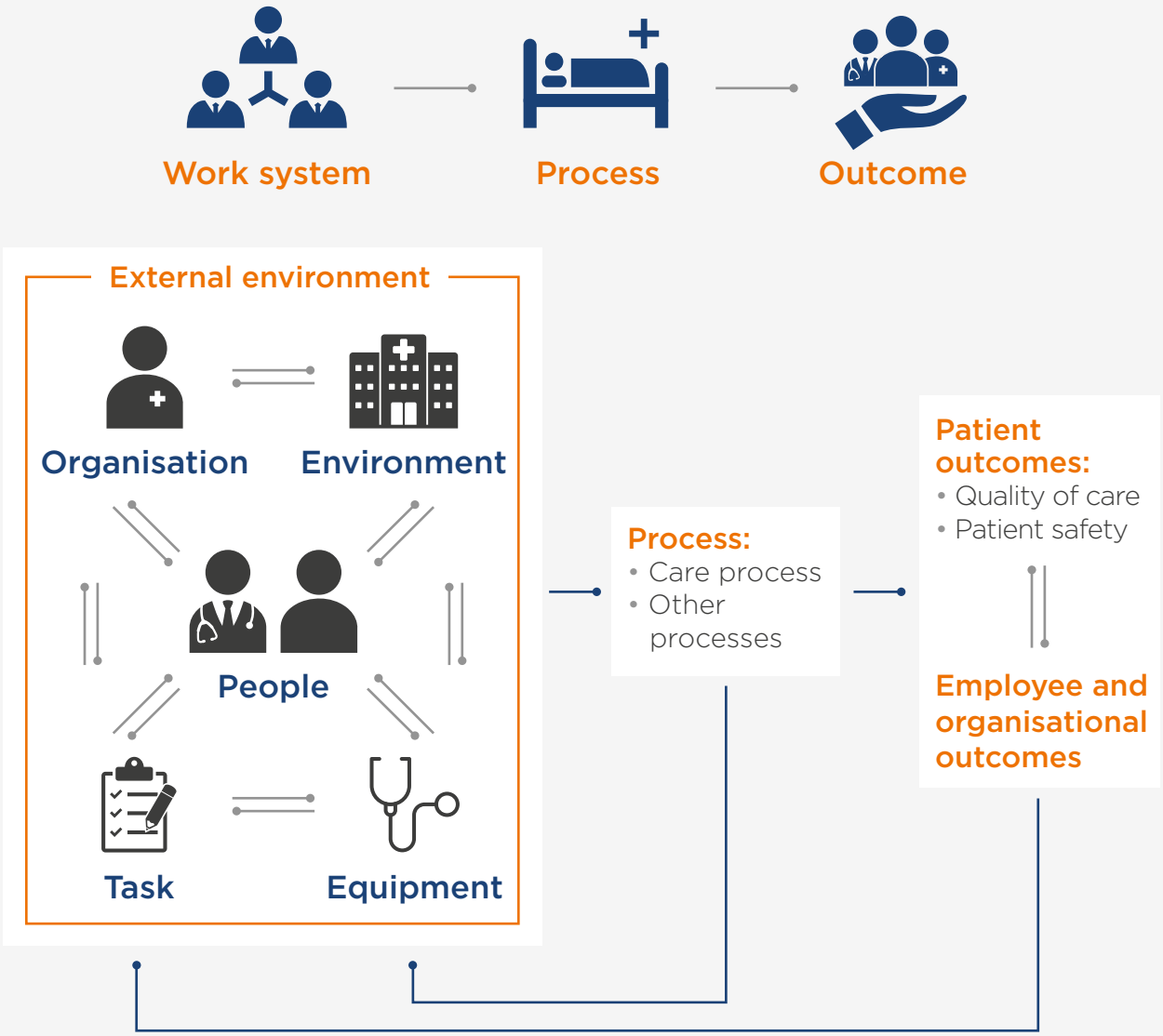
3.2.3 The thematic analysis was completed using a framework to categorise and sort the report text (Ritchie et al, 2014). This enabled the gathering of information referring to 'similar things' to be collated and reviewed to understand common themes across multiple reports. The summary and findings sections of the reports were omitted from coding, as they duplicated information in the main body of the reports. A team of five

staff completed the task of coding including experts in maternity care and system safety science. Joint coding sessions were completed across the team to ensure consistency in the interpretation and use of codes.

3.2.4 The thematic analysis framework created several coding levels for coding to be completed. The framework starts (at the top) with a basic categorisation of 'what' the healthcare processes were and 'where' they occurred. At the next level, codes reflect 'how' the relationship between the structures, work and processes within the healthcare systems influence the findings within the investigation. The 'how' level of coding was informed by the Systems Engineering Initiative for Patient Safety (SEIPS, see figure 3) (Holden et al, 2013; Carayon et al, 2006).

3.2.5 The final level of coding, 'why', was developed through the capture of emergent themes grounded within the evidence and based on knowledge of systems and safety science. This level of coding aimed to establish 'why' certain factors may have influenced the risk and outcome of an intrapartum stillbirth.

Figure 3 The Systems Engineering Initiative for Patient Safety framework (SEIPS) adapted from Holden et al (2013)



4 Analysis of the characteristics and circumstances of the 37 intrapartum stillbirths

This section describes the frequency and number of specific characteristics associated with the women and pregnant people and their pregnancy, in the 37 cases of intrapartum stillbirth investigated by HSIB during April to June 2020. To preserve anonymity, the report has reduced statistical descriptions where there are fewer than three women and pregnant people or babies in a category; some categories are therefore merged.

4.1 Cause of death and conditions associated with death

4.1.1 There are three key processes that are used to gain an understanding of why a baby died (Sands, 2016; Frøen et al, 2009):

- post-mortem examination (PME) – a clinical investigation of a baby undertaken by a perinatal pathologist
- histopathological examination (studying cells using a microscope) of the placenta by a pathologist
- a review of the circumstances and events prior to the death of a baby and the care provided.

4.1.2 In the 37 cases reviewed, all the families were offered a PME of the baby; 17 (46%) declined and 20 (54%) families consented.

4.1.3 The Royal College of Pathologists (Cox and Evans, 2019) recommends that 'As a minimum, all placentas from stillbirths, fetal growth restriction (FGR – below 10th centile with abnormal fetal growth curve during pregnancy), immaturity (less than 32+0 completed weeks gestation), and cases of severe fetal distress requiring admission to a neonatal intensive care unit (NICU), maternal pyrexia (a high temperature >38°C) and late miscarriages (20+0 to 23+6 completed weeks gestation) should be referred' for full pathological examination including histology. In line with national guidance all the placentas were sent for histological examination.

4.1.4 The cause of death and associated conditions as defined by CODAC (Frøen et al, 2009) are shown in figure 4 and figure 5, using information from the clinical investigations and the HSIB reports.

4.1.5 For 10 babies (27%) the cause of death was related to placental function including problems with the function and structure of the placenta.

4.1.6 Two of the babies died following placental abruption – the separation of the placenta from the woman and pregnant person's uterine wall before a baby is born.

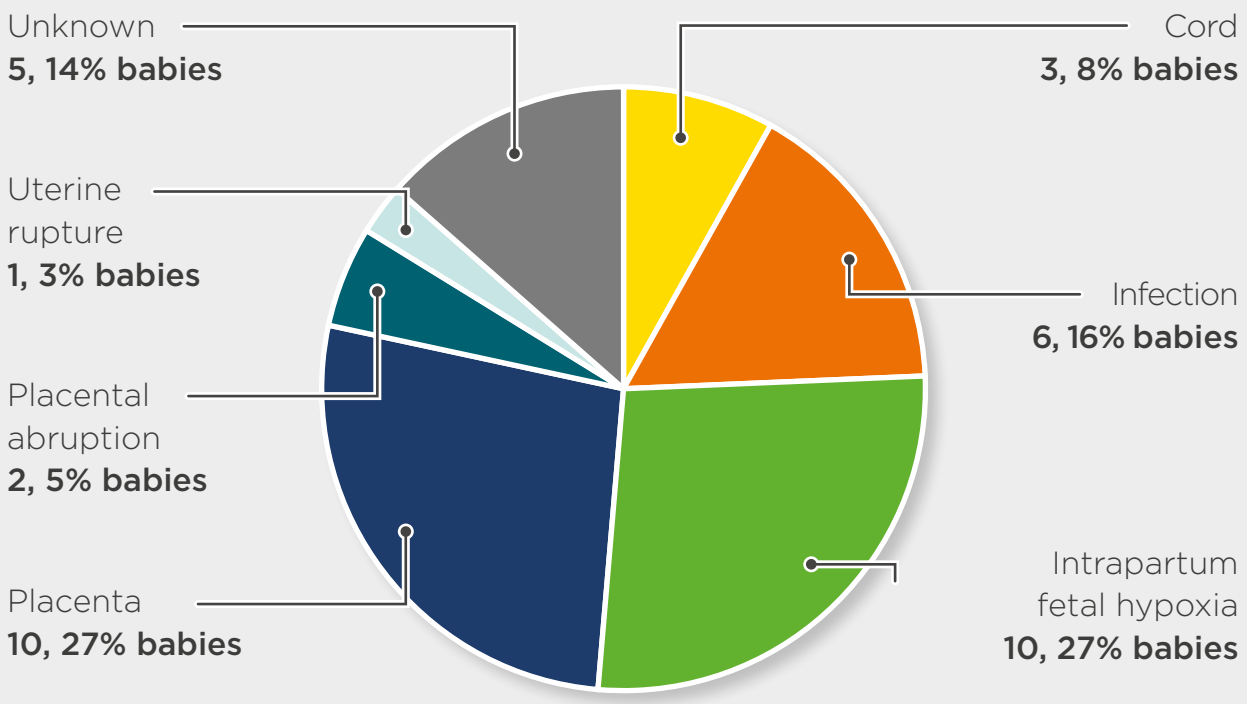
4.1.7 One of the babies died following uterine rupture, where the woman and pregnant person's uterus spontaneously opens, most often along healed scar lines from a previous caesarean birth or surgery on the uterus. Uterine rupture is rare (Royal College of Obstetricians and Gynaecologists, 2015b).

4.1.8 Three of the babies died following complications with the umbilical cord, such as cord prolapse (when the cord slips out of the woman and pregnant person's cervix and blood flow through the cord, and therefore oxygen to the baby, is reduced).

4.1.9 An infective organism was identified from clinical investigations, such as placental swabs, following the death of 6 (16%) of the babies, including group B streptococcus. None of the women and pregnant people presented with any signs of infection, such as temperature or history of infection, prior to death of the baby.

4.1.10 Intrapartum hypoxia (lack of oxygen to a baby during labour) was identified as a cause of death for 10 babies (27%). Five (14%) of the babies had an unknown cause of death. The majority of these did not have a PME, which can assist in understanding the cause of death. Figure 5 shows the associated conditions from the clinical examinations undertaken, such as histopathology, blood tests and cord gasses. Problems with the structure or function of the placenta or cord were found to be an associated condition in many of the babies.

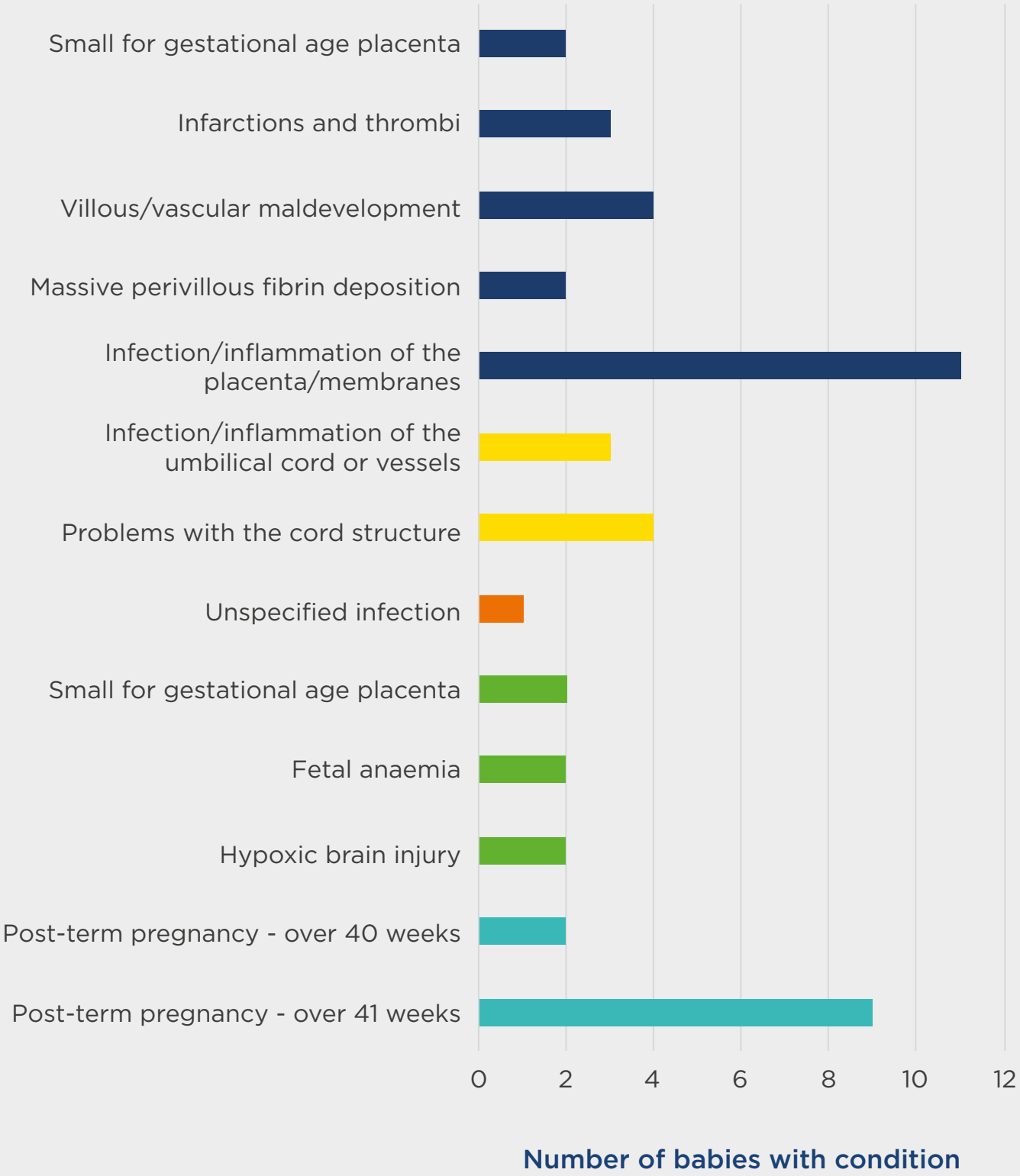
Figure 4 Cause of death as defined by CODAC, Level 1 data (Frøen et al, 2009)



4.1.11 The placenta is an organ that develops during pregnancy and is vital to the wellbeing of a baby. The placenta performs many functions including delivering oxygen and nutrients, transporting waste products such as carbon dioxide, and producing hormones that help babies grow and develop (Griffiths and Campbell, 2015). The umbilical cord connects the placenta and baby.

4.1.12 Problems with the placenta or cord, excluding chorioamnionitis (inflammation or infection of the placenta and membranes), featured in 24 (65%) of the 37 intrapartum stillbirths. These included problems with the development of the placenta (delayed chorionic villous maturation), the structure and function of the placenta (massive perivillous fibrin deposition), placental infarctions (death of parts of the placental tissue due to an interruption in blood flow), small for gestational age placenta and vasa praevia (when umbilical blood vessels run close to the cervix through the placental membranes, unprotected by placental tissue). These conditions put the babies at higher risk of stillbirth. Many of the diagnoses cannot be

Figure 5 Associated conditions, as defined by CODAC (Frøen et al, 2009) for babies where the cause of death was intrapartum hypoxia or unknown



detected during pregnancy with the technology available or through the current national risk assessments provided (see supplementary information). There are often no warning signs or symptoms that the baby's wellbeing is compromised, thus limiting cues for healthcare professionals to plan appropriate care. This is discussed further in **section 5**.

4.1.13 Of the 37 cases reviewed, 11 babies (30%) were identified as being small for gestational age (SGA) or having fetal growth restriction following birth. SGA is associated with many of the placental problems described above. Eight out of 11 of these babies were not identified as SGA during pregnancy. SGA is associated with higher risk of stillbirth (Gardosi et al, 2013). This is explored further in **section 5.4**.

4.2 COVID-19 infection

4.2.1 Cough, high temperature and a loss of sense of smell are associated with COVID-19 infection (World Health Organization, 2020); one or more of these symptoms were experienced by five (13.5%) of the women and pregnant people during their pregnancy.

4.2.2 Eight women and pregnant people received a COVID-19 test; none tested positive. Twenty-three women and pregnant people were not tested, in line with changes in testing policy during the period covered by this report (Department of Health and Social Care, 2020). Tests may have false negative and false positive results (Surkova et al, 2020). Testing information was not available for six of the women and pregnant people. None of the women and pregnant people were diagnosed with COVID-19.

4.3 Timing of intrapartum stillbirth

4.3.1 A typical pregnancy ends between 37 weeks' and 42 weeks' gestation (NHS, 2018). The estimated delivery date is calculated as the date of 40 completed weeks of gestation. The stage of pregnancy gestation at which the baby was found to have died in the 37 cases reviewed is described in figure 6.

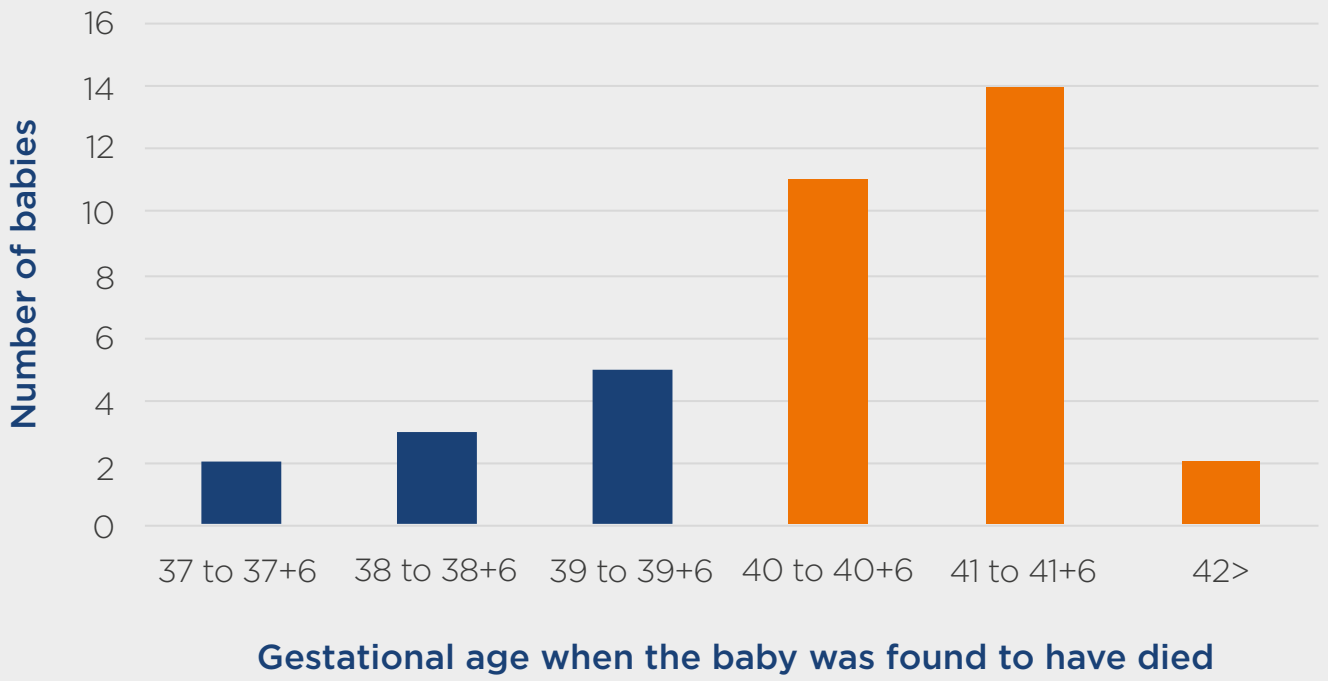
4.3.2 Twenty-seven babies (73%) were beyond 40 completed weeks of gestation, marked in orange in Figure 6 The women and pregnant people were offered induction of labour, in line with national guidance, because they had gone beyond the due date between 41+5 weeks and 42 weeks. This is explored further in **section 5.1**.

4.3.3 The timing of the babies' deaths in relation to contact with healthcare services was reviewed by clinicians (**see figure 7**). Nineteen of the babies (51%) had no signs of life at the first visit to hospital or to see a healthcare

professional when the woman and pregnant person was in early labour; 11 (58%) of these women and pregnant people had made telephone contact for healthcare advice and were advised to remain at home.

4.3.4 For five (14%) of the babies, the baby's heart rate was identified during a visit to hospital, then no signs of life were found when the woman and pregnant person next visited hospital several hours later or the following day. This includes women and pregnant people who attended in early labour and were advised to return home, in line with local and national guidelines, and women and pregnant people undergoing an outpatient induction of labour at home.

Figure 6 The stage of gestation at which the baby was found to have died



Key:

The baby was found to have died prior to the estimated delivery date

The baby was found to have died following the estimated delivery date

4.3.5 In total 24 (65%) of the babies were thought to have died outside of a hospital environment (see figure 7).

4.3.6 Six (16%) of the women and pregnant people were in hospital for labour care or induction of labour, and no signs of life of the baby were found at the next fetal heart rate check in hospital.

4.3.7 Seven (19%) of the babies were thought to have been alive during labour and showed no signs of life when they were born.

Figure 7 The timing of the death of the baby in relation to contact with healthcare services

4.4 Healthcare received

4.4.1 As described in appendix 1, the number of appointments offered during pregnancy differs depending on whether a person has had a child before and/or has any additional pregnancy complications. In the 37 cases reviewed, the people who were pregnant with their first child attended between 7 and 20 appointments during the pregnancy with a midwife, GP, or obstetrician. The women and pregnant people who had previously given birth attended between 7 and 15 appointments, as recommended in national guidance. Thirty-six out of the 37 women and pregnant people were offered antenatal appointments with a healthcare professional in line with local and national guidance (National Institute for Health and Care Excellence, 2019a).

4.4.2 All of the women and pregnant people received two or more ultrasound scans in line with local and national guidance: the dating scan and anomaly scan. Twenty-five of the women and pregnant people received additional ultrasound scans, in line with guidance, during the pregnancy.

4.4.3 In addition, many of the women and pregnant people attended maternity assessment units or emergency departments with concerns during their pregnancy. Sixteen (43%) of the women and pregnant people contacted healthcare services with concerns about reduced fetal movements. This is explored further in **sections 5.1** and **5.4**.

4.5 Demographics and clinical characteristics

4.5.1 A summary of demographic and clinical details of the 37 women and pregnant people is provided below. Full details are provided in **appendix 2**.

- Twenty-seven (73%) of the women and pregnant people were aged between 20 years and 34 years.
- Twenty-four (65%) had a body mass index of less than 30kg/m2.
- Five had a pre-existing medical condition, including diabetes.
- Thirty-five (95%) of the women and pregnant people were non-smokers.
- English was not the first language for 16 (43%) of the women and pregnant people; four of the parents were provided with interpretation services during the HSIB investigation process. This is explored further in section 5.5.
- Twenty-two (59%) of the women and pregnant people had no other children and the baby who died was their first child.

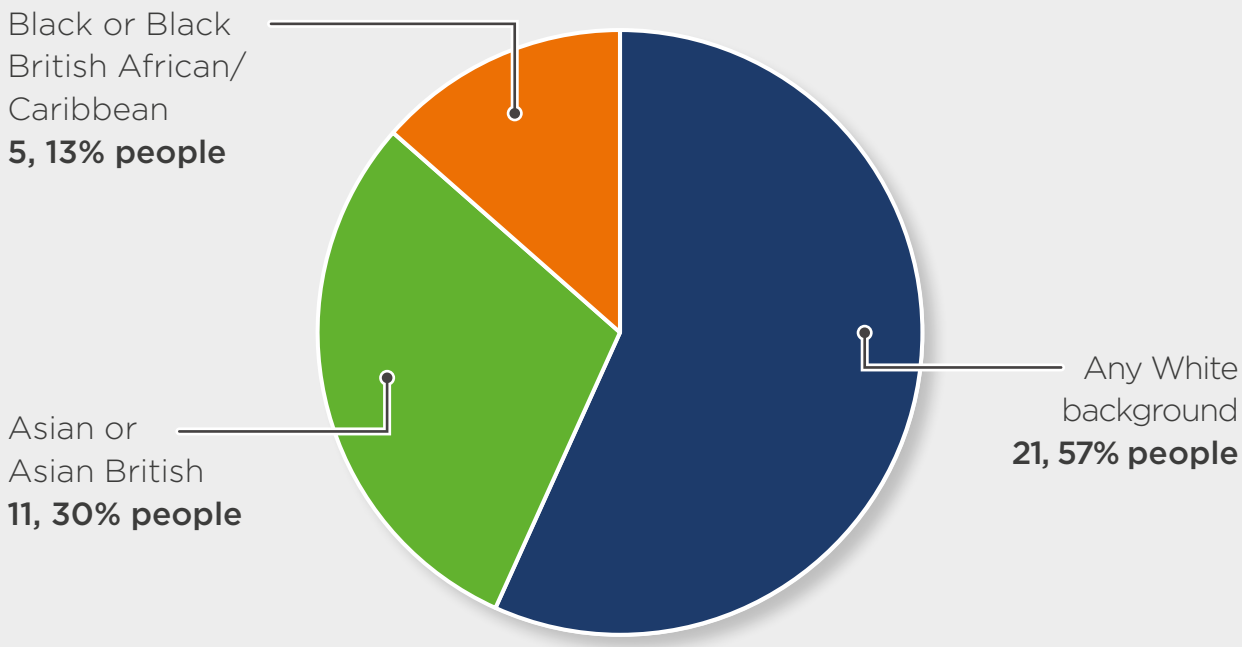
4.6 Ethnicity

4.6.1 To protect the confidentiality of the women and pregnant people and their families, because of small numbers, this report groups together women and pregnant people from different ethnic heritages, as defined by the Office for National Statistics (2017).

4.6.2 Eleven women and pregnant people (30%) were from an Asian British, Asian Indian, or Asian Pakistani background. Five (14%) were from a Black British, Black Caribbean or Black African ethnic background (see figure 8).

4.6.3 At the time of writing, data about ethnicity and birth for the period covered by this report is not available to provide comparison with the pregnant population. Data from all babies born in England and Wales between 2015 and 2019 shows 8.7% of babies born were from an Asian British or Asian Indian, Pakistani, and Bangladeshi background, and 4.2% of babies were from a Black British, Black African and Black Caribbean background (Office for National Statistics, 2021). This concurs with contemporary perinatal mortality survey data that women and pregnant people from Asian and Black ethnic groups have increased risk of stillbirth (MBRRACE-UK, 2020a).

Figure 8 The ethnic backgrounds of the women and pregnant people



4.6.4 HSIB investigations did not identify specific aspects of the healthcare system which could explain this disparity. A key focus for future research will be racial health inequalities in maternity care (Ford, 2021).

4.7 Index of Multiple Deprivation

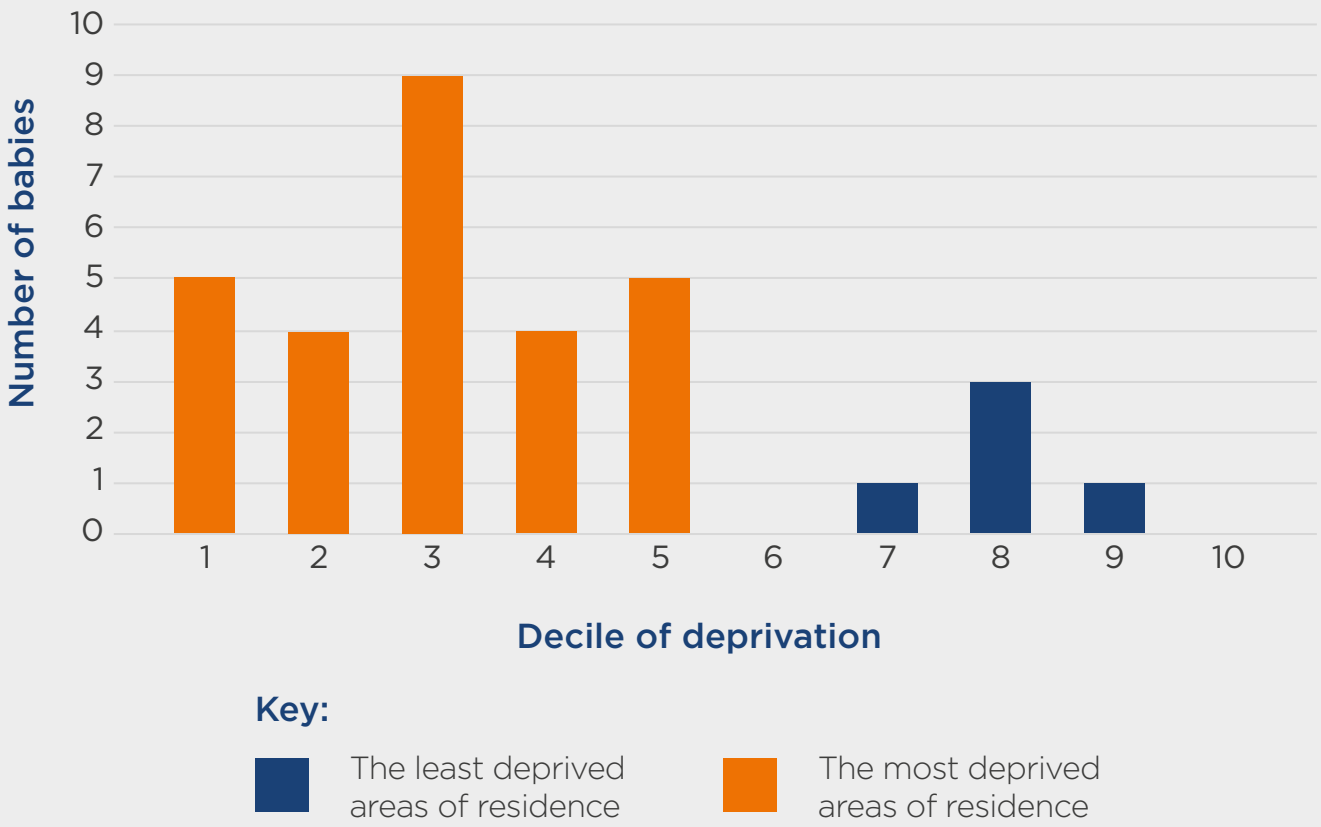
4.7.1 People who live in the most deprived areas of England and Wales are at an increased risk of stillbirth (Office for National Statistics, 2021; O'Dowd, 2020). HSIB uses the Index of Multiple Deprivation (IMD) to measure deprivation. The IMD is based on seven domains including income deprivation, crime, and education, giving a combined score ranging from 1 for the most deprived areas of the country (the lowest 10%), to 10 for the least deprived (the highest 10%) (Ministry of Housing, Communities and Local Government, 2019).

4.7.2 The areas of residence for 27 (73%) of the women and pregnant people whose cases are included in this report were rated between 1 and 5 using IMD, most deprived (see figure 9), marked in orange in figure 9. Five (14%) were from the least deprived, marked in blue in figure 9, and it was not possible to identify the IMD for an additional five women and pregnant people.

HSIB makes the following safety observation

Safety observation O/2021/126:
It may be beneficial if further work is done to understand the specific aspects of the healthcare system which could explain the disparity in the experience and risk for women and pregnant people from Black, Asian and minority ethnic backgrounds and those with higher socio-economic deprivation

Figure 9 Index of Multiple Deprivation



5 Themes from the 37 intrapartum stillbirth maternity investigations

This section describes the detailed analysis of the findings of the 37 cases of intrapartum stillbirth referred to HSIB between April and June 2020. It reviews the woman and pregnant person's interactions with healthcare systems and considers how modifications made due to the COVID-19 pandemic may have affected these interactions. Figure 10 represents the six main themes discussed here:

1 Guidance

2 Management of risk

3 Telephone triage

4 Interpretation services

5 Work demands and capacity to respond

6 Neonatal resuscitation

These themes are colour coded within the report, and reflect issues identified within the delivery of maternity care in one of three categories: pre-existing, exacerbated by or specific to the COVID-19 pandemic. HSIB makes safety recommendations throughout this report, which have been informed by issues from at least one or more of these categories.

In most of the HSIB maternity investigations it is not possible to state confidently that the impact of the COVID-19 pandemic on the NHS was explicitly the 'cause' of the stillbirth as there were many potential factors. Figure 11 uses a recognised system analysis tool, AcciMap (Svedung and Rasmussen, 2000) to give a generic illustration of the review findings and the interaction of contributory factors across different levels of the healthcare system.

Figure 10 Main themes extracted from 37 maternity investigations of intrapartum stillbirth B

1 Guidance

2 Management of risk

3 Telephone triage

4 Interpretation services

5 Work demands and capacity to respond

6 Neonatal resuscitation

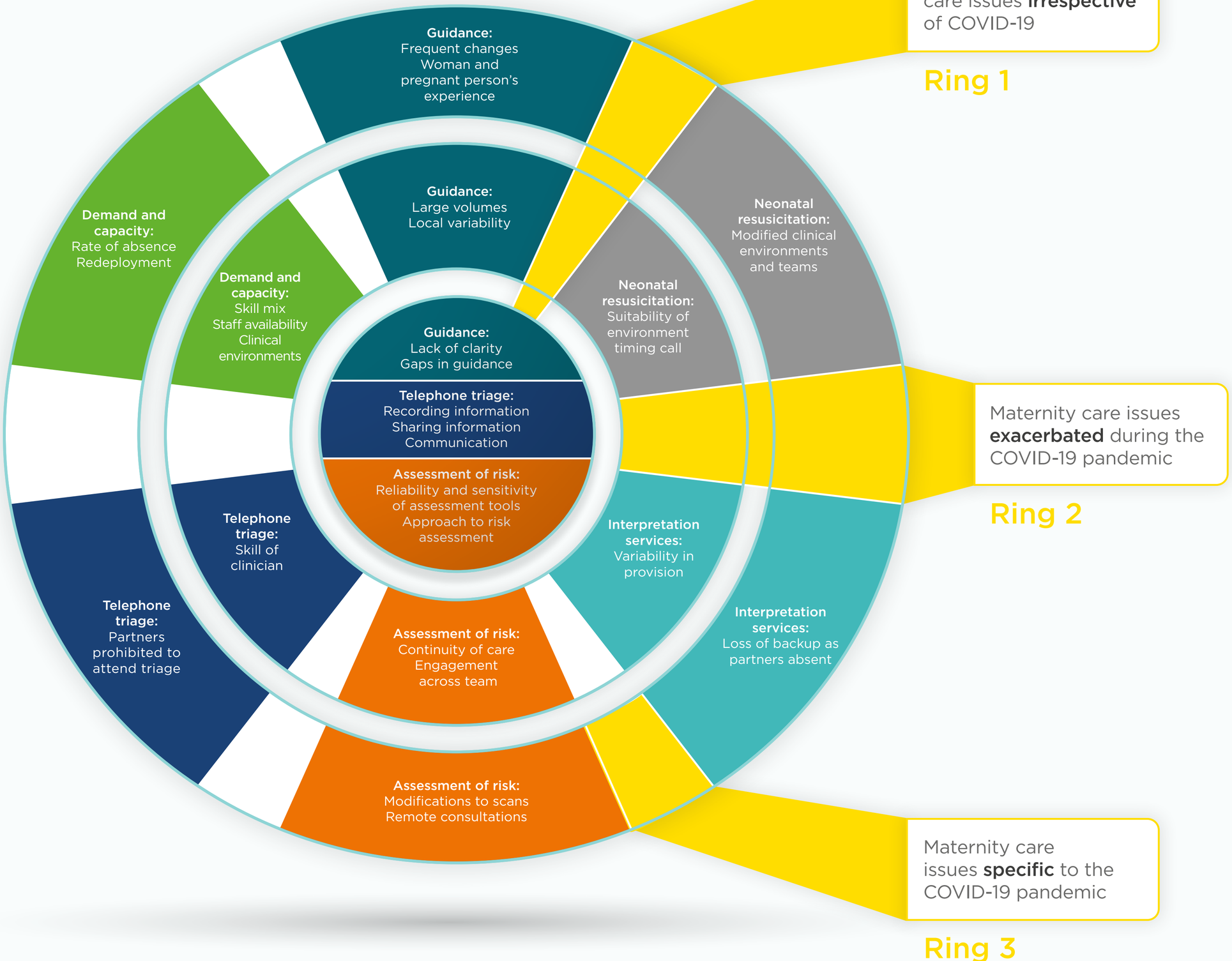
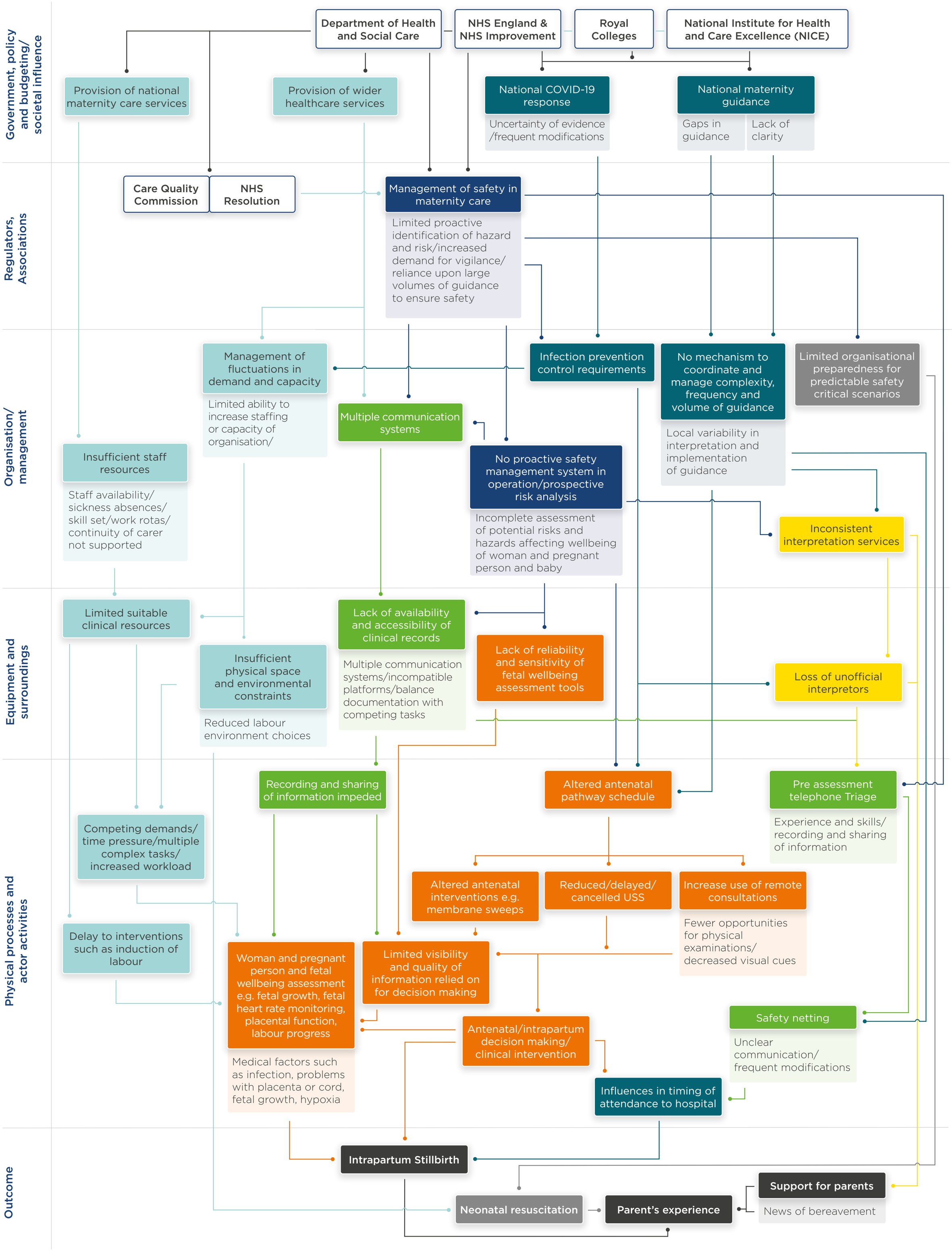


Figure 11 AcciMap of the contributory factors identified with and outcome of intrapartum stillbirth in the 37 cases reviewed



The following sections set out the investigation's findings in relation to the reference event. The findings are structured under colour-coded headings, which correspond to figure 10. The findings are illustrated by quotes from the maternity investigation reports that were included in the review.'

5.1 Management of safety in maternity care

This section considers the findings are illustrated by quotes from the maternity investigation reports that were included in the review. The section considers:

- the reliance on large volumes of guidance to ensure safety
- variability in the implementation of national guidance
- the approach to the modification of guidance and maternity services during the COVID-19 pandemic
- national variability across trusts in the management of risks relating to the assessment of fetal wellbeing
- the impact of variability of demand and capacity within maternity services and the availability of healthcare staff.

Volume of guidance

5.1.1 The complexity created by the volume of guidance associated with maternity care is evident from a review of the relevant web pages of the organisations that provide guidance. The need to consider guidance from multiple national organisations makes it more difficult for trusts to ensure the most recent guidance is included in local policies.

'The HSIB investigation team found that the RCOG [Royal College of Obstetricians and Gynaecologists] 2011 guidance has been superseded by 'Saving Babies' Lives version 2 (NHS England and NHS Improvement, 2019). A care bundle for reducing perinatal mortality' (2019), to guide safer maternity care for raising awareness of reduced fetal movements in pregnancy.'

5.1.2 Like many areas of healthcare, maternity care is supported by a large volume of regularly updated guidance, developed nationally by the National Institute for Health and Care Excellence (NICE), NHS England and NHS Improvement and medical royal colleges (House of Commons, 2020; MBRRACE-UK, 2020b; Royal College of Obstetricians and Gynaecologists, 2019). High volumes of guidance can make it challenging for staff to

accurately recall large amounts of detail when attempting to work within the necessary guidelines (Braithwaite, 2018; Carthey et al, 2011). National bodies are working hard to address ease of access to this guidance, for example via the Royal College of Obstetricians and Gynaecologists (RCOG) app and NICE flow charts. However, this does not address the impact of the plethora of complex guidance that staff need to apply to their everyday work, which will include situations requiring rapid decision making.

5.1.3 Previous maternity safety reviews have identified incidents, and the subsequent identification of risks, associated with antenatal and intrapartum care, and have recommended the development of maternity guidance (MBRRACE-UK, 2020b; House of Commons, 2020). This is recognised as a reactive approach to safety, rather than a proactive consideration of potential emerging hazards and risks (Hollnagel et al, 2006).

HSIB makes the following safety recommendation

Safety recommendation R/2021/144:
HSIB recommends that NHS England and NHS Improvement leads work to develop a process to ensure consistency and clarity across national maternity clinical guidance.

5.1.4 Other safety-critical industries have identified that increasing the amount of guidance in response to safety incidents does not ensure an increased level of safety, unless it is a component of a broader approach to safety management (**see appendix 3**). There is a body of opinion that the continual writing of new guidance can lead to an overwhelming volume of information, which does not ensure a change to the level of safety (Braithwaite, 2018). The multiplicity of guidance may conflict, or be challenging to update, at both national and local level. Reliance on guidance as a key approach to the management of safety issues is not an effective approach to ensuring safety (Dekker, 2014).

Local variation in the implementation of guidance

5.1.5 The complexity and capacity of local services means that maternity services are delivered in different ways in different places. This variation is reflected in how national maternity guidance is implemented regionally.

5.1.6 The review highlights variability in the extent to which the latest national guidance is incorporated into decision-making and documentation tools. This influences the details, assessment and recording of the relevant risks at critical stages of the maternity pathway. This was illustrated in a number of cases that were reviewed, for example:

'... the local guidance does not recognise raised BMI as a factor to be considered when planning the timing of an IOL [induction of labour] ...'

5.1.7 The review found that there does not appear to be a mechanism by which local maternity care systems can co-ordinate and manage the complexity of updated guidance. This means that the positive safety actions taken by regularly updating guidance to reflect newly developing scientific evidence are not fully optimised. It was possible to identify several occasions when guidance had not been fully incorporated into local practice. This does not appear unique to the period of the COVID-19 pandemic (Lau et al, 2020; Jokhan et al, 2015).

'The maternity telephone advice record does not align fully with the Trust's guideline for reduced fetal movements (2019) or national guidance RCOG (2011).'

5.1.8 Local interpretation and subsequent implementation of national guidance is acknowledged as variable across the NHS (Healthcare Safety Investigation Branch, 2021c; MBRRACE-UK, 2020b, Lau et al, 2020; MBRRACE-UK, 2017a).

5.1.9 Recent national reports highlight challenges and inconsistencies in adherence to the guidance. They also identify omissions in national guidance related to the management of risks which can develop during pregnancy (**Healthcare Safety Investigation Branch, 2021c**; MBRRACE-UK, 2020b; Royal College of Obstetricians and Gynaecologists, 2019).

5.1.10 HSIB maternity investigations have identified a specific gap in the national guidance on the frequency of monitoring fetal heart rate during the management of the latent phase of labour.

Frequent modifications to maternity guidance responding to the COVID-19 pandemic

5.1.11 This review identified that national and local maternity guidance was frequently modified during the COVID-19 pandemic in response to changing knowledge and emerging risks associated with the disease. These modifications aimed to balance the management of established risk factors for adverse outcomes in pregnancy with COVID-19 risks. This has been highlighted in previous HSIB reports (**Healthcare Safety Investigation Branch, 2021b**). The pace and volume of guidance change created a huge challenge for all NHS maternity departments during the early stages of the pandemic.

'... clinicians were receiving 'multiple emails a day' with regular changes to the hospital guidance and advice to be given to women and pregnant people. This was secondary to the rapidly changing national picture and guidelines.'

5.1.12 One example of how local trusts interpreted this modified guidance was in the withdrawal of membrane sweeps or only offering these in specific circumstances.

'The HSIB investigation team found that the purpose of the changes were to reduce the time of face-to-face antenatal appointments with the aim of limiting contact time to 15 minutes. The offer of membrane sweeping would have increased the length of contact to greater than 15 minutes. There was a variation in practice at this time as women and pregnant people on the high risk pathway requiring earlier IOL [induction of labour] continued to be offered membrane sweeping during obstetric antenatal clinics.'

5.1.13 The benefit of membrane sweeps in avoiding prolonged pregnancy (Finucane et al, 2020) does not appear to be reflected by local policies withdrawing this service, which aimed to minimise opportunities for the transmission of COVID-19. The desire to reduce contact times to a maximum of 15 minutes, as cited in the quote above, is believed to have originated from the Centers for Disease Control and Prevention (2020). This organisation provided guidance for healthcare staff at risk of exposure to patients who have, or could potentially have, COVID-19. The guidance stated that the risk of transmission increased where 'close contact' had occurred, without personal protective equipment (PPE) to provide protection and where 'prolonged exposure' was suggested as a duration of 15 minutes, either at a single point of contact or cumulative over several interactions within 24 hours. The uncertainty and lack of evidence influenced local trust decision making.

5.1.14 The unintended consequence of a reduction in membrane sweeps may have been the extension of some pregnancies or the need for formal induction of labour (IOL) for prolonged pregnancy. This review included 27 cases which were post term (40 weeks) pregnancies, 16 beyond 41 weeks and 2 beyond 42 weeks. The modified COVID-19 guidance (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020i) recommends that the woman and pregnant person's appointment at 41weeks should also include the IOL. The HSIB maternity investigations do not report that IOLs occurred in conjunction with appointments scheduled at this time in any of the cases reviewed.

Interpretation of risk to inform local guidance

5.1.15 In addition to following recommendations made within national guidance, prior to the pandemic some trusts had adopted further assessments based on contemporary research to inform their local guidance. This suggests there is variability across trusts in how risks are assessed during pregnancy. It has been suggested that additional assessments can increase the reliability of the identification of factors associated with fetal size relative to gestational age, a known risk associated with stillbirth (Heazell et al, 2019; Smith et al, 2014; Lorenzo et al, 2013). For example, some trusts had developed the standardised practice of offering 36-week ultrasound scans, to monitor fetal growth, but the value of 36-week scans is yet to be understood (**see supplementary information**) and this is not currently national guidance, which recommends symphysis-fundal height (SFH) measurements for women with uncomplicated pregnancies (National Institute for Health and Care Excellence, 2019a; 2008). However, there is evidence to suggest that SFH measurements alone may be inadequate to identify reduction in fetal growth in the later stages of pregnancy (Pay et al, 2015; Hargreaves et al, 2011; Royal College of Obstetricians and Gynaecologists, 2011). This localised approach creates a discrepancy in maternal services across the UK. The review identified that in some cases these recently established practices were withdrawn during the pandemic, which caused concern for clinicians (highlighted below) in two trusts included within this review.

'... prior to COVID-19 all women and pregnant people at this Trust, who were not having serial USS [regular ultrasound scans], were offered a growth USS at 36 weeks. In line with national guidance the Trust undertook assessments to reduce the risk of the spread of COVID-19. One of the changes implemented was to cancel the 36 week growth USS for women and pregnant people who were at low risk of having a SGA [small for gestational age] baby.'

5.1.16 In other safety-critical industries there is a process that is undertaken, as part of a system to manage safety (**see appendix 3**), which informs how risk is considered and influences service design, modification and assurance of safety measures. These industries do not solely rely on learning from incidents but adopt a prospective approach to understanding and managing risks within the system. In other industries the assessment of risk is based on understanding the likelihood of an event, for example the chance of fetal growth restriction being present and identified, and the severity of the consequence, such as stillbirth. In these industries any identified risks may be subject to detailed analysis to provide an overview of the probability of risk and human reliability within the system (Health and Safety Executive, 1999).

This may include analysis of individual tasks, for example the reliability of fetal size assessments, and the potential for failure in completion of the task, such as the probability the assessment will be accurate, which may consider factors likely to influence the performance of such assessments, including the work context, workload and fatigue. This enables organisations to provide transparency and acknowledgement of inherent risks within a system.

5.1.17 The uncertainty in the emerging evidence relating to COVID-19 created the context for an intervention with varied scientific evidence to be removed. This challenged the effectiveness of organisational risk assessments. For example, some trusts chose to consider a woman and pregnant person's risk of exposure to COVID-19 during a face-to-face appointment with a clinician as greater than the concern associated with prolonged pregnancy and the associated risk to the fetus by not administering a membrane sweep. The variability in the decisions made by individual trusts reflects a lack of agreement about how to compare clinical and emerging COVID-19 risks at a national level.

Lack of clarity across national guidance for change in fetal movement

5.1.18 The physical characteristics or symptoms which led to women and pregnant people seeking healthcare assistance in the third trimester were varied. Concerns raised included reduced fetal movements (RFM), pain, vaginal bleeding and vomiting.

5.1.19 The review identified a lack of clarity in guidance for staff managing cases of reported RFM in the third trimester of pregnancy; this resulted in variability in the telephone advice provided.

'The clinician commenced giving latent stage labour advice and the Mother [woman and pregnant person] then reported RFM. The clinician advised her to attend as soon as possible.'

'During the first call at 38+2 weeks, the Mother [woman and pregnant person] was not sure of feeling her baby's movements. Staff reported that they advised the Mother [woman and pregnant person] to have breakfast, a bath, put hands on her tummy and monitor the Baby's movements and to telephone back in two hours if she was still concerned.'

5.1.20 In 16 (43%) of the 37 cases there were reports of changes in fetal movement by the women and pregnant people prior to the stillbirth of their baby. Reports of RFM were the most frequently cited symptoms in 10 of the 37 cases reviewed. Nine of these cases were clinically investigated further.

This is similar to the findings of the MBRRACE-UK confidential enquiry into intrapartum-related perinatal deaths which found that 43% of intrapartum stillbirths had presented with RFM. This report identified suboptimal management of RFM in cases of intrapartum stillbirth (MBRRACE-UK, 2017b).

5.1.21 RCOG guidance (Royal College of Obstetricians and Gynaecologists , 2011) reviewed in 2017, states that 'If women are unsure whether movements are reduced after 28+0 weeks of gestation, they should be advised to lie on their left side and focus on fetal movements for 2 hours. If they do not feel 10 or more discrete movements in 2 hours, they should contact their midwife or maternity unit immediately.'

5.1.22 In contrast, NHS England guidance from 2019 (Greater Manchester and Eastern Cheshire Strategic Clinical Networks, 2019) states 'If a woman reports reduced/absent movement she should not be told to wait for two hours and monitor movements before presenting.'

5.1.23 Lack of clarity creates the potential for variation in local practice. The review recognised that the variability in guidance made it more challenging for clinicians to follow the most up-to-date evidence to inform the advice and their decision making.

HSIB makes the following safety recommendation

Safety recommendation R/2021/145:
HSIB recommends that future iterations of the Royal College of Obstetricians and Gynaecologists' guidance clarify the management of a reported change in fetal movements during the third trimester of pregnancy with due regard to national policy.

Management of demand and capacity

5.1.24 The dynamic state of maternity care means there is a constant tension between ensuring safety and providing an effective response to fluctuating levels of demand. This includes provision of sufficient physical space and staffing (Royal College of Obstetricians and Gynaecologists, 2019). This review illustrates these challenges and highlights episodes where tasks may have been delayed because the required clinical area or clinical expertise was unavailable.

'Following this there was documentation to indicate that the staff member working on the antenatal ward was busy elsewhere in the ward and not able to return to the Mother [woman and pregnant person] following the administration of pain relief.'

'The Mother [woman and pregnant person] could not immediately be transferred to the delivery suite for the Artificial Rupture of Membranes (ARM) due to increased activity on the delivery suite.'

'... staff felt unable to perform a CTG [cardiotocograph] at this time due to the high ward activity and task load they possessed ...'

5.1.25 The way care is delivered and the sustainability of staffing levels has been repeatedly highlighted as influencing the quality of care provided within maternity units (Liberati et al, 2020; MBRRACE-UK, 2017a; MBRRACE-UK, 2017b). There has been a recognition of the need to ensure organisations have systems in place to ensure escalation of concerns relating to staffing levels (Liberati et al, 2020; MBRRACE-UK, 2017a). It is apparent that organisations worked hard during the COVID-19 pandemic to ensure the resilience of maternity services and to accommodate fluctuations in demand. Sustaining such strategies became difficult as demands increased with little ability to increase the resources required. This will ultimately lead to trade-offs in how work is achieved and care is managed (Sujan, 2015).

'The coordinator will consider the number of high risk cases already booked, staff skill mix and agree further IOL on a case by case basis according to clinical need. These options were explored and there was no additional capacity to accommodate the Mother's [woman and pregnant person] IOL any earlier than 41+6 weeks.'

5.1.26 One trust observed that there had been an inexplicable increase in the demand for IOLs during the COVID-19 pandemic. Within the 37 cases reviewed for this report, 27 babies (73%) were born beyond 40 completed weeks of gestation. All women and pregnant people pregnant beyond 41+5 weeks were offered IOLs in line with national guidance, six (16%) of the women and pregnant people were in hospital for labour care or induction of labour.

'... there are usually four planned induction of labours (IOL) each day with two slots saved for urgent cases. More recently the IOL rate for the hospital had increased and it had become more common to have more women and pregnant people booked for IOL each day which has had some impact on the timing of transfer to the delivery suite ... Before the COVID-19 pandemic the IOL rate had been reduced by 10%, during the pandemic the IOL rate had increased to the original figure.'

5.1.27 Staff in one trust highlighted how normal work practices or organisational cultures may not always ensure a timely response to concerns raised about rising demands on the healthcare system.

'The HSIB investigation team were informed that previous experience when requesting staffing support in similar situations had not resulted in change or the provision of additional clinical support.'

5.1.28 In some cases staffing provision was adjusted due to the response to the COVID-19 pandemic and this influenced normal work patterns and the consistency and availability of clinicians. This has been highlighted in previous reports considering the provision of clinical care during the COVID-19 pandemic (Healthcare Safety Investigation Branch, 2020b; MBRRACE-UK, 2020c). This may have further limited the options available to trusts to adjust the provision of care provided.

'... staffing levels were below expected and there were high levels of activity ... There was no escalation to alert the senior management that staff felt it was not possible to perform CTG surveillance [monitoring] of the Baby [heart rate] ... It was explained that the activity levels were known, and that staff had already been moved from other areas to support the delivery suite by the senior midwife who had oversight of the unit and staffing.'

5.1.29 The Ockenden review (House of Commons, 2020), highlights the lack of resilience and ability to adhere to guidance on the provision of anaesthetic support (Royal College of Anaesthetists, 2020). One example where the organisational adjustments made due to COVID-19 had a positive influence is in a trust where a dedicated obstetric anaesthetist was allocated to maternity services, in line with national guidance. This ensured there was a greater consistency in the provision of anaesthetic support.

'COVID-19 had implemented a positive change for the maternity service as there was now a dedicated obstetric anaesthetist 24 hours a day seven days a week, along with the presence of an operating department assistant.'

5.1.30 In other clinical areas necessary adjustments may have compromised the continuity some clinical roles.

'... the consultant rota had changed during the COVID-19 pandemic. Ordinarily, during the night time there was one resident consultant covering [both] the paediatric and neonatal departments. During the COVID-19 pandemic the consultants are separated during the night time for each department.'

'The Mother [woman and pregnant person] was then reviewed by consultant 3 the next day on the labour ward round. Consultant 4 was made aware of concerns about the Mother's [woman and pregnant person] CTG monitoring on the third evening of her inpatient admission when she had been transferred

back to the antenatal ward. The Mother [woman and pregnant person] was discussed with consultant 5 twice on the fourth day of her admission, and the CTG recording was shown to them to review ...'

Staff availability

5.1.31 The HSIB maternity reports showed how the COVID-19 pandemic affected the number of staff available to allocate to rotas and trusts' ability to provide a full quota of staff to meet national requirements.

'The staffing numbers were below the usual agreed establishment, by three midwives across the whole unit, due to sickness and reallocation of staff due to the COVID-19 pandemic.'

'The obstetric team had a high level of sickness/not able to attend work (20%). This meant that the team were expected to work different shift patterns, in different clinical areas to their 'normal'.'

5.1.32 It has been suggested that sickness and absences combined with the reassignment of staff had the greatest impact on organisations' ability to respond to demands in maternity care during the first peak of the COVID-19 pandemic (Healthcare Safety Investigation Branch, 2020b, MBRRACE-UK, 2020c). Data collected by NHS Digital (NHS Digital, 2020) supports this, with the highest level of sickness and absence in 2020, across all staff groups, occurring in April 2020. This was greater than the three previous years. Sickness and absence data specific to midwives also suggests a slightly higher than average level between April and June 2020 compared to the previous three years. However, it is difficult to draw conclusions in relation to the cases reviewed as staffing data was not routinely collected.

5.1.33 Some organisations were constrained in terms of which staff were available to be allocated to certain duties, due to the staffing and expertise levels available. This had implications for the intensity of work created by modified staff rotas, and the level of expertise and skills present in a maternity unit at any specific time.

5.1.34 Attention to staff wellbeing is noted as a contributor to the safety of any maternity unit (Liberati et al, 2020). Unlike other safety-critical industries such as rail, aviation, oil and gas which have a safety management system in place (**see appendix 3**), healthcare does not have systems in place to manage the risk of staff fatigue (Ipieca, 2019; Greig and Snow, 2017; Office of Rail and Road, 2012; International Civil Aviation Organisation, n.d.).

5.2 Adjustments to antenatal consultations during the COVID-19 pandemic

The RCOG, with the Royal College of Midwives (RCM), issued COVID-19 guidance which emphasised the need to retain six face-to-face consultations in antenatal care (**see appendix 1**). In all of the 37 cases reviewed, the women and pregnant people attended more than six face-to-face appointments. The guidance also advised that maternity services 'aim to maximise the use of remote means to provide additional antenatal consultations. Remote consulting enables greater compliance with social distancing measures recommended for pregnant women and maternity staff' (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020i). The co-ordination of antenatal care varied across trusts, with some women and pregnant people's care not following the original plan agreed prior to the COVID-19 pandemic. This section presents the findings of the review and the implications of these changes relative to the 37 cases of intrapartum stillbirth, which include:

- modifications to planned ultrasound scans
- reduced opportunities to complete physical assessments
- a reduction in the frequency in the measurement and plotting of the trend in symphysis-fundal height (SFH)
- lack of access to all relevant clinical information to inform clinical decision making
- a reduction in the continuity of care and engagement of a multidisciplinary team.

Modifications to the provision of scans

5.2.1 Amended guidance issued by RCOG and RCM (2020i) advised that any ultrasound scan should be conducted during the same hospital visit as a face-to-face appointment in order to minimise the number of hospital visits. The interpretation of this guidance seemed to influence the assessment of maternal and fetal wellbeing.

'... due to the COVID-19 pandemic the Trust were aiming to reduce attendance at the hospital, therefore reducing maternal exposure to the COVID-19 virus. Instead of attending the [antenatal clinic] for a growth USS [ultrasound scan] at 33 weeks the Mother [woman and pregnant person] received a telephone consultation from the obstetric consultant, who, following telephone discussion cancelled both USSs for raised BMI [body mass index] [39.3kg/m2] as no concerns were identified.'

5.2.2 The trust's decision about which ultrasound scans to provide was balanced against the reduction of attendances at hospital and the availability of staff. This clearly influenced access to planned growth scans in one case, where a planned growth scan did not go ahead.

'... the Trust were aiming to reduce attendance at the hospital, therefore reducing maternal exposure to the COVID-19 virus. National guidance (RCOG, appendix G, 2020) on growth USS [ultrasound scan] during COVID-19 pandemic, suggests that normal service should continue unless USS staffing was reduced by 50%. The HSIB investigation team learnt from sonography staffing rotas in the Trust at the time of the 33-week USS, that the number of sonographers available to work in ANC [ante natal clinic] USS was acceptable/normal and not affected by the COVID-19 pandemic ...'

Remote consultations

5.2.3 The proportion of consultations undertaken remotely is not known and the impact of remote consultations is not clear from this review. However, there was evidence that remote consultations impeded certain activities. Specifically, there were fewer opportunities for physical examinations to be carried out, limiting the opportunity to establish trends for symphysis-fundal height (SFH) measurements. The review identified that consultations beyond the 28-week stage did not always include monitoring of SFH for pregnancies, where it was clinically required. The review also identified a lack of recording and plotting of SFH information, with some face-to-face appointments postponed until later in the person's pregnancy.

5.2.4 In some remote consultations clinicians did not have access to the person's clinical notes, ultrasound scan reports or a record of any planned changes to care or intentions around the timing of induction of labour. In three instances this resulted in ultrasound scans either being cancelled or not being made available.

'... the planned telephone review took place and the USS [ultrasound scan] was discussed. The HSIB investigation team learned that the Mother [woman and pregnant person] had to read the results of the USS to the obstetrician over the telephone as they said that they did not have access to them in the hospital. The Mother [woman and pregnant person] recalled that based on the USS report which she read out over the telephone, induction of labour was no longer recommended and a further USS was scheduled for two weeks' time.'

5.2.5 The extract above highlights the potential vulnerability of remote consultation if the clinician does not have full access to all information. In this case it resulted in a significant change to the intended birth plan.

5.2.6 Continuity of antenatal care appears to have reduced due to the response to the COVID-19 pandemic.

> 'Prior to the outbreak of COVID-19, the Mother [woman and pregnant person] had continuity of care and received care from the same midwife. Antenatal care then changed for all women and pregnant people, where they were directed to one venue meaning that continuity of care may not be continued. The HSIB investigation team learned that the Mother's [woman and pregnant person] venue for her antenatal care changed.'

5.2.7 This review has recognised factors which influence clinicians' ability to undertake remote consultations, including a lack of integrated technical systems and lack of access to all relevant clinical information. However, these may not be the only factors which influence communication in the context of a consultation, whether remote or face-to-face. A scoping review considered how communication failures related to patient harm (Campbell et al, 2018). This research rated factors most likely to lead to harm, which included failure to listen and provide appropriate, timely information to patients and failure to share an appropriate level of information between colleagues. The associated risks specific to remote consultation should be understood. This would enable organisations to understand how to balance emerging risks; in this review the context considered is the risk of contracting COVID-19 against the ability to assess and communicate the risk and benefits of any given management for the wellbeing of women and pregnant people and their babies. This knowledge would inform how to manage critical points in care, and when face-to-face consultations are acceptable or preferable in view of the associated risks.

HSIB makes the following safety recommendation

Safety recommendation R/2021/146:
HSIB recommends that NHS England and NHS Improvement leads work to collate and act on the evidence on the risks and benefits associated with the use of remote consultations at critical points in the maternity care pathway.

Safety recommendation R/2021/147:
HSIB recommends that NHSX develops specifications for electronic patient record (EPR) systems that require adherence to national interconnectivity standards for the exchange of core maternity healthcare information. The specifications should include functionality to enable both women and pregnant people and professionals to add to the record, and also support alerting functionality.

5.3 Women and pregnant people's experience of maternity care during the COVID-19 pandemic

During the pandemic the experience of women and pregnant people and their partners was influenced by how hospitals interpreted national guidance. The impact of the COVID-19 pandemic on families included:

- emotional support for women and pregnant people on receiving news of the death of their baby
- parental decision making.

Women and pregnant people's experience

5.3.1 The decision by many trusts to limit the number of people in hospitals meant that in some trusts partners were not allowed to accompany women and pregnant people unless they were in established labour. This may have affected the woman and pregnant person's desire to attend their maternity unit when in labour.

'The Mother [woman and pregnant person] telephoned the maternity triage line for a second time at 21:23 hours as she wanted to know if the Father [partner] could attend the triage area when she came in for assessment. The Mother [woman and pregnant person] was advised that due to COVID-19 restrictions, he could not attend until it was confirmed that she was in labour … It was documented that the Mother [woman and pregnant person] wanted 'to stay at home'.'

5.3.2 The lack of the emotional support from a partner was evident in some cases when the death of their baby was first detected without the partner present.

'… the senior obstetrician confirmed to the Mother [woman and pregnant person] that the Baby's heart had stopped beating and that the Baby had died, without the presence of the Father [partner].'

5.3.3 There was some evidence to suggest that women and pregnant people may have made different decisions if the perceived risk of COVID-19 had not existed. Public information and the uncertainty of the emerging risks associated with COVID-19 may have informed women and pregnant people's decision making.

'… she chose not to attend the appointment after considering the risks of COVID-19 against the risk of not attending the appointment and on balance chose the latter.'

5.3.4 The uncertainty around what would be provided and later the withdrawal of services such as home birth or use of a birthing pool affected some women and pregnant people's decision making, and in one case a choice to transfer to an independent provider.

'... the Mother [woman and pregnant person] discussed the suspension of both the homebirth and waterbirth service with the senior midwifery management team ... It was confirmed with the Trust that the homebirth service remained suspended and that they would be unable to support a waterbirth service until further guidance had been received from the infection control team. The Mother [woman and pregnant person] made the decision to transfer her care to a private midwifery company who would support her plans for birth in the home environment.'

5.3.5 The physical and mental wellbeing and social circumstances of the Mother [woman and pregnant person] form part of the risk assessment routinely completed during antenatal care. The analysis within this review suggests that at least 50% of the cases involved women and pregnant people with greater levels of social deprivation. This reflects other national reports, which highlight that women and pregnant people living in the most deprived areas have an 80% excess risk of stillbirth compared to women and pregnant people in the least deprived areas (MBRRACE-UK, 2020a). In two of the cases reviewed, social circumstances were considered by the maternity investigation team to have a direct impact on the Mother's [woman and pregnant person] attendance at antenatal appointments.

5.3.6 The national recommendations regarding the way in which care was delivered during the early stage of the COVID-19 pandemic aimed to prioritise the physical wellbeing of families, babies, and staff. However, there was local variability in care delivery, particularly regarding which trusts allowed partners in at which stage of maternity care.

5.3.7 The review found that trusts had met the standard of bereavement care outlined in the care pathway for pregnancy and baby loss set out by the National Bereavement Care Pathway (2018). There were two cases where bereavement care had been compromised. In one case this was a consequence of the reconfiguration of a maternity unit due to COVID-19, which meant that a designated bereavement suite could not be provided. However, in this case a specialist bereavement team was involved in the woman and pregnant person's care. The second case was the result of a clinical decision to transfer the baby and Father [partner] to the emergency department to continue resuscitation.

5.4 Risks associated with clinical assessment, decision making and response

The information that is available to assess a situation and the ability to give the information sufficient attention is important for decision making (Zsambok and Klein, 1997). During a person's pregnancy, clinical assessments, measurements and symptoms provide critical information to help evaluate and understand fetal wellbeing. This review has highlighted how the reliability of these may influence early detection of concerns to indicate the likelihood of stillbirth. This section considers how the system influences the risks associated with clinical assessment, decision making and response to risks recognised during antenatal and intrapartum care. These influences include:

- the visibility and quality of clinical information relied upon to make decisions
- the reliability and sensitivity of assessments and tools and technology used during antenatal and intrapartum care
- the effectiveness of communication processes relied upon to understand and explain risks to fetal and maternal wellbeing
- the level of preparation to respond to predictable safety-critical scenarios within a maternity department.

Visibility and quality of information relied on for clinical assessment

5.4.1 The communication of clinical information or symptoms informs clinicians and influences their ability to assess a situation. The equipment, IT systems and recording systems available to clinicians vary between healthcare settings This review has identified several factors that contribute to clinicians giving limited attention to information. These include:

a) frequent lack of recorded information

'The risk assessment was not reviewed or updated to reflect the Mother's [woman and pregnant person] blood results that showed the presence of antibodies and no evaluation of her changed risk was recorded.'

b) the way information to assist decision making is presented

'The HSIB investigation team also learned that the Mother [woman and pregnant person] and babies' observations are not charted on the same side of the partogram [the graph in which all the relevant observations of a

Mother [woman and pregnant person] and the unborn baby during labour are written], making it difficult for clinicians to see developing trends and patterns including similar heart rates.'

c) the availability and relevance/importance of information to different members of the team.

'On the six occasions whenever the [computerised CTG] criteria were not met, the numbered reasons were not documented in the Mother's [woman and pregnant person] handheld notes or commented upon by clinicians.'

5.4.2 The ability or likelihood of staff finding and extracting relevant clinical information influences the timing and quality of the assessment of a presenting situation. Situation awareness (an awareness and understanding by staff of everything that is going on around them and its potential effects) is a term often used in the field of maternity care and is suggested as an approach to improving safety.

'Try to anticipate lost situational awareness when under periods of stress, fatigue and high activity, and ask for help early, rather than when it is already lost.' (Royal College of Obstetricians and Gynaecologists, 2019).

5.4.3 An individual's ability to maintain situation awareness may not be within their control. The ability of the system to provide an environment and context in which the assessment of a situation is prompted and supported by clear and reliable information or cues, is an organisational issue.

5.4.4 Situation assessment is an essential stage of decision making for staff skilled and familiar with a particular field of work. The recognition-primed decision (RPD) model explains how situation assessment and sensemaking processes assist in evaluating options through mental simulation or recognising familiar patterns. Real-world decision making is a product of the knowledge held by staff and the context or environment, which may or may not support how cues and information are received (Kahneman and Klein, 2009; Klein et al, 2007). Real-world decision making is recognised as occurring in 'messy' contexts, where uncertainty is common, and staff must make decisions informed by their knowledge and experience to accommodate the uncertainty created by missing or ambiguous information amidst other organisational pressures and time pressured environments (Flach, 2017).

5.4.5 The HSIB investigation team learned that the community midwifery team log their maternal contacts onto the community computerised midwifery care system. In one of the cases included in the review the maternity

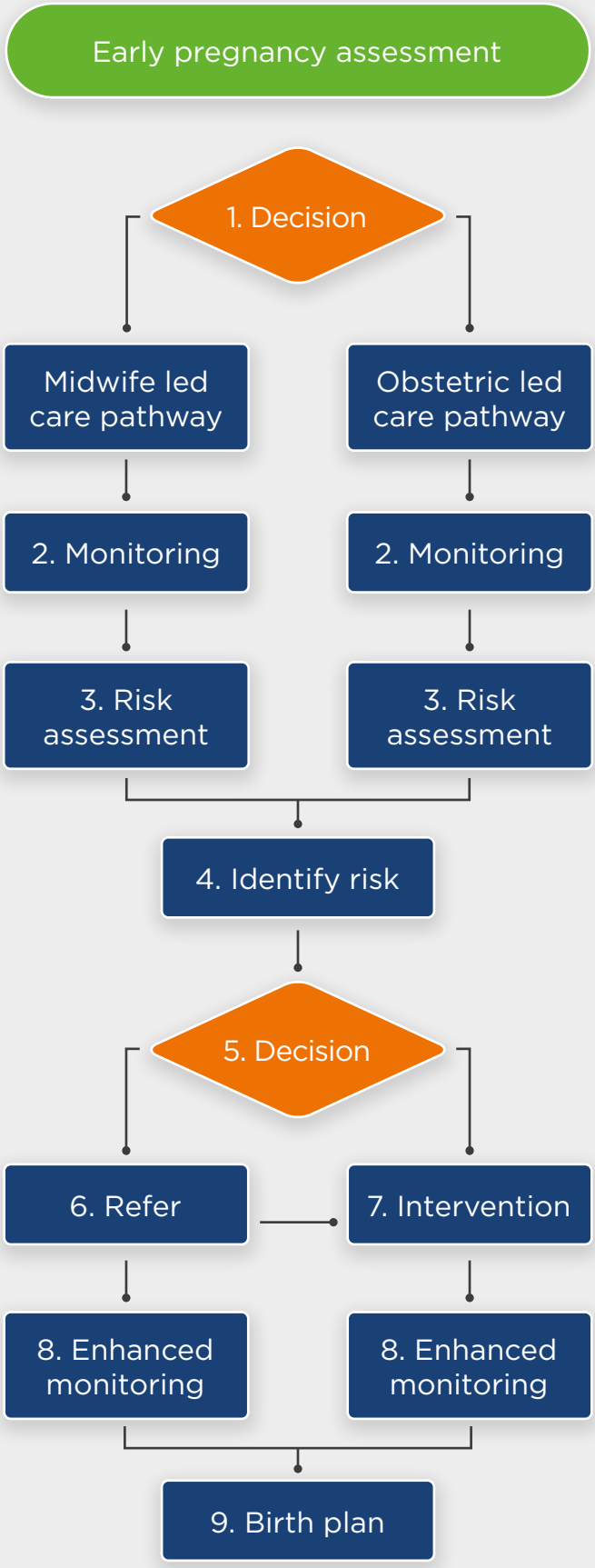
investigation team learned that 'if they have time they will try to look on the hospital computerised care system as to what has happened with the Mother [woman and pregnant person] in the ANC [antenatal care] visits. Due to time constraints community staff are 'very often reliant on the women and pregnant people telling them what the hospital has had to say'.

5.4.6 This review highlights periods of increased organisational pressure, time pressure and staff resource constraints. Several reviews of maternity care (Liberati et al, 2020; Royal College of Obstetricians and Gynaecologists, 2019) highlight existing and longstanding challenges that affect staff members' ability to balance requirements for documentation with other duties and the usability of communication systems. These resonate with the demands associated with working during the COVID-19 pandemic.

'... the Mother's [woman and pregnant person] maternity health records were documented in several systems ... it was difficult for the hospital and community staff to have complete oversight of the Mother's [woman and pregnant person] care and health contacts. This was due to the hospital-based electronic system not linking records to the electronic system used by the community midwifery team.'

'... the Mother [woman and pregnant person] attended an obstetric appointment at 33+0 weeks for which the record was not saved on the Trust's electronic patient record system due to it being simultaneously used by different clinicians and there being no 'auto save' function.'

Figure 12 Antenatal care points for risk assessment and decision making



Reliability and sensitivity of assessments tools and technology for antenatal and intrapartum care

Critical information indicating fetal growth

5.4.7 Reduced fetal growth is known, in some cases, to lead to stillbirth. Figure 12 shows the care points at which decisions may be made about monitoring fetal growth (**see figure 2** for the full context of decision making in the maternity pathway). Figure 2 is used to orientate the reader to which stage of the maternity pathway is being considered. The decision on which care pathway the woman and pregnant person will follow, either midwife of obstetrician led, is informed by the history they provide (see figure 12, number 1) The identification of previous pregnancies resulting in the birth of small for gestational age (SGA) babies is considered to inform the need for closer monitoring and identify the level of risk (see figure 12, number 4) in the existing pregnancy.

5.4.8 In the 11 cases of SGA babies within this review, 8 were undetected until birth. This implies that the cues relied upon to identify the risk (see figure 12, number 4) and inform the decision (number 5) may not be reliable.

5.4.9 The implications of the COVID-19 pandemic and the reduction in some ultrasound scans for certain care pathways and fewer face-to-face consultations, were suggested as reducing the opportunity to obtain SFH measurements.

> 'The Mother's [woman and pregnant person] antenatal appointment at 37+5 weeks was conducted over the telephone in line with local COVID-19 guidance. This meant that the Mother [woman and pregnant person] did not have a physical examination, or her observations taken.'

5.4.10 The Perinatal Institute highlights specific challenges associated with the identification of late onset fetal growth restriction (Perinatal Institute, n.d.). The false negatives (a result which incorrectly indicates no reason for concern) associated with SFH measurement (Pay et al, 2015) may create overconfidence in the assessment finding and a risk, as there is an acknowledged low level of confidence in this measure. As suggested earlier, although not a recommended practice, some trusts have adopted the use of routine ultrasound scans at 36 weeks to minimise the risk associated with the identification of fetal growth in the third trimester of pregnancy. The evidence suggests it is more effective in identifying SGA babies; however, this may have no impact on outcomes at birth (Henrichs et al, 2019).

5.4.11 The findings of this review reflect known concerns about the reliability of SFH to indicate fetal size, the accuracy of plotting of SFH measurements, the recognition of a drop in a baby's SFH growth rate and the likelihood that SFH measurements prompt clinicians to assess the situation accurately and refer for an ultrasound (**see supplementary information**). In the 37 cases reviewed, if SGA was considered to be a concern an ultrasound was provided.

5.4.12 The evidence (**see supplementary information**) suggests that the use of growth charts, recording of measurements, plotting of data points and the interpretation of trends all contribute to the reliability with which a clinician can monitor a baby's growth using SFH measurements. This review suggests that the usability of the method to record and interpret SFH contributes to making it harder for clinicians to identify the cumulative measurements easily and quickly. The usability and reliability of obtaining SFH measurements, combined with the recognised lack of sensitivity of SFH as a measure of reduced fetal growth, creates a concerning level of risk to the identification of the most significant indicator associated with stillbirth. 'Saving Babies' Lives version 2. A care bundle for reducing perinatal mortality' (NHS England and NHS Improvement, 2019) recommends the need for continuous learning in the effective measurement of SFH.

Critical information to interpret fetal heart rate

5.4.13 The detection of fetal movement and fetal heart rate are critical cues that clinicians rely on to assess intrapartum risks (see figure 13, number 15) and to decide on potential interventions (see figure 13, number 16) such as induction of labour or birth by caesarean section, which may minimise the risk of intrapartum stillbirth (NHS England and NHS Improvement, 2019).

Figure 13 Intrapartum care points for risk assessment and decision making

5.4.14 The prominence and reliability of information available to assess fetal heart rate and fetal movement will have a direct impact on the interpretation of risk. The following sections consider the factors identified by this review as influencing clinician's ability to identify a situation of increasing risk to fetal wellbeing.

Assessment of fetal heart rate

5.4.15 The aim of fetal heart rate assessment is to detect if the heart rate is outside the expected range (a normal resting (baseline) heart rate is between 110 and 160 beats per minute (bpm)), or whether there is reduced or increased variability (usually 5 to 25 bpm), decelerations (temporary slowing) or accelerations (temporary increase) in the fetal heart rate (National Institute for Health and Care Excellence, 2017). Clinicians' ability to make this judgement will influence their assessment of emerging situations, which may prevent some intrapartum stillbirths.

5.4.16 Difficulty in establishing the fetal heart rate has been identified as a contributory factor relating to different levels of harm, including stillbirth (Royal College of Obstetricians and Gynaecologists, 2019). There are different methods that may be used to assess the fetal heart rate during intrapartum care. These include intermittent auscultation (IA) usually using a hand-held Doppler device, and methods which require increasingly greater interaction including cardiotocography (CTG) via abdominal transducers or a fetal scalp electrode (FSE). The level of clinical concern and the location of the woman and pregnant person will determine the monitoring method and equipment selected or available for use, to ensure escalation of care. A CTG is mainly available in environments such as triage, antenatal and consultant-led labour units, where women and pregnant people will be observed once a level of concern has been raised either by parent or clinician.

5.4.17 Where there is no clinical concern or a low level of concern, IA would be used to monitor the fetal heart rate. While there are established protocols for monitoring a baby's heart rate in established labour, this review has highlighted the absence of national guidance on the frequency of assessing the fetal heart rate in the latent stages of labour, which leads to variation in practice.

5.4.18 There are many other factors that can influence how IA is used. These include individualised risk assessment, staff members' experience of and ability to use IA, time management, acuity of a unit and staff availability, lack of awareness of guidance, and the recognition and escalation of IA findings that are outside the expected range (Patey et al, 2017). These different factors have all been identified within this review but none of the investigations suggested that issues with IA were directly linked to the 37 stillbirths reported.

5.4.19 Increased clinical concern would require the use of a CTG, which can be used to record the fetal heart rate before and during labour. A CTG provides a paper printout or an electronic record of the 'trace' (the graph showing the fetal heart rate data) presented on a monitor. Software may be integral to some CTG monitoring systems, referred to as computerised CTGs. However, computerised assessment of the CTG during labour has not been found to be superior to manual interpretation of CTG alone (The INFANT Collaborative Group, 2017). 'Saving Babies' Lives version 2. A care bundle for reducing perinatal mortality' (NHS England and NHS Improvement, 2019) recommends the use of computerised CTG over a visual interpretation by clinicians, for antepartum care. There has been a trial in the use of software during intrapartum care; however, there is some dispute about the benefit of its use over clinical judgement in the interpretation of the CTG trace in labour (The INFANT Collaborative Group, 2017).

5.4.20 The reliability of CTG monitoring has been highlighted as one of the top five factors associated with contributing to neonatal harm (Royal College of Obstetricians and Gynaecologists, 2019; MBRRACE-UK, 2017b). HSIB has recently published a national investigation report on this topic (**Healthcare Safety Investigation Branch, 2021d**). The following sections consider how fetal heart rate was indicated as an issue in the review of the 37 cases of intrapartum stillbirth.

Interpreting and managing CTG recordings

5.4.21 NICE guidelines (2017) clearly state that CTG findings alone should not inform decisions about the care of a woman and pregnant person and their baby. The CTG reading provides one piece of information to indicate the potential chance of fetal compromise. CTG readings are judged on specified characteristics to establish whether the findings of the CTG suggest increasing levels of concern. The individual characteristics of the fetal heart rate pattern should be described as 'reassuring', 'non-reassuring' or 'abnormal' (National Institute for Health and Care Excellence, 2017). Clinicians are then required to categorise the CTG reading as 'normal', 'suspicious', 'pathological' or 'need for urgent intervention'. Clinicians are expected to receive annual education on fetal monitoring and CTG interpretation; however, there is little assurance that this is happening at a national level (NHS England and NHS Improvement, 2019). The lack of a competency framework to ensure training is prioritised in trusts and a lack of time to free staff up for training have both been identified as reasons for inadequate training (**Healthcare Safety Investigation Branch, 2021d**).

5.4.22 This review identified inconsistencies in the clinical approach to interpreting computerised CTG traces, and the subsequent need to act.

> 'On the six occasions whenever the criteria were not met, the numbered reasons were not documented in the woman and pregnant person's handheld notes or commented upon by clinicians. There is no evidence to suggest that clinicians explored why the criteria were not being met. The different numbered reasons were not escalated and no precise plan to address the specific reasons for the criteria not being met was put in place.'

> '... the clinicians in maternity triage that they were not familiar with what the 'number' codes specifically referred to in the analysis. The local guideline, 'Use of computerised CTG (cCTG)', does not refer to the codes...'

5.4.23 The interpretation of CTG has been suggested to be at high risk of 'human error' (NHS England and NHS Improvement, 2019). The presentation of information, the reliability of equipment to provide trusted information and the availability of systems to support interpretation are all factors identified within this review as likely to influence human reliability in interpreting a CTG trace. The reliability of any human can only ever be as good as the system designed to support them. Therefore, the term 'human error' would seem inappropriate in the context of well-recognised issues relating to the usability and reliability of existing equipment.

5.4.24 Effective processes to support clinicians at the bedside and guarantee escalation were not evident. The approach to safety relies on staff members' recall of training, which, as suggested earlier, is not consistently occurring.

> 'There was a tendency towards waiting for the CTG to improve or normalise, which seemed to negate the previous abnormal period of monitoring and possible evidence of a potentially compromised baby.'

5.4.25 One of the cases reviewed suggested that there was a change in the way CTG reviews were undertaken during the first peak of the COVID-19 pandemic.

> 'The HSIB investigation team learnt that when a senior review is requested for a CTG, clinicians occasionally review the CTG trace on the central monitoring system rather than attending a Mother's [woman and pregnant person] delivery room. The central monitoring system enables clinicians to view on a large screen all the CTG traces that are in progress on the delivery suite. The HSIB investigation team learned that staff considered it preferable to enter a Mother's [woman and pregnant person] delivery room to review the CTG trace ... during the COVID-19 pandemic there had been an increase in clinicians reviewing the CTG via the central monitoring system ...'

Differentiating maternal and fetal heartrate

5.4.26 The cases reviewed demonstrate the risk of mistaking a woman and pregnant person's heart rate for the fetal heart rate. The national guidelines state that clinicians should 'differentiate between fetal and maternal heart rates hourly' (National Institute for Health and Care Excellence, 2017). This review suggests that this may be a challenge for clinicians. This may be influenced by the experience of the clinician and how the information is recorded and presented.

'... the Baby's and the Mother's [woman and pregnant person] pulse rates were similar at the time of starting CTG monitoring ... it is possible with the benefit of hindsight having reviewed the CTG's, that the Mother's [woman and pregnant person] pulse rate was being recorded from the start of the CTG.'

5.4.27 It is well recognised that the way information is presented influences how reliably people can accurately read and synthesise it. The case quoted above led to HSIB making the recommendation for the Trust to ensure that the local partogram (a graph in which all the relevant observations of a woman and pregnant person and the unborn baby during labour are written) is updated to include all vital sign observations (such as temperature, blood pressure, heart rate, respiration rate) of the woman and pregnant person alongside the baby's observations (such as heart rate) to provide a clear picture of their wellbeing during labour.

5.4.28 The way fetal heart rate monitoring equipment is applied may also influence clinicians' ability to differentiate between a woman and pregnant person's and the fetal heart rate. The usability of CTG and FSE equipment influences the reliability of its use and subsequently the reliability of the information provided.

'... the FSE was found to be attached to the Mother's [woman and pregnant person] cervix. The FSE was repositioned and CTG monitoring was recommenced ... The FSE was not recording the Baby's heart rate.'

5.4.29 The risk of confusion between heart rates was acknowledged in an alert from the Medicines and Healthcare products Regulatory Agency (MHRA) (2002). This alert suggests that actions should include making clinical staff aware of the limitations and risk of the equipment preventing disassociation between the woman and pregnant person's and baby's pulse. The MHRA advises the use of additional equipment to record the woman and pregnant person's pulse, for example, pulse oximetry, to enable a comparison between the readings obtained. The unreliability of the equipment requires clinicians to manage this risk. This implies that in a time-critical situation they have to judge the degree of trust they have in the information presented on fetal heart rate, which provides a level of uncertainty.

'... clinicians considered that there may be a problem with the transducer as this had occurred before ... For this reason the transducer was changed and at 03:20 hours the Baby's heart rate was recorded by one clinician as 55 bpm and by another as 92 bpm. A second USS [ultrasound scan] was performed by a member of the obstetric team ... The CTG and USS may have been falsely reassuring and the changing of the leads and equipment added to the delay.'

5.4.30 The design and choices made in the procurement of equipment may also influence the ability to monitor heart rates continuously and to meet all the requirements of a woman and pregnant person in labour, for example, enabling them to be as mobile as possible as suggested by guidance (National Institute for Health and Care Excellence, 2017).

'... that it is usual practice at the Trust to disconnect a CTG to allow a Mother [woman and pregnant person] to use the toilet if there had been no concerns with the tracing ... Telemetry (wireless monitoring) ... would allow the Mother [woman and pregnant person] to mobilise during labour including using the toilet whilst maintaining continuous CTG monitoring. Staff reported that there are not enough telemetry units available to allow every Mother [woman and pregnant person] who requires continuous monitoring to use this technology.'

5.4.31 The impact of the existing procurement process within the NHS and monitoring through use of CTG equipment is covered in depth by a previous HSIB report on fetal heart rate monitoring (**Healthcare Safety Investigation Branch, 2021d**).

5.4.32 The RCOG (2015a) suggests 'several practical things you can do' to enhance the reliability of measuring the fetal heart rate. These all rely on the behaviours or actions of clinicians, which could be influenced by the context and the system in which they are required to monitor a baby's wellbeing. For example, their actions could be affected by equipment issues, time pressure, competing tasks and high workloads. There appears to be a need to consider the inherent reliability of the tools relied on by clinicians to enable the evaluation of fetal wellbeing.

HSIB makes the following safety recommendation

Safety recommendation R/2021/148:
HSIB recommends that the Department of Health and Social Care commission a review to improve the reliability of existing assessment tools for fetal growth and fetal heart rate to minimise the risk for babies.

5.5 Maternity telephone triage calls

Pre-admission telephone triage provides the gateway for women and pregnant people to raise concerns and allows healthcare staff to identify whether there is a need for a person to attend the maternity unit for further assessment or closer monitoring after some interactions. The communication at this point is between the woman and pregnant person or their support partner and a member of hospital staff. The variability in how information is conveyed over the telephone is influenced by the style of communication. How the clinician receives the information is influenced by their knowledge of the subject in the context of the healthcare environment.

Pre-admission triage call

5.5.1 A telephone triage call provides an opportunity to recognise critical cues and make critical judgements and decisions, which may impact upon subsequent actions and outcomes. This review has identified that maternity triage is an important safety control and any loss of information at this critical stage may prevent staff from identifying signals which may indicate emerging problems with a person's pregnancy. These symptoms and signs may be subtle, so effort is required to ensure they are not missed.

5.5.2 The work arrangements within a triage area will influence which staff may respond to incoming telephone calls. The level of staff members' qualification, competence and expertise may vary.

'... she had telephoned the Trust in the morning and that the clinician she talked with was a student midwife ...'

'... the second triage call was answered by a member of the support staff.'

5.5.3 HSIB investigations indicate that variability in staff qualifications may influence the quality of the questioning of women and pregnant people, who are often in pain or anxious. The organisational strategy and capability to support maternity staff to manage the workload of a maternity unit and accommodate staff breaks, will determine how likely it is that a suitably qualified person is available to respond to calls. One consequence of the COVID-19 pandemic, as suggested earlier in this review, is a negative impact on staffing levels. However, the extent of the impact of low staffing levels on the way triage telephone calls were managed, compared to normal practices, is not clear.

'The Mother [woman and pregnant person] reported that a second call was made as advised, following ongoing concerns with the Baby's movements … during the telephone call the clinician expressed that they "were not concerned about the Baby's movements". The call proforma was not completed at the time of this call … the maternity triage unit was extremely busy at this time, there were five women and pregnant people in the maternity triage unit, the clinician was also responsible for answering and documenting phone calls made to the triage assessment unit.'

5.5.4 The number of calls made by a woman and pregnant person during their pregnancy may suggest the level of their concern or the presence of more severe or persistent symptoms. A reliable system is needed to ensure all calls are logged, so that all staff answering calls can see how often a person has called.

'Local guidance states women and pregnant people who telephone the maternity unit for advice should be seen following their third call in a 24-hour period.'

'… it is not usual practice to add a summary from the telephone assessment onto the Mother's [woman and pregnant person] electronic patient record. There is no system in place within the triage department to monitor the frequency of calls being made by women and pregnant people into the department.'

5.5.5 NICE guidance (2017) requires clinical staff to document the advice they have provided in a triage context. This review established that the reliability with which this happens may vary.

'The fact that the second call was not recorded on the triage call proforma means that other clinicians were unaware of how many calls the Mother [woman and pregnant person] had made, the advice given and the ongoing issues that were identified at each call.'

5.5.6 Safety netting describes the information and advice provided to parents to ensure they are aware of general and specific risks that they should look out for. This advice may be delivered verbally or through leaflets and is tailored to risks that staff consider most relevant to the woman and pregnant person. In the cases reviewed, generally the advice provided reflected national guidance; however, there were suggestions that this standard was not always achieved (**Healthcare Safety Investigation Branch, 2021b**).

'… she was asked to "eat chocolate so that the Baby would move" and that she understood that staff were concerned about the Baby's heartbeat.'

'... the Mother [woman and pregnant person] reported that her Baby was moving less than normal and was informed to expect this at the end of pregnancy due to the size of the Baby.'

5.5.7 The woman and pregnant person's perception of patterns in fetal movement is considered important (Norman et al, 2018). How a woman and pregnant person communicates their perception of reduced fetal movement, the risk interpreted by staff receiving the woman and pregnant person's observations and variability in the advice communicated to manage the risk will determine how successfully information is communicated.

5.5.8 The woman and pregnant person's ability to assess and understand the symptoms and signs they should look out for in late pregnancy is influenced by the information provided on what would be considered 'normal' and what is concerning.

'... the Mother [woman and pregnant person] and Father [partner] could not recollect being advised how long to observe the Baby's movements, how to monitor them when the contractions were making it difficult to assess or what sort of movement or lack of movement they should be concerned about.'

'... generally women and pregnant people are informed that towards the end of pregnancy movements may change to a 'squirm rather than a poke' and that they should still feel regular movements throughout the day.'

5.5.9 The need for staff to ask parents questions in a meaningful way in order to understand clinical risk is not unique to maternity care. This issue exists in other healthcare contexts and presents challenges to ensure an accurate description of symptoms. The development of questions to extract information on relevant symptoms can increase the quality and reliability of the questions asked. The use of decision aids can assist clinicians make decision and judgements based on the risks described (Greenhalgh, 2016).

5.5.10 The style of communication and the language used may also influence the level of urgency, perceived by parents, to attend the hospital.

'When the Father [partner] called the delivery suite later that day at approximately 21:30 hours, five hours later and reported there were now some concerns with their Baby's movements they were advised to attend the delivery suite for CTG monitoring. They recalled that advice given appeared to be a "choice" for them to make rather than a recommendation.'

5.5.11 It is recognised that the use of passive or active language can influence how effectively messages are communicated. The way instructions are phrased and delivered is acknowledged as a potential barrier to communication when the intention is to ensure that a specific action is completed (Flin, 2008). In the context of stressful situations and demanding work environments, strategies for effective communication between parents and staff need to minimise all barriers in order to help staff make reliable decisions and take action within limited timeframes. The purpose of telephone triage is to enable clinicians to reliably capture and interpret information about the woman and pregnant person's condition; this review has identified significant variability in the reliability and effectiveness of communication in telephone triage.

5.5.12 The evidence from the review identifies the critical importance of a pre-admission telephone triage service and the provision of consistent assessment and advice.

HSIB makes the following safety recommendation

Safety recommendation R/2021/149:
HSIB recommends that NHS England and NHS Improvement leads the development of minimum operating standards for pre assessment maternity telephone triage services to support safe and consistent telephone triage to ensure reliable identification of risks.

Communication and assessment of risk and safety netting

5.5.13 A core principle of healthcare, required by law, is that service users should be informed of relevant risks associated with their care (Supreme Court, 2015). This has been re-emphasised in the recently published Ockenden report.

'Women must be enabled to participate equally in all decision making processes and to make informed choices about their care.'
(House of Commons, 2020)

5.5.14 The General Medical Council (2020) has published new guidance on decision making and consent. This guidance explains that the exchange of information between the doctor and the woman and pregnant person is essential and that supported decision making and consent are fundamental to good practice.

5.5.15 This review highlights several factors which are considered to influence how the communication of risks may occur and how communication issues may affect shared decision making. The holistic approach adopted by staff may determine how they deliver information relating to potential relevant

risks. Concern for the woman and pregnant person's level of distress may reduce the emphasis they place on a potential risk.

'... staff offering the IOL [induction of labour] did not want to make the Mother [woman and pregnant person] anxious and felt that the communication used to deliver the message was done in a sensitive manner to avoid causing unnecessary distress ... the Mother [woman and pregnant person] said that she did not understand that there was any potential risk to the Baby as the movements were still reduced.'

'The Mother [woman and pregnant person] shared with the HSIB investigation team that, when she had asked why the USS [ultrasound scan] was required, staff explained to her that larger babies sometimes have "a little trouble". The risk of having a large baby increasing the risk of uterine rupture was not discussed.'

Interpretation services

5.5.16 Information or verbal communication in a language and format that is accessible to parents is essential to support the communication of relevant risks and to enable situation assessment by staff. Variability in the provision of or access to information in a relevant language/format suggests that an organisation's system is vulnerable in terms of ensuring patients' full understanding of risk and enabling shared decision making.

5.5.17 There are high standards and expectations in place for the provision of interpretation services during maternity care, which reflect the legal rights of all patients. The standards stipulate that the need for interpretation services should be established early in the maternity care pathway. Interpretation and interpretation services should be provided and be of high quality, accessible and responsive to a patient's linguistic needs, and relatives should not act as interpreters (Royal College of Obstetricians and Gynaecologists, 2008).

5.5.18 This review identified variable adherence to guidance on the use of interpretation services. In the 37 investigations reviewed, 8 (22%) of those concerning families whose first language was not English highlighted a lack of access to interpretation services. In four of these eight cases it was possible to identify that this affected the care received. These cases highlighted that typically relatives act as interpretors where unplanned maternal care is provided, for example, a telephone call or attendance at the triage unit, or when a timely or appropriate interpretation service cannot be provided, for example accommodating local dialects. The inability to identify timely or appropriate interpretation services presented the greatest risk to the safety of women and pregnant people and babies during unplanned admissions.

'The HSIB investigation team learned from the Mother [woman and pregnant person] that she was offered an interpreter and declined as it was thought that if there was anything she did not understand the Father [parent] would be able to assist. During the pregnancy there was the outbreak of the COVID-19 pandemic and the Father [parent] was no longer permitted to attend the appointments.'

'... staff tried to arrange a face-to-face interpreter for these appointments. An interpreter who spoke the mother's [woman and pregnant person's] language was not available and the telephone services had to be used on both occasions. ... it can be difficult to get a face-to-face interpreter and ... the usual practice for using the interpreting service is via telephone interpreters as this was usually easy to organise.'

5.5.19 The review identified instances where trusts had interpreted national COVID-19 guidance as prohibiting partners from accompanying women and pregnant people either to antenatal appointments or into a maternity unit until confirmed labour was established. This interpretation of guidance meant that a partner who would have been relied on to interpretate was not present. Although guidance states that partners should not be relied on to interpretate for women and pregnant people during pregnancy, as highlighted in the previous paragraph it appears that in some periods of maternity care, particularly in emergency or unplanned admissions, this can become a necessity. This review has highlighted cases where this risk was not managed during the COVID-19 pandemic.

5.5.20 The review identified a lack of robustness in the system of interpretation service provision to support all maternity care, planned and unplanned. The adjustment to guidance during the COVID-19 pandemic created the unexpected consequence of women and pregnant people being without any form of translation or support in the early stages of labour or when they found out that their baby had died.

5.5.21 The inconsistent provision of interpretation services is not unique to the COVID-19 pandemic – it is a challenge in normal circumstances (MBRRACE-UK, 2017b). The impact, suggested by this review, includes a reduction in the quality and reliability of the information shared with parents to inform their understanding and decision making.

'... the use of an interpretation service for these conversations would have enabled the Mother [woman and pregnant person] and Father [partner] to understand their situation and the information given to them.'

5.5.22 The investigations saw some cases where routine appointments were delayed to ensure an interpreter was present. This suggests the need for clinicians to manage the risk associated with language as a barrier relative to the delay to the delivery of care. The ability of healthcare services to deliver interpretation services does not appear to be resilient and it may not be feasible in all circumstances. Reflecting limitations within guidance and stress testing of systems may provide valuable learning for organisations.

HSIB makes the following safety recommendation

Safety recommendation R/2021/150:
HSIB recommends that NHS England and NHS Improvement develop minimum operating standards for interpretation services in maternity care which will include a communication risk assessment.

Organisational preparedness for predictable safety-critical scenarios

5.5.23 The ability of staff and organisations to implement and adhere to guidance/policies can be influenced by the clinical and workplace context and demands placed on healthcare systems (Vincent and Amalberti, 2016). Safety can be compromised by the gaps, which evolve over time, in how work is prescribed within policies, how organisations imagine work can be achieved and how staff accommodate system demands and work is usually done (Braithwaite et al, 2015).

5.5.24 Understanding and acknowledging how a system influences the way work is done by staff in predictable circumstances can provide invaluable information to understand how existing risks may be magnified, influencing how services respond to unpredictable or unexpected circumstances (Hollnagel, 2014). This can inform a prospective assessment of risk, including understanding how practicable and achievable guidance remains in the context of the organisational environment and demands (Sujan, 2015).

5.5.25 Guidelines suggest that at birth the condition of the baby should be assessed. Based on these guidelines neonatal resuscitation was deemed necessary for at least 9 of the 37 cases reviewed (Resuscitation Council UK, 2015). This allows for uncertainty about when the stillbirth occurred during labour and an opportunity to preserve life.

5.5.26 Prior to a birth, staff specially trained in neonatal resuscitation should be in attendance if intrapartum fetal distress has been identified. Equipment should be prepared, and a briefing undertaken where time allows. The need for resuscitation at birth is suggested as a 'predictable event' (European

Resuscitation Council, 2015), which suggests the environments used for delivering babies and the staff attending should have the required equipment and skills (National Institute for Health and Care Excellence, 2017).

5.5.27 The reports included in this review showed that the calling of neonatal support prior to the birth of a baby considered to be in distress did not consistently happen as recommended (National Institute for Health and Care Excellence, 2019b; Resuscitation Council UK, 2015).

'Following birth, the clinical co-ordinator requested the attendance of a neonatal nurse who arrived to provide assistance when the Baby was approximately 4 minutes of age.'

5.5.28 Additional delays to some emergency responses were reported due to adjustments made as a result of the COVID-19 pandemic.

'The neonatal nurse described having been supported to don the required COVID-19 PPE [personal protective equipment] prior to entering the operating theatre, which took approximately 2 minutes.'

'... the resuscitaire used in the obstetric theatre had recently been moved from a standalone room between two maternity operating theatres into the operating theatre. This was to accommodate a secure area for all staff to prepare themselves in PPE.'

5.5.29 The early arrival of neonatal support can ensure the equipment that might be required is available and can be checked.

'... the first member of the neonatal team arrived in the labour ward delivery room at the same time that the Baby was born. This meant that they did not have time to prepare the equipment in the way that they usually would.'

5.5.30 On some occasions, staff members' confidence in the reliability and availability of the equipment available to support resuscitation appeared to be under question.

'Staff were unable to hear a heartbeat and swapped the stethoscope for a different one in case the original was faulty. The Baby's airway was suctioned, with 'thick meconium' documented. The staff were concerned that the suction may be faulty and a second resuscitaire was brought into the room.'

'... clinicians needed to obtain the necessary kit from the maternity operating theatre, leading to a delay. It is not clear what standard equipment is available in each delivery room ... some rooms contain the

equipment and some rooms have a sign reminding the team that the supplementary equipment needed for an advanced resuscitation is located in the maternity operating theatre.'

5.5.31 Adjustments in the physical layout of environments during the pandemic changed the environment in which staff were working. Staff may have benefited from simulation activities to ensure they could continue to practise safely in planned and emergency situations in this new context.

'The oxygen saturation monitor cable was too short for the machine to be placed in an upright position and had to be laid on its side. Equipment was placed on the floor due to lack of space causing a hazard to staff. The checking of instruments and swab count was impacted due to limited space. The neonatal staff were constrained and could not move freely around the resuscitaire. The member of staff assigned to scribe during the resuscitation was unable to see the clock on the resuscitaire. Staff described to the HSIB investigation team that the operating theatre felt "crowded". This changed the environment and flow of work, adding to increased stress for the whole team.'

5.5.32 In maternity care simulation is currently seen as a method to identify and address 'personal and team behaviours' and seek behavioural change (Royal College of Obstetricians and Gynaecologists, 2015a). In other safety-critical industries simulation is a tool within existing safety management systems (**see appendix 3**) which is used to consider modifications to processes and environments. Insitu simulation is recommended in healthcare to assist in the identification of system issues in high-risk settings (Patterson et al, 2013).

5.5.33 Existing systems, equipment, and environments to support neonatal resuscitation do not appear to consistently enable all staff to act and respond as required by guidance. The expertise available to attend neonatal resuscitations may also be compromised depending on the acuity and work demands within a maternity unit.

'A junior neonatal doctor was called to attend the Caesarean Section, which was not in line with local guidance (Attendance at deliveries, 2018) which states that in the presence of meconium with any evidence of fetal compromise a more senior doctor is required to attend. The HSIB investigation team learnt that the senior doctor was reviewing another baby on the NICU [neonatal intensive care unit] and the plan was that they would attend once the safety of the Baby on NICU had been assured.'

5.5.34 The additional challenges caused by the COVID-19 pandemic led to organisational adjustments; these influenced the expertise of doctors attending a call for neonatal resuscitation and created the requirement to don PPE.

'The Baby was born during the COVID-19 pandemic. To manage the impact of the pandemic on the Trust the rota for the neonatal team was changed. The HSIB investigation team learnt that resuscitations are usually initially attended by a tier one [junior] doctor. During COVID-19 time the tier one role was covered by a tier two [senior] doctor.'

5.5.35 This review has highlighted gaps between how neonatal resuscitation is expected or imagined to work and how it may actually happen. There was no evidence of clear prospective risk assessment (evaluation of the potential for harm, **see section 2.3.5**) to determine how existing challenges and adjustments made during the COVID-19 pandemic may influence emergency procedures in maternity services. The cases reviewed provide examples of how the system impeded staff members' ability to respond.

HSIB makes the following safety recommendation

Safety recommendation R/2021/151:
HSIB recommends that NHS England and NHS Improvement develop a framework to support Trusts to anticipate operational risk in maternity services when delivering neonatal resuscitation.

HSIB makes the following safety observation

Safety observation O/2021/127:
It may be beneficial if multidisciplinary simulation is considered as a tool to support prospective risk analysis for neonatal resuscitation.

6 Conclusion

6.1 This review has identified a series of factors during the COVID-19 pandemic which have influenced the care associated with the 37 cases of intrapartum stillbirth reviewed. The findings suggest that many of the existing safety issues are known to maternity care providers but may have been exacerbated further during the pandemic. This includes the sustainability of staffing levels in maternity units. This review highlights how the maternity system aimed to balance the risk associated with the uncertainty and emerging evidence about the transmission of COVID-19 with the risk of clinical assessments relied upon to manage the risk to the wellbeing of women and pregnant people and their babies.

6.2 The findings of this report highlight the adjustments made to limit face-to-face interactions, local guidance, approaches to antenatal scanning practices, and an increased use of remote consultations. The move to remote consultations required integrated technical systems and reliability in the recording of information across maternity settings. Insufficiencies in existing systems sometimes impeded these consultations and may have affected clinical decision making.

6.3 The experience of parents was clearly influenced by the restrictions on partners attending healthcare settings with the woman and pregnant person, with some suggestion that these limitations may have influenced a woman and pregnant person's decision making about when to go to hospital. A further unintended consequence was the restriction in communication for women and pregnant people whose first language was not English.

6.4 As part of their safety management systems, (**see appendix 3**) organisations in other safety-critical industries undertake a process which informs how risk and organisational performance is influenced by service design and modification. These industries do not rely solely on the use of guidance and learning from incidents but adopt a prospective approach to understanding and managing risks within the system. The assessment of risk is based on understanding the likelihood of an event, for example fetal growth assessment being accurate, and the severity of the consequence, such as stillbirth. In these industries any identified risks may be subject to detailed analysis to provide an overview of the probability of risk and human reliability within the system (Health and Safety Executive, 1999). This may include analysis of individual tasks, for example the reliability of fetal size assessments, and the potential for failure in completion of the task, such as the probability the assessment will be accurate, which may in turn consider

factors likely to influence the performance of such assessments, including the work context, workload and fatigue. This enables organisations to provide transparency and acknowledge inherent risks within a system.

6.5 In conclusion, this review recognises that the current maternity system, over recent years, has been addressing a number of systemic risks to reduce stillbirths through national initiatives with some evidence of success. The COVID-19 pandemic, in this already challenged system, may have put extra strain on organisations. This would have been a challenge for any safety-critical organisation, but especially one without a comprehensive system for managing safety.

HSIB makes the following safety observation

Safety observation O/2021/128:
It may be beneficial if expertise applied within other safety critical industries is integrated into the development and implementation of a maternity-focused proactive safety management system.

7 Safety recommendations and safety observations

1 Guidance

In response to the changing situation and developing understanding of risks during the first wave of the COVID-19 pandemic, a large volume of rapidly changing guidance was produced. Despite best efforts to make this accessible to staff, investigations found variation in local implementation, difficulty in assimilating the changes and in one instance an important discrepancy between two sets of current national guidance on the management of reduced fetal movements.

2 Management of risk

Although the NHS identified continued provision of maternity services as a priority, operational changes were made to reflect the need to reduce the risk of transmission of infection. In all the cases reviewed, the women and pregnant people received the recommended number of appointments and scans, and appropriate bereavement care was provided. Some face-to-face antenatal (pre-birth) visits were replaced with remote consultations, resulting in fewer opportunities to perform physical examinations such as symphysis-fundal height measurement (measurement of the size of the uterus which is used to assess a baby's growth during pregnancy), and carbon monoxide testing (a simple non-invasive breath test which gives women an immediate indication of the carbon monoxide level in their body) was paused. Some hospital ultrasound scans were stopped or delayed during this period.

3 Telephone triage

Difficulties in communication were identified, relating to the availability and presentation of clinical records, documentation and communication of information from triage calls, and availability of interpretors particularly in urgent circumstances. The usual reliance on family members to provide translation support, which is not in line with national guidance, was emphasised when policies were introduced requiring women and pregnant people to attend antenatal appointments alone.

4 Interpretation services

The review identified that family members do provide translation support when interpretation services cannot be provided by the local maternity service, even though this is not in line with national guidance. However, during the first wave of the pandemic, when women and pregnant people were required to attend antenatal appointments alone, the provision of interpretation services was even more critical.

5 Work demands and capacity to respond

Changes were identified in work processes, staffing levels and physical layout of the space in which staff were working, resulting from the pandemic. Membrane sweeps (a midwife or doctor uses a single finger to sweep around the cervix), designed to reduce the need for formal induction of labour, were stopped in some centres, to reduce the infection risk associated with more prolonged contact between patients and staff. Some of the necessary changes made to the physical space, for example to enable staff to don and doff (put on and take off) personal protective equipment, had unintended and unforeseen consequences in terms of the usability of equipment in its new position.

6 Neonatal resuscitation

The review highlighted gaps between how neonatal resuscitation (delivery of inflation breaths with or without chest compressions) is expected or imagined to work and how it actually happens. This issue has been highlighted in other types of national reports. The review identified that existing systems, equipment and environments to support neonatal resuscitation do not appear to consistently enable all staff to act and respond as required by the guidance.

Conclusion

This HSIB national learning report has identified significant efforts to maintain good care for patients during an unprecedented pandemic and the resulting changes in healthcare systems. HSIB makes safety recommendations safety observations to reduce variation and improve safety regarding remote consultation, communication, monitoring of fetal wellbeing, triage, and availability of interpretation services. Further safety recommendations relate to taking a proactive approach to the assessment of patient safety risks and the use of an overall safety management system in maternity care, as used in other safety-critical industries.

HSIB makes the following safety recommendations

Safety recommendation R/2021/144:
HSIB recommends that NHS England and NHS Improvement leads work to develop a process to ensure consistency and clarity across national maternity clinical guidance.

Safety recommendation R/2021/145:
HSIB recommends that future iterations of the Royal College of Obstetricians and Gynaecologists' guidance clarify the management of a reported change in fetal movements during the third trimester of pregnancy with due regard to

national policy.

Safety recommendation R/2021/146:
HSIB recommends that NHS England and NHS Improvement leads work to collate and act on the evidence on the risks and benefits associated with the use of remote consultations at critical points in the maternity care pathway.

Safety recommendation R/2021/147:
HSIB recommends that NHSX develops specifications for electronic patient record (EPR) systems that require adherence to national interconnectivity standards for the exchange of core maternity healthcare information. The specifications should include functionality to enable both women and pregnant people and professionals to add to the record, and also support alerting functionality.

Safety recommendation R/2021/148:
HSIB recommends that the Department of Health and Social Care commission a review to improve the reliability of existing assessment tools for fetal growth and fetal heart rate to minimise the risk for babies.

Safety recommendation R/2021/149:
HSIB recommends that NHS England and NHS Improvement leads the development of minimum operating standards for pre assessment maternity telephone triage services to support safe and consistent telephone triage to ensure reliable identification of risks.

Safety recommendation R/2021/150:
HSIB recommends that NHS England and NHS Improvement develop minimum operating standards for interpretation services in maternity care which will include a communication risk assessment.

Safety recommendation R/2021/151:
HSIB recommends that NHS England and NHS Improvement develop a framework to support Trusts to anticipate operational risk in maternity services when delivering neonatal resuscitation.

HSIB makes the following safety observations

Safety observation O/2021/126:
It may be beneficial if further work is done to understand the specific aspects of the healthcare system which could explain the disparity in the experience and risk for women and pregnant people from Black, Asian and minority ethnic backgrounds and those with higher socio-economic deprivation.

Safety observation O/2021/127:
It may be beneficial if multidisciplinary simulation is considered as a tool to support prospective risk analysis for neonatal resuscitation.

Safety observation O/2021/128:
It may be beneficial if expertise applied within other safety critical industries is integrated into the development and implementation of a maternity-focused proactive safety management system.

8 References

Ashish, K. G. (2020) Effect of the COVID-19 pandemic response on intrapartum care, stillbirth, and neonatal mortality outcomes in Nepal: a prospective observational study. Lancet Global Health, 1273-1281 [Online]. DOI: 10.1016/S2214-109X(20)30345-4.

Braithwaite, J. (2018) Changing how we think about healthcare improvement. BMJ, 361 [Online]. DOI: 10.1136/bmj.k2014.

Braithwaite, J., Wears, R. and Hollnagel, E. (2015) Resilient health care: turning patient safety on its head. International Journal for Quality in Health Care, 27 (5), 418-420 [Online]. DOI: 10.1093/intqhc/mzv063.

Campbell, P., Torrens, C., Pollock, A. and Maxwell, M. (2018) A scoping review of evidence relating to communication failures that lead to patient harm [Online]. Available at **https://www.gmc-uk.org/-/media/documents/a-scoping-review-of-evidence-relating-to-communication-failures-that-lead-to-patient-harm_p-80569509.pdf** (Accessed 5 February 2021).

Carayon, P., Schoofs Hundt, A., Karsh, B.-T., Gurse, A., Alvardo, C., Smith, M. and Faltley Brennan, P. (2006) Work system design for patient safety: the SEIPS model. BMJ Quality & Safety [Online]. DOI: 10.1136/qshc.2005.015842
Carthey, J., Walker, S., Vincent, C. and Griffiths, W.H. (2011) Breaking the rules: understanding non-compliance with policies and guidelines [Online]. BMJ, 343. DOI: 10.1136/bmj.d5283.

Centers for Disease Control and Prevention. (2020) Interim U.S. guidance for risk assessment and work restrictions for healthcare personnel with potential exposure to COVID-19 [Online]. Available at **https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html** (Accessed 29 January 2021).

Chmielewska, B., Barratt, I., Townsend, R., Kalafat, E., van der Meulen, J., Gurol-Urganci, I., O'Brien, P., Morris, E., Draycott, T., Thangaratinam, S., Le Doare, K., Ladhani, S., von Dadelszen, P., Magee, L. and Khalil, A. (2021) Effects of the COVID-19 pandemic on maternal and perinatal outcomes: a systematic review and meta-analysis. Lancet [Online]. DOI: 10.1016/S2214-109X(21)00079-6.

Cox, P. and Evans, C. (2019) Tissue pathway for histopathological examination of the placenta. The Royal College of Pathologists [Online]. Available at **https://www.rcpath.org/uploads/assets/ec614dfa-007c-4a93-8173cb202a071a72/G108-Tissue-pathway-for-histopathological-examination-of-the-placenta.pdf** (Accessed 8 July 2021).

De Curtis, M., Villani, L. and Polo, A. (2020) Increase of stillbirth and decrease of late preterm infants during the COVID-19 pandemic lockdown. Archives of Disease in Childhood – Fetal Neonatal Edition [Online]. DOI: 10.1136/archdischild-2020-320682. Epub ahead of print.

Dekker, S. (2014) Creating an effective safety department, in Dekker, S. The Field Guide to Understanding 'Human Error' (pp.143-160). Farnham: Ashgate.

Department of Health and Social Care. (2020) Policy paper. Coronavirus (COVID-19): scaling up testing programmes [Online]. Available at **https://www.gov.uk/government/publications/coronavirus-covid-19-scaling-up-testing-programmes** (Accessed 8 July 2021).

Di Mascio, D. (2020) Risk factors associated with adverse fetal outcomes in pregnancies affected by Coronavirus disease 2019 (COVID-19): a secondary analysis of the WAPM study on COVID-19. Journal of Perinatal Medicine, 48 (9), 950-958 [Online]. DOI: 10.1515/jpm-2020-0355.

Dixon-Woods, M., Martin, G., Tarrang, C., Bion, J., Goeschel, C., Provonost, P., Brewster, L., Shaw, L., Sutton, L., Willars, J., Ketley, D. and Woodcock, T. (2014) Safer Clinical Systems: evaluation findings. Learning from the independent evaluation of the second phase of the Safer Clinical Systems programme. The Health Foundation. Available at **https://www.health.org.uk/sites/default/files/SaferClinicalSystemsEvaluationFindings_fullversion.pdf** (Accessed 13 May 2021).

European Resuscitation Council. (2015) European Resuscitation Council guidelines for resuscitation 2015: Section 7. Resuscitation and support of transition of babies at birth [Online]. Available at **https://ercguidelines.elsevierresource.com/european-resuscitation-council-guidelines-resuscitation-2015-section-7-resuscitation-and-support#Preparation** (Accessed 10 February 2021).

Federal Aviation Administration. (2014) Safety management system ml version 4.0. Air Traffic Organisation 2014. Available at **https://www.skybrary.aero/bookshelf/books/1255.pdf** (Accessed 13 May 2021).

Finucane, E. M., Murphy, D. J., Biesty, L. M., Gyte, G. M. L., Cotter, A. M., Ryan, E. M., Boulvain, M. and Devane, D. (2020) Membrane sweeping for induction of labour. Cochrane Database of Systematic Reviews, 2 (2) [Online]. DOI: 10.1002/14651858.CD000451.pub3

Flach, J. (2017) Muddling through in the ED, Perspicacity, 29 August [Online]. Available at **https://blogs.wright.edu/learn/johnflach/2017/08/29/muddling-through-in-the-ed** (Accessed 3 April 2021).

Flin, R. O. (2008) Communication, in Flin, R. O. Safety at the Sharp End (pp.69-91). Farnham, Ashgate.

Ford, M. (2021) Inaugural head of midwifery research at NHS England announced. Nursing Times. Available at **https://www.nursingtimes.net/news/research-and-innovation/inaugural-head-of-midwifery-research-at-nhs-england-announced-02-02-2021/** (Accessed 5 February 2021).

Frøen, J., Pinar, H., Flenady, V., Bahrin, S., Charles, A., Chauke L., Day, K., Duke, C. W., Facchinetti, F., Fretts, R. C., Gardener, G., Gilshenan, K., Gordijn, S. J., Gordon, A., Guyon, G., Harrison, C., Koshy, R., Pattinson, R. C., Petersson, K., Russell, L., Saastad, E., Smith, G. C. S and Torabi, R. (2009) Causes of death and associated conditions (Codac) – a utilitarian approach to the classification of perinatal deaths. BMC Pregnancy Childbirth 9, 22 [Online]. DOI: 10.1186/1471-2393-9-22

Gardosi, J., Madurasinghe, V., Williams, M., Malik, A. and Francis, A. (2013) Maternal and fetal risk factors for stillbirth: population based study. BMJ, 346 [Online]. DOI: 10.1136/bmj.f108

General Medical Council. (2020) Decision making and consent [Online]. Available at **https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf?la=en&hash=BE327A1C584627D12BC51F66E790443F0E0651DA** (Accessed 27 July 2021).

Greenhalgh, S. T. (2016) Development of a toolkit for early identification of cauda equina syndrome. Primary Health Care Research and Development, 17 (6), 559-567 [Online]. DOI: 10.1017/S1463423616000062.

Greig, P. and Snow, R. (2017) Fatigue and risk: are train drivers safer than doctors? BMJ, 359 [Online]. DOI: 10.1136/bmj.j5107.

Greater Manchester and Eastern Cheshire Strategic Clinical Networks. (2019) Reduced fetal movement (RFM) in pregnancy guidelines [Online]. Available at **https://www.england.nhs.uk/north-west/wp-content/uploads/sites/48/2019/09/Reduced-Fetal-Movement-Guidelines.pdf** (Accessed 23 March 2021).

Griffiths, S., & Campbell, J. (2015) Placental structure, function and drug transfer. Continuing Education in Anaesthesia Critical Care & Pain, 15, 2. 84-89 [Online]. DOI: 10.1093/bjaceaccp/mku013.

Hargreaves, K., Cameron, M., Edwards, H., Gray, R. and Deane, K. J. (2011) Is the use of symphysis-fundal height measurement and ultrasound examination effective in detecting small or large fetuses? Journal of Obstetrics and Gynaecology, 31 (5), 380-383 [Online]. DOI: 10.3109/01443615.2011.567343

Health and Safety Executive. (n.d.). Principles and guidelines to assist HSE in its judgements that duty-holders have reduced risk as low as reasonably practicable. Available at **https://www.hse.gov.uk/managing/theory/alarp1.htm** (Accessed 10 February 2021).

Health and Safety Executive. (1999) Reducing error and influencing behaviour [Online]. Available at **https://www.hse.gov.uk/pubns/priced/hsg48.pdf** (Accessed 9 September 2020).

Health and Safety Executive. (2020). Risk assessment during the coronavirus (COVID-19) pandemic. Available at **https://www.hse.gov.uk/coronavirus/working-safely/risk-assessment.htm** (Accessed 20 September 2020).

Healthcare Safety Investigation Branch. (2021a) What we investigate. Criteria for carrying out maternity investigations [Online]. Available at **https://www.hsib.org.uk/maternity/what-we-investigate/** (Accessed 20 April 2021).

Healthcare Safety Investigation Branch. (2021b) Maternal death: learning from maternal death investigations during the first wave of the COVID-19 pandemic [Online]. Available at **https://www.hsib.org.uk/investigations-cases/maternal-death-national-learning-report/** (Accessed 20 April 2021).

Healthcare Safety Investigation Branch. (2021c) Severe brain injury, early neonatal death and intrapartum stillbirth associated with larger babies and shoulder dystocia. HSIB [Online]. Available at **https://www.hsib.org.uk/investigations-cases/severe-brain-injury-early-neonatal-death-and-intrapartum-stillbirth-associated-larger-babies-and-shoulder-dystocia/national-learning-report/** (Accessed 20 April 2021).

Healthcare Safety Investigation Branch. (2021d) Suitability of equipment and technology used for continuous fetal heart rate monitoring [Online]. Available at **https://www.hsib.org.uk/documents/340/Suitability_of_equipment_and_technology_used_for_continuous_fetal_heart_rate_monitorin.pdf** (Accessed 27 July 2021).

Heazell, A. E., Hayes, D. J .L., Whitworth, M., Takwoingi, Y., Bayliss, S. E. and Davenport. C. (2019) Biochemical tests of placental function versus ultrasound assessment of fetal size for stillbirth and small-for-gestational-age infants. Cochrane Database of Systematic Reviews, 5 (5) [Online]. DOI: 10.1002/14651858.CD012245.

Heazell, A. E., Siassakos, D., Blencowe, H., Burden, C., Bhutta, Z. A., Cacciatore, J., Dang, N., Das, J., Flenady, V., Gold, K. J., Mensah, O. K., Millum, J., Nuzum, '., O'Donoghue, K., Redshaw, M., Rizvi, A., Roberts, T., Toyin Saraki, H. E., Storey, C., Wojcieszek, A. M. and Downe, S; Lancet Ending Preventable Stillbirths Series study group; Lancet Ending Preventable Stillbirths investigator group. (2016) Stillbirths: economic and psychosocial consequences. Lancet, 387 (10018), 604-16 [Online]. DOI: 10.1016/S0140-6736(15)00836-3.

Henrichs, J., Verfaille, V., Jellema, P., Viester, L., Pajkrt, E., Wilschut, J., van der Horst, H. E., Franx, A. and de Jonge, A. (2019) Effectiveness of routine third trimester ultrasonography to reduce adverse perinatal outcomes in low risk pregnancy (the IRIS study): nationwide, pragmatic, multicentre, stepped wedge cluster randomised trial. BMJ, 367 [Online]. DOI: 10.1136/bmj.l5517.

Holden, R., Carayon, P., Gurses, A., Hoonakker, P., Schoofs Hundt, A., Ozok, A. and Rivera-Rodriguez, A. (2013) SEIPS 2.0: a human factors framework for studying and improving the work of healthcare professionals and patients. Ergonomics56 (11), 1669-1686 [Online]. DOI: 10.1080/00140139.2013.838643.

Hollnagel, E. (2014) Safety-I and Safety-II. Farnham: Ashgate.
Hollnagel, E., Woods, D. and Leveson, N. (2006) Resilience Engineering: Concepts and Precepts. Surrey,UK: Ashgate.

House of Commons. (2020) Emerging findings and recommendations from the independent review of maternity services at the Shrewsbury and Telford Hospital NHS Trust [Online]. Available at **https://www.donnaockenden.com/downloads/news/2020/12/ockenden-report.pdf** (Accessed 21 December 2020).

The INFANT Collaborative Group. (2017). Computerised interpretation of fetal heart rate during labour (INFANT): a randomised controlled trial. The Lancet, 389 (10080), 1719-1729 [Online]. DOI: 10.1016/S0140-6736(17)30568-8.

International Civil Aviation Organisation. (n.d.) Fatigue management [Online]. Available at **https://www.icao.int/safety/fatiguemanagement/Pages/default.aspx** (Accessed 20 October 2020).

International Confederation of Midwives. (2020) Women's rights in childbirth must be upheld during the coronavirus pandemic [Online]. Available at **https://www.internationalmidwives.org/assets/files/news-files/2020/03/icm-statement_upholding-womens-rights-during-covid19-5e83ae2ebfe59.pdf** (Accessed 23 June 2021).

Ipieca (2019) Managing fatigue in the workplace [Online]. Available at **https://www.ipieca.org/resources/good-practice/managing-fatigue-in-the-workplace/** (Accessed 23 October 2020).

Jokhan, S., Whitworth, M., Jones, F. S. and Heazell, A. (2015) Evaluation of the quality of guidelines for the management of reduced fetal movements in UK maternity units. BMC Pregnancy and Childbirth, 15 (54) [Online]. DOI: 10.1186/s12884-015-0484-5.

Kahneman, D. and Klein, G. (2009) Conditions for intuitive expertise: a failure to disagree. American Psychologist, 64 (6), 515-526 [Online]. DOI: 10.1037/a0016755.

Khalil, A., von Dadelszen, P., Draycott, T., Ugwumadu, A., O'Brien, P. and Magee, L. (2020) Change in the incidence of stillbirth and preterm delivery during the COVID-19 pandemic. JAMA, 324 (7), 705-706 [Online]. DOI: 10.1001/jama.2020.12746.

Kirtsman, M., Diambomba, Y., Poutanen, S. M., Malinowski, A. K., Vlachodimitropoulou, E., Parks, W. T., Erdman, L., Morris, S. K. and Shah, P.S. (2020) Probable congenital SARS-CoV-2 infection in a neonate born to a woman with active SARS-CoV-2 infection. Canadian Medical Association Journal, 192 (24), 647-650 [Online]. DOI: 10.1503/cmaj.200821.

Klein, G., Phillips, J. K., Rall, E. L. and Peluso, D. A. (2007) A data-frame theory of sensemaking, in Erlbaum, L. (Ed.), Expertise out of context: proceedings of the sixth international conference on naturalistic decision making (pp. 113-155). Mahwah, N. J.: Lawrence Erlbaum Associates.

Knight, M., Bunch, K., Vousden, N., Morris, E., Simpson, N., Gale, C', O'Brien, P., Quigley, M., Brocklehurst, P. and Kurinczuk, J. J. (2020) Characteristics and outcomes of pregnant women hospitalised with confirmed SARS-CoV-2 infection in the UK: a national cohort study using the UK Obstetric Surveillance System (UKOSS). BMJ [Online]. DOI: 10.1101/2020.05.08.20089268.

Kumar, M., Puri, M., Yadav, R., Biswas, R., Singh, M., Choudhary, V., Jaiswal, N. and Meena, D. (2020). Stillbirths and the COVID-19 pandemic: looking beyond SARS-CoV-2 infection. International Journal of Gynaecology & Obstetrics, 153, 76-82 [Online]. DOI: 10.1002/ijgo.13564. Epub ahead of print.

Lau, Y., Widdows, K., Roberts, S., Khizar, S., Stephen, G., Rauf, S. and Heazell, A. (2020) Assessment of the quality, content and perceived utility of local maternity guidelines in hospitals in England implementing. BMJ Open Quality, 9 (2), e000756 [Online]. DOI: 10.1136/bmjoq-2019-000756.

Leary, A. (2021) Why does healthcare reject the precautionary principle? BMJ [Online]. Available at **https://blogs.bmj.com/bmj/2021/03/12/alison-leary-why-does-healthcare-reject-the-precautionary-principle/** (Accessed 13 May 2021).

Liberati, E. G., Tarrant, C., Willars, J., Draycott, T., Winter. C., Kuberska, K., Paton, A., Marjanovic, S., Leach, B., Lichten, C., Hocking, L., Ball, S. and Dixon-Woods, M. (2020) Seven features of safety in maternity units: a framework based on multisite ethnography and stakeholder consultation. BMJ Quality & Safety, 30 (6), 444-456 [Online]. DOI: 10.1136/bmjqs-2020-010988.

Linehan, L', O'Donoghue, K., Dineen, S., White, J., Higgins, J. R. and Fitzgerald, B. (2021) SARS-CoV-2 placentitis: an uncommon complication of maternal COVID-19. Placenta, 104, 261-266 [Online]. DOI: 10.1016/j.placenta.2021.01.012.

Lorenzo, G. D., Monasta, L., Ceccarello, M., Cecotti, V. 'nd D'Ottavio, G. (2013) Third trimester abdominal circumference, estimated fetal weight and uterine artery doppler for the identification of newborns small and large for gestational age. European Journal of Obstetrics & Gynecology and Reproductive Biology, 166 (2), 133-138 [Online]. DOI: 10.1016/j.ejogrb.2012.10.010.

Lucraft, M. (2020) Chief Coroner's guidance on COVID-19. 26 March 2020 [Online]. Available at **https://www.judiciary.uk/wp-content/uploads/2020/03/Chief-Coroner-Guidance-No.-34-COVID-19_26_March_2020-.pdf** (Accessed 8 July 2021).

Medicines and Healthcare products Regulatory Agency. (2002) Fetal monitor/cardiotocograph (CTG) – adverse outcomes still reported. (All) adverse outcomes are still reported when CTG traces appear normal – this replaces alert SN 2002(23) (MDA/2010/054) [Online]. Available at **https://www.gov.uk/drug-device-alerts/medical-device-alert-fetal-monitor-cardiotocograph-ctg-adverse-outcomes-still-reported** (Accessed 8 February 2021).

MBRRACE-UK. (2017a) Saving Lives, Improving Mothers' Care: Lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2013-15 [Online]. Available at **https://www.npeu.ox.ac.uk/mbrrace-uk/presentations/saving-lives-improving-mothers-care** (Accessed 29 January 2021).

MBRRACE-UK. (2017b) Perinatal Confidential Enquiry: term, singleton, intrapartum stillbirth and intrapartum-related neonatal death [Online]. Available at **https://www.npeu.ox.ac.uk/assets/downloads/mbrrace-uk/reports/MBRRACE-UK%20Intrapartum%20Confidential%20Enquiry%20Report%202017%20-%20final%20version.pdf** (Accessed 24 March 2021).

MBRRACE-UK. (2020a) Perinatal Mortality Surveillance Report: UK Perinatal Deaths for Births from January to December 2018 [Online]. Available at **https://www.hqip.org.uk/wp-content/uploads/2020/12/Ref.-203-MNI-Perinatal-surveillance-report-2018-Full-report-FINAL.pdf** (Accessed 02 February 2021).

MBRRACE-UK. (2020b) Saving Lives, Improving Mothers' Care: lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2016-2018 [Online]. Available at **https://www.birthcompanions.org.uk/resources/244-mbrrace-uk-saving-lives-improving-mothers-care-2020** (Accessed 08 July 2021).

MBRRACE-UK. (2020c). Saving Lives, Improving Mothers' Care. Rapid report: learning from SARS-CoV-2-related and associated maternal deaths in the UK [Online]. Available at **https://www.hqip.org.uk/wp-content/uploads/2020/08/Ref.-201-MBRRACE-UK-maternal-COVID-19-Report-FINAL.pdf** (Accessed 2 February 2021).

Ministry of Housing, Communities and Local Government. (2019) Statistical release: the English Indices of Deprivation [Online]. Available at **https://www.gov.uk/government/statistics/english-indices-of-deprivation-2019** (Accessed 8 July 2021).

Mor, M., Kugler, N., Jauniaux, E., Betser, M., Wiener, Y., Cuckle, H. and Maymon, R. (2020) Impact of the COVID-19 pandemic on excess perinatal mortality and morbidity in Israel. American Journal of Perinatology [Online]. DOI: 10.1055/s-0040-1721515. Epub ahead of print.

National Bereavement Care Pathway. (2018) NBCP standards [Online]. Available at **https://nbcpathway.org.uk/nbcp-standards** (Accessed 01 March 2021).

National Institute for Health and Care Excellence. (n.d.) Intrapartum care for healthy women and babies [Online]. Available at **https://pathways.nice.org.uk/pathways/intrapartum-care#path=view%3A/pathways/intrapartum-care/intrapartum-care-overview.xmlandcontent=view-index** (Accessed 23 March 2021).

National Institute for Health and Care Excellence. (2008) Antenatal care for uncomplicated pregnancies. Clinical guideline [CG62] [Online]. Available at https://www.nice.org.uk/Guidance/CG62 (Accessed 29 January 2021).

National Institute for Health and Care Excellence. (2017) Intrapartum care for healthy women and babies. Clinical guideline [CG190] [Online]. Available at **www.nice.org.uk/guidance/cg190** (Accessed 2 February 2021).

National Institute for Health and Care Excellence. (2019a) Antenatal care for uncomplicated pregnancies. Clinical guideline [CG62] [Online]. Available at **https://www.nice.org.uk/Guidance/CG62** (Accessed 10 February 2021).

National Institute for Health and Care Excellence. (2019b) Caesarean section. Clinical guideline [CG132] [Online]. Available at **https://www.nice.org.uk/guidance/cg132/resources/caesarean-section-pdf-35109507009733** (Accessed 10 February 2021).

NHS. (2018) You and your baby at 37 weeks pregnant [Online]. Available at **https://www.nhs.uk/pregnancy/week-by-week/28-to-40-plus/37-weeks/** (Accessed 8 February 2021).

NHS Digital. (2020) NHS sickness absence rates April 2020 to June 2020, provisional statistics [Online]. Available at **https://digital.nhs.uk/data-and-information/publications/statistical/nhs-sickness-absence-rates/june-2020** (Accessed 29 January 2021).

NHS England and NHS Improvement. (2019) Saving Babies' Lives version two: a care bundle for reducing perinatal mortality [Online]. Available at **https://www.england.nhs.uk/publication/saving-babies-lives-version-two-a-care-bundle-for-reducing-perinatal-mortality/** (Accessed 4 February 2021).

NHS England and NHS Improvement. (2020a) Supporting pregnant women using maternity services during the coronavirus pandemic: Actions for NHS providers. [Online] Available at: **https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/12/C0961-supporting-pregnant-women-using-maternity-services-during-the-coronavirus-pandemic-14-december-2020.pdf** (Accessed 19 April 2021).

NHS England and NHS Improvement. (2020b) Letter: Second phase of NHS response to COVID-19 [Online]. Available at **https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/04/second-phase-of-nhs-response-to-covid-19-letter-to-chief-execs-29-april-2** (Accessed 19 April 2021).

NHS England and NHS Improvement. (2020c) Next steps on NHS response to COVID-19: letter from NHS Chief Executive Sir Simon Stevens and NHS Chief Operating Officer Amanda Pritchard [Online]. Available at **https://www.england.nhs.uk/coronavirus/publication/next-steps-on-nhs-response-to-COVID-19-letter-from-simon-stevens-and-amanda-pritchard/** (Accessed 19 April 2021).

NHS England and NHS Improvement. (2020d) Millions of patients benefiting from remote consultations as family doctors respond to COVID-19 [Online]. Available at **https://www.england.nhs.uk/2020/05/millions-of-patients-benefiting-from-remote-consultations-as-family-doctors-respond-to-COVID-19/** (Accessed 19 April 2021).

NHS England and NHS Improvement. (2020e) NHS visitors guidance. Visiting healthcare inpatient settings during the COVID-19 pandemic. Version 1 dated 16 March 2020 [Online]. Available at **https://www.england.nhs.uk/coronavirus/publication/visitor-guidance/** (Accessed 19 April 2021).

NHS England and NHS Improvement. (2020f) Saving Babies' Lives care bundle version 2: COVID-19 information. Appendix G: Guidance for maternity services regarding fetal growth surveillance and management during the coronavirus (COVID19) pandemic [Online]. Available at **https://www.england.nhs.uk/wp-content/uploads/2020/04/C0122_Appendix-G-Fetal-growth-surveillance-COVID19_1-April.pdf** (Accessed 19 April 2021).

NHS England and NHS Improvement. (2020g) Specialty guides for patient management during the coronavirus pandemic. Clinical guide for the management of surge during the Coronavirus pandemic: critical care rapid learning [Online]. Available at **https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/05/C0167-clinical-guide-surge-mgt-critical-care-rapid-learning-16-may-update-v3.pdf** (Accessed 19 April 2021).

NHS England and NHS Improvement. (2020h) Clinical guide for the temporary reorganisation of intrapartum maternity care during the coronavirus pandemic, 9 April version 1 [Online]. Available at **https://madeinheene.hee.nhs.uk/Portals/0/Clinical%20guide%20for%20the%20temporary%20reorganisation%20of%20intrapartum%20maternity%20care.pdf** (Accessed 19 April 2021).

NHS England and NHS Improvement. (2021) Supporting pregnant women using maternity services during the coronavirus pandemic: Actions for NHS providers. [Online]. Available at: **https://www.england.nhs.uk/coronavirus/publication/supporting-pregnant-women-using-maternity-services-during-the-coronavirus-pandemic-actions-for-nhs-providers/** (Accessed 26 04 2021).

NHS Providers. (2021) NHS provider selection regime [Online]. Available at **https://www.england.nhs.uk/wp-content/uploads/2021/02/B0135-provider-selection-regime-consultation-document.pdf** (Accessed 29 March 2021).

Norman, J. E., Heazell, A. E. P., Rodriguez, A., Weir, C. J., Stock, S. J. E., Calderwood, C. J., Cunningham Burley, S., Frøen, J. F., Geary, M., Breathnach, F., Hunter, A., McAuliffe, F. M., Higgins, M. F., Murdoch, E., Ross-Davie, M., Scott, J. and Whyte, S. (2018) Awareness of fetal movements and care package to reduce fetal mortality (AFFIRM): a stepped wedge, cluster-randomised trial. The Lancet, 392 (10158), 1629-1638 [Online]. DOI: 10.1016/S0140-6736(18)31543-5.

Nuzum, D. O. (2018) The impact of stillbirth on bereaved parents: a qualitative study. PLOS ONE [Online]. DOI: org/10.1371/journal.pone.0191635.

O'Dowd, A. (2020) Covid-19: people in most deprived areas of England and Wales twice as likely to die. British Medical Journal, 369, m2389 [Online]. DOI: 10.1136/bmj.m2389.

Office for National Statistics. (n.d.) User guide to child and infant mortality statistics [Online]. Available at **https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/methodologies/userguidetochildmortalitystatistics#gloss** (Accessed 4 March 2021).

Office for National Statistics. (2017) Harmonised concepts and questions for social data sources. Government Statistical Service harmonised principle: ethnic group. Version 3.4 [Online]. Available at **https://gss.civilservice.gov.uk/wp-content/uploads/2019/04/Ethnic-Group-June-17.pdf** (Accessed 8 March 2021).

Office for National Statistics. (2020) Provisional births in England and Wales: 2020 [Online]. Available at **https://www.ons.gov.uk/releases/provisionalbirthsinenglandandwales2020** (Accessed 8 March 2021).

Office for National Statistics. (2021). Live births by sex, parity and ethnicity, England and Wales in 2015 to 2019 aggregated [Online]. Available at **https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/adhocs/12720livebirthsbysexparityandethnicityenglandandwales2015to2019aggregated** (Accessed 8 March 2021).

Office of Rail and Road. (2012) Managing rail staff fatigue [Online]. Available at **https://www.orr.gov.uk/media/10934** (Accessed 22 October 2020).

Patey, A. M., Curran, J. A., Sprague, A. E., Francis, J. J., Driedger, S. M., Legare, F., Lemyre, L., Pomey, M.-P. A. and Grimshaw, J. (2017) Intermittent auscultation versus continuous fetal monitoring: exploring factors that influence birthing unit nurses' fetal surveillance practice using theoretical domains framework. BMC Pregnancy Childbirth, 17 (1) 320 [Online]. DOI: 10.1186/s12884-017-1517-z.

Patterson, M. D., Geis, G. L., Falcone, R. A., LeMaster, T. and Wears, R. L. (2013) In situ simulation: detection of safety threats and teamwork training in a high risk emergency department. BMJ Quality & Safety, 22, (6) 468-477 [Online]. DOI: 10.1136/bmjqs-2012-000942.

Pay, A., Wiik, J., Backe, B., Jacobsson, B., Strandell, A. and Klovning, A. (2015) Symphysis-fundus height measurement to predict small-for-gestational-age status at birth: a systematic review. BMC Pregnancy and Childbirth, 15 (22). DOI: 10.1186/s12884-015-0461-z.

Perinatal Institute. (n.d.) FAQs. Fundal height measurements [Online]. Available at **https://www.perinatal.org.uk/FAQ/FHMeasurements/** (Accessed 21 April 2021).

Prime Minister's Office. (2020) Speech. Prime Minister's statement on

coronavirus (COVID-19): 23 March 2020 [Online]. Available at **https://www.gov.uk/government/speeches/pm-address-to-the-nation-on-coronavirus-23-march-2020** (Accessed 19 April 2021).

Public Health England. (2020a) Guidance on social distancing for everyone in the UK [Online]. Available at **https://www.gov.uk/government/publications/COVID-19-guidance-on-social-distancing-and-for-vulnerable-people/guidance-on-social-distancing-for-everyone-in-the-uk-and-protecting-older-people-and-vulnerable-adults** (Accessed 19 April 2021).

Public Health England. (2020b) Guidance. COVID-19: infection prevention and control [Online]. Available at **https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control** (Accessed 19 April 2021).

Public Health England. (2020c) Guidance. COVID-19: management of staff and exposed patients or residents in health and social care settings [Online]. Available at **https://www.gov.uk/government/publications/covid-19-management-of-exposed-healthcare-workers-and-patients-in-hospital-settings/covid-19-management-of-exposed-healthcare-workers-and-patients-in-hospital-settings** (Accessed 19 April 2021).

Resuscitation Council UK. (2015) Newborn resuscitation and support of transition of infants at birth guidelines [Online]. Available at **https://www.resus.org.uk/library/2015-resuscitation-guidelines/resuscitation-and-support-transition-babies-birth** (Accessed 10 February 2021).

Ritchie, J., Lewis, J., Nicholls, M. and Ormston, R. (2014) Qualitative Research Practice. A guide for social science students and researchers. London, United Kingdom: Sage.

Royal College of Anaesthetists. (2020) Guidelines for the provision of anaesthesia services (GPAS). Chapter 9: Guidelines for the provision of anaesthesia services for an obstetric population [Online]. Available at **https://www.rcoa.ac.uk/gpas/chapter-9** (Accessed 29 January 2021).

Royal College of Anaesthetists, Association of Anaesthetists, Faculty of Intensive Care Medicine, Intensive Care Society, Obstetric Anaesthetists Association. (2021) Choice of PPE for obstetric anaesthetists according to mode of transmission risk [Online]. Available at **https://static1.squarespace.com/static/5e6613a1dc75b87df82b78e1/t/5e96d79ef01cf06d99c34920/1586943905918/OAA-PPE-infographic_11.04.20.pdf** (Accessed 23 June 2021).

Royal College of Midwives. (2016) The RCM standards for midwifery services

in the UK [Online]. Available at **https://www.rcm.org.uk/media/2283/rcm-standards-midwifery-services-uk.pdf** (Accessed 23 June 2021).

Royal College of Obstetricians and Gynaecologists. (2008) Standards for maternity care – report of a working party [Online]. Available at **https://www.rcog.org.uk/globalassets/documents/guidelines/wprmaternitystandards2008.pdf** (Accessed 3 February 2021).

Royal College of Obstetricians and Gynaecologists. (2011) Reduced fetal movements. Green-top guideline no. 57 [Online]. Available at **https://www.rcog.org.uk/globalassets/documents/guidelines/gtg_57.pdf** (Accessed 3 February 2021).

Royal College of Obstetricians and Gynaecologists. (2015a) Each Baby Counts: 2015 full report [Online]. Available at **https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/each-baby-counts/ebc-2015-report/** (Accessed 4 February 2021).

Royal College of Obstetricians and Gynaecologists. (2015b) Birth after previous caesarean birth. Green-top guideline no. 45 [Online]. Available at **https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg45/** (Accessed 4 February 2021).

Royal College of Obstetricians and Gynaecologists. (2019) Each Baby Counts 2019 progress report [Online]. Available at **https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/each-baby-counts/reports-updates/2019-progress-report/** (Accessed 29 January 2021).

Royal College of Obstetricians and Gynaecologists and Royal College of Midwives. (2020a) Coronavirus (COVID-19) infection in pregnancy. Information for healthcare professionals. Version 1 [Online]. Available at **https://www.rcog.org.uk/en/guidelines-research-services/guidelines/coronavirus-pregnancy/** (Accessed 29 January 2021).

Royal College of Obstetricians and Gynaecologists and Royal College of Midwives. (2020b) Coronavirus (COVID-19) infection in pregnancy. Information for healthcare professionals. Version 3 [Online]. Available at **https://www.rcog.org.uk/en/guidelines-research-services/guidelines/coronavirus-pregnancy//** (Accessed 29 January 2021).

Royal College of Obstetricians and Gynaecologists and Royal College of

Midwives. (2020c). Coronavirus (COVID-19) infection in pregnancy. Information for healthcare professionals. Version 4 [Online]. Available at **https://www.rcm.org.uk/media/3800/2020-03-21-covid19-pregnancy-guidance.pdf/** (Accessed 29 January 2021).

Royal College of Obstetricians and Gynaecologists and Royal College of Midwives. (2020d) Coronavirus (COVID-19) infection in pregnancy. Information for healthcare professionals. Version 5 [Online]. Available at **https://www.rcog.org.uk/en/guidelines-research-services/guidelines/coronavirus-pregnancy/** (Accessed 29 January 2021).

Royal College of Obstetricians and Gynaecologists and Royal College of Midwives. (2020e) Coronavirus (COVID-19) infection in pregnancy. Information for healthcare professionals. Version 6 [Online]. Available at **https://www.rcm.org.uk/media/3843/2020-04-03-coronavirus-covid-19-infection-in-pregnancy.pdf** (Accessed 29 January 2021).

Royal College of Obstetricians and Gynaecologists and Royal College of Midwives. (2020f) Guidance for provision of midwife-led settings and home birth in the evolving coronavirus (COVID-19) pandemic [Online]. Available at **https://www.rcm.org.uk/media/3875/midiwfe-led-settings-and-guidance.pdf** (Accessed 31 March 2021).

Royal College of Obstetricians and Gynaecologists and Royal College of Midwives. (2020g) Coronavirus (COVID-19) infection in pregnancy. Information for healthcare professionals. Version 7 [Online]. Available at **https://www.rcm.org.uk/media/3843/2020-04-03-coronavirus-covid-19-infection-in-pregnancy.pdf** (Accessed 21 April 2021).

Royal College of Obstetricians and Gynaecologists and Royal College of Midwives. (2020h) Guidance for provision of midwife-led settings and home birth in the evolving coronavirus (COVID-19) pandemic. Version 1.2 [Online]. Available at **https://www.rcm.org.uk/media/4099/2020-05-22-guidance-for-provision-of-midwife-led-settings-and-home-birth-in-the-evolving-coronavirus-covid-19-pandemic.pdf** (Accessed 19 April 2021).

Royal College of Obstetricians and Gynaecologists and Royal College of Midwives. (2020i) Guidance for antenatal and postnatal services in the evolving coronavirus (COVID-19) pandemic: version 1.0 [Online]. Available at **https://www.rcog.org.uk/en/guidelines-research-services/guidelines/** (Accessed 2 February 2021).

Royal College of Obstetricians and Gynaecologists and Royal College of

Midwives. (2020j) Guidance for antenatal and postnatal services in the evolving coronavirus (COVID-19) pandemic: version 3.0 [Online]. Available at **https://www.rcog.org.uk/globalassets/documents/guidelines/2020-10-21-guidance-for-antenatal-and-postnatal-services-in-the-evolving-coronavirus-covid-19-pandemic-v3.pdf** (Accessed 2 February 2021).

Salvatore, C. H., Han, J.-H., Acker, K. P., Tiwari, P., Jin, J., Brandler, M., Cangemi, C., Gordon, L., Parow, A., DiPace, J. and DeLaMora, P. (2020) Neonatal management and outcomes during the COVID-19 pandemic: an observation cohort study. The Lancet Child and Adolescent Health, 4 (10), 721-727 [Online]. DOI: 10.1016/S2352-4642(20)30235-2.

Sands. (2016) Understanding why your baby died [Online]. Available at **https://www.sands.org.uk/support-you/understanding-why-your-baby-died** (Accessed 2 February 2021).

Sharps, M. C., Hayes, D. J. L., Lee, S., Zou, Z., Brady, C. A., Almoghrabi, Y., Kerby, A., Tamber, K. K., Jones, C. J., Adams Waldorf, K. M. and Heazell, A. E. P. (2020) A structured review of placental morphology and histopathological lesions associated with SARS-CoV-2 infection. Placenta, 101, 13-29 [Online]. DOI: 10.1016/j.placenta.2020.08.018.

Smith, N. A., Bukowski, R., Thomas, A. M., Cantonwine, D., Zera, C. and Robinson, J. N. (2014) Identification of pathologically small fetuses using customized, ultrasound and population-based growth norms . Ultrasound in Obstetrics & Gynecology, 44 (5), 595-599 [Online]. DOI: 10.1002/uog.13333.

Stowe, J., Smith, H., Thurland, K., Ramsay, M. E., Andrews, N. and Ladhani, S.N. (2021) Stillbirths during the COVID-19 pandemic in England, April-June 2020. JAMA, 325 (1), 86-87 [Online]. DOI:10.1001/jama.2020.21369.

Sujan, M. S. (2015) The role of dynamic trade-offs in creating safety – a qualitative study of handover across care boundaries in emergency care. Reliability Engineering and System Safety 141, 54-62 [Online]. DOI: 10.1016/j.ress.2015.03.006.

Sujan, M., Habli, I., Kelly, T., Guhnemann, A., Pozzi, S. and Johnson, C. (2017) How can healthcare organisations make and justify decisions about risk reduction? Lessons from across-industry review and a healthcare stakeholder consensus development process. Reliability Engineering and System safety, 161, 1-11 [Online]. DOI: 10.1016/j.ress.2017.01.001.

Supreme Court. (2015) Judgment. Montgomery (Appellant) v Lanarkshire Health

Board (Respondent) (Scotland) [Online]. Available at **https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf** (Accessed 1 April 2021).

Surkova, E., Nikolayevsky, V. and Drobniewski, F. (2020) False-positive COVID-19 results: hidden problems and costs. The Lancet Respiratory Medicine, 8 (12): 1167-1168 [Online]. DOI: 10.1016/S2213-2600(20)30453-7.

Svedung, I. and Rasmussen, J. (2000) Proactive risk management in a dynamic society.

Vincent, C. and Amalberti, R. (2016) The ideal and the real, in Vincent, C. Safer healthcare; Strategies for the Real World (pp.13-25). Springer [Online]. DOI: 10.1007/978-3-319-25559-0.

Vincent, C., Burnett, S. and Carthey, C. (2013.) The measurement and monitoring of safety in healthcare [Online]. Available at **https://www.health.org.uk/publications/the-measurement-and-monitoring-of-safety** (Accessed 13 May 2021).

Walker, K., O'Donoghue, K., Grace, N., Dorling, J., Comeau, J., Li, W. and Thornton, J. (2020) Maternal transmission of SARS-COV-2 to the neonate, and possible routes for such transmission: a systematic review and critical analysis. BJOG, 127 (11), 1324-1336 [Online]. DOI: 10.1111/1471-0528.16362.

Watson, C. (2020) Stillbirth rate rises during coronavirus pandemic. Nature, 585, 490-491 [Online]. Available at **https://media.nature.com/original/magazine-assets/d41586-020-02618-5/d41586-020-02618-5.pdf** (Accessed 8 January 2021).

World Health Organization. (2020) Clinical management of COVID-19: interim guidance [Online]. Available at **https://www.who.int/publications/i/item/clinical-management-of-covid-19** (Accessed 8 January 2021).

Zamaniyan, M. E., Ebadi, Aghdas, A., Aghajanpoor, S., Haghshenas, M. and Azizi, S. (2020) Preterm delivery, maternal death, and vertical transmission in a pregnant woman with COVID-19 infection. Prenatal Diagnosis, 40 (13), 1759-1761 [Online]. DOI: 10.1002/pd.5713.

Zsambok, C. and Klein, G. (1997). Naturalistic Decision Making. Oxon: Routledge.

Appendix 1 Maternity guidance

National Institute for Health and Care Excellence clinical guideline: Antenatal care for uncomplicated pregnancies (National Institute for Health and Care Excellence, 2008 (last updated 2019))	COVID-19 pandemic guidance
Ideally 10 weeks' gestation: booking appointment. Discuss past medical/ obstetric history, care pathway, place of birth, antenatal classes, maternity benefits, undertake screening blood and urine tests.	Coronavirus (COVID-19) infection in pregnancy version 1, 9 March 2020 (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020a) Maternity units to rapidly seek to adopt teleconferencing and videoconferencing capability and to consider what appointments may be conducted remotely.
Two routine ultrasound scan assessments: • between 10+0-13+6 weeks' gestation, for dating and additional screening for chromosomal anomalies if so desired • fetal anomaly scan between 18+0-20+6 weeks' gestation. Dependent on any maternal or fetal risk factors the clinical and ultrasound scan appointments may increase in frequency.	Guidance for antenatal and postnatal services in the evolving coronavirus (COVID-19) pandemic version 1, 30 March 2020 (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020i) If capacity for scanning was compromised, to prioritise ultrasound scans in the order of: • anomaly scan at 18+0-23+0 weeks' gestation • dating ± screening scan at 11+2-14+1 weeks' gestation • growth scans.

Nulliparous women and pregnant people = 10 ante natal (AN) appointments.

Multiparous women and pregnant people = 7 AN appointments.

- symphysis-fundal height (SFH) recorded at each an appointment from 24/40 weeks.
- 28 weeks appointment
- 31 weeks appointment (nulliparous people)
- 34 weeks appointment
- 36 weeks appointment to discuss: infant feeding, signs of labour, vitamin K, care of newborn. Abdominal palpation for fetal presentation from 36/40 onwards, offer external cephalic version (ECV) between 36 - 37/40 for breech presentation.
- 38 weeks discuss: options for management of prolonged pregnancy.
- 40 weeks' (nulliparous people)
- 41 weeks offer membrane sweep.

Coronavirus (COVID-19) infection in pregnancy version 5, 28 March 2020 (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020d)

Advises maximising the use of remote antenatal consultations and considering:

- the suspension of carbon monoxide (CO) monitoring as a precautionary measure over concerns of coronavirus transmission
- reducing inductions of labour (IOL) where they are not deemed clinically strictly necessary
- reducing growth scans where there is not a strict guideline-based reason for them.

Offer induction of labour (IOL) between 41+0 and 42+0 weeks. In the case of identified maternal or fetal risk factors, IOL or birth by elective caesarean section may be recommended at an earlier gestation.	Guidance for antenatal and postnatal services in the evolving coronavirus (COVID-19) pandemic, version 1, 30 March 2020 (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020i) Maintain essential monitoring and that 'many elements of antenatal care may require in-person assessment in particular blood pressure and urine checks, measurement of fetal growth and blood tests'. Recommends a minimum of 6 face-to-face antenatal consultations. Consideration of appointments from 41+0 weeks' gestation to be followed immediately by either an outpatient or inpatient IOL to avoid a further attendance.
	Coronavirus (COVID-19) infection in pregnancy guidance version 6, 3 April 2020 (Royal college of Obstetricians and Gynaecologists and Royal College of Midwives, 2020e) Women and pregnant people to be permitted and encouraged to have a birth partner present with them in labour and during the birth'. Acknowledgement that there would be an expectation to restrict the number or swapping of birth partners, and that some/all visitors may be restricted in the ante and postnatal settings, in line with individual hospital policies.

	Guidance for the provision of midwife-led settings and homebirth in the evolving coronavirus (COVID-19) pandemic, 9 April 2020 (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020h) Providing safe services means balancing the response to the COVID-19 pandemic with the continuing need to manage obstetric risk. The need for the suspension of some services is acknowledged, with a potential consequence on place of birth choice. Secondary considerations for place of birth, away from an obstetric-led maternity unit includes the potential impact on transfer times, with the increase burden placed on the ambulance services. Different phases of response escalation were suggested dependent on midwifery shortages and ambulance service provision in an attempt to maintain all place of birth options for as long as possible.
	Coronavirus (COVID-19) infection in pregnancy version 7, 9 April 2020 (Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, 2020g) Increasing anxiety around COVID-19 transmission in hospital and attending maternity services, particularly when located in hospitals, may cause significant anxiety about the possibility of contracting COVID-19.

	Guidance for antenatal and postnatal services in the evolving coronavirus (COVID-19) pandemic: version 3.0, 21 October 2020 (Royal college of Obstetricians and Gynaecologists and Royal College of Midwives, 2020j) The need to ensure wider dissemination of information to all user groups was highlighted; 'such information should be available in community languages other than in English and in visual or easy to understand formats as far as possible – where such interpretation services are not available consideration should be given to providing local community online groups and radio stations with information about any service changes to enable them to share key information with the local communities'. Accessing more vulnerable groups of women and pregnant people was also addressed in this guidance with advice to prioritise face-to-face contacts for women and pregnant people with an increased risk of complications due to COVID-19, including women and pregnant people from all ethnic minorities (excluding White minorities) or Black, Asian and ethnic minority backgrounds (excluding White minorities) and women and pregnant people living in socio-economic deprivation.

Appendix 2 Demographic and clinical details of the 37 women and pregnant people

Characteristics of women and pregnant people whose cases were the subject of intrapartum stillbirth investigations		
Age bracket	under 20	1
	20 to 24	5
	25 to 29	13
	30 to 34	9
	35 to 9	9
Body mass index (BMI)	below 18.5	0
	between 18.5 and 24.9	14
	between 25 and 29.9	10
	between 30 and 39.9	12
	above 40	1
Ethnicity (using NHS Office for National Statistics codes)	Any White background	21
	Asian or Asian British	11
	Black or Black British	5
Number of women and pregnant people with pre-existing medical condition	**Yes**	**5**
	No	32
Deprivation score (1= most deprived 10= least deprived)	1 to 2	9
	3 to 4	13
	5 to 6	5
	7 to 8	4
	9 to 10	1
	Unknown	5

First pregnancy (no previous births) at start of this pregnancy	**Yes**	**22**
	No	15
Gestation at time of stillbirth	37 to 37 weeks + 6 days	2
	38 to 38+6	3
	39 to 39+6	5
	40 to 40+6	11
	41 to 41+6	14
	more than 42	2
Did the parents consent to a post-mortem examination?	Yes	20 (54%)
	No	17 (46%)
Was the placenta sent to histopathology?	**Yes**	**37 (100%)**
	No	0
Number of women and pregnant people who attended the intensive care unit prior to death	**Yes**	**0**
	No	37
Was the person suspected of having COVID-19 in pregnancy?	**Yes**	**1**
	No	34
	Unknown	2
Any potential COVID-19 symptoms: cough, temperature, loss of smell.	**Yes**	**5**
	No	30
	Unknown	2
Numbers of women and pregnant people who had a COVID-19 swab test	**Yes**	**8**
	No	23
	Unknown	6
Number of women and pregnant people who received a positive COVID-19 swab test	**Yes**	**0**
	No	37

Number of women and pregnant people diagnosed with COVID-19	**Yes**	**0**
	No	37
Mode of birth	Spontaneous vaginal	27
	Assisted vaginal	3
	Caesarean	7
Were there any local safety recommendations in the investigation?	**Yes**	**22 (59%)**
	No	15 (41%)
Healthcare settings contacted or attended in 14 days prior to death	Emergency services, maternal assessment units, labour ward, accident and emergency, GPs, community healthcare services such as midwifery appointments	

Appendix 3 Safety management systems

What is a safety management system?

A safety management system is an organised approach to managing safety. It specifies the necessary system-wide processes needed to identify new safety hazards and effectively manage known safety risks. It also monitors safety performance, manages change, and promotes effective safety communication.

Where are safety management systems used?

Safety management systems are used across many high-risk industries, for example in aviation (Federal Aviation Administration, 2014). They are not widely used in healthcare and are therefore not well understood in this setting. The NHS does not have an overarching safety management system, which means that safety activities are often fragmented. Unlike other industries, a formal safety management system is not a regulatory requirement in healthcare (Dixon-Woods et al, 2014).

What would a safety management system for healthcare look like?

Healthcare has a complex landscape of stakeholders. Those with regulatory power or influence are often independently responsible for the various safety activities. However, activities are not always integrated across the system to allow for a unified, proactive approach. The adoption of a safety management system could facilitate an operational shift within healthcare. This necessitates that the system provides proof that the system is safe now, and that it will be safe in the future. This represents a shift from proving that something is dangerous, to proving that things are safe (Leary, 2021).

Safety governance systems and patient safety roles form a basic structure common to many NHS organisations with a focus on quality improvement. However, existing roles do not ensure the individuals employed have expertise in safety management, an essential requirement within other safety-critical industries. Vincent et al's report (2013) into how safety is managed in healthcare has highlighted that although healthcare has processes for quality improvement, it has not developed an embedded safety management system. The healthcare system needs to be both reactive to safety concerns and proactive to achieve longer-term safety objectives.

The functions of a safety management system

Identifying hazards

A hazard has the potential to cause or contribute to an undesirable outcome. Learning from safety reporting systems requires processes that allow for the identification of new hazards and that enable an understanding of situations where these hazards are emerging. The processes needed to provide a meaningful analysis of safety reporting data do not always exist. Reporting, therefore, often becomes part of a retrospective local performance audit, rather than a proactive mechanism for system-wide learning.

Managing known safety risks

A safety risk is the predicted probability and severity of the consequences or outcomes of a hazard. Known safety risks have the potential to result in undesirable outcomes even when there are evidence-based ways of managing the safety risk. Problems when implementing interventions can mean that safety risks are not being managed effectively. Situations can arise where pressures on the system mean that it no longer becomes possible to manage the safety risk. This can occur when other functions have been prioritised, when demand is greater than the system's capacity to provide safe care.

Monitoring safety performance

There needs to be a means of assuring the system that its functions are meeting their intended safety objectives or achieving desired outcomes. In a complex system there are multiple stakeholders. The way that stakeholders, such as regulators and organisations with regulatory influence, measure the system's performance will influence what is monitored. Many safety risks go beyond organisational boundaries and may not be monitored if they involve different core services that are being monitored independently of each other.

Managing change

New demands and services may introduce hazards that may impact on the effectiveness of the management of safety risks. A safety management system needs to identify any unintended consequences that might impact on patient safety when introducing new ways of working.

Safety promotion

The system should ensure that the relevant people are aware of the need for action and that training and education programmes are in place and that their efficacy has been evaluated.

WWW.HSIB.ORG.UK
@hsib_org

HSIB
HEALTHCARE SAFETY INVESTIGATION BRANCH

Further information

More information about HSIB – including its team, investigations and history – is available at **www.hsib.org.uk**

If you would like to request an investigation then please read our **guidance** before contacting us.

@hsib_org is our Twitter handle. We use this feed to raise awareness of our work and to direct followers to our publications, news and events.

Contact us

If you would like a response to a query or concern please contact us via email using **enquiries@hsib.org.uk**

We monitor this inbox during normal office hours - Monday to Friday from 09:00 hours to 17:00 hours. We aim to respond to enquiries within five working days.

To access this document in a different format – including braille, large-print or easy-read – please contact **enquiries@hsib.org.uk**