



Investigation report

Detection of jaundice in newborn babies

Date Published:

31/01/2023

Theme:

Missed diagnosis, Neonatal

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A note of acknowledgement

We would like to thank Baby Elliana's mother, Ellen, whose experience is documented in this report. We would also like to thank the healthcare staff who engaged with the investigation for their openness and willingness to support improvements in this area of care.

About this report

This report is intended for healthcare organisations, policymakers and the public to help improve patient safety in relation to the detection of jaundice in newborn babies.

Executive summary

Background

This report explored the detection and diagnosis of jaundice in newborn babies, in particular babies born prematurely (before 37 weeks of pregnancy). Specifically, it explored delayed diagnosis due to there being no obvious visual signs of jaundice apparent to clinical staff.

Jaundice is a condition caused by too much bilirubin in a person's blood. Bilirubin is a yellow substance produced when red blood cells are broken down. If left undiagnosed and untreated, high bilirubin levels in newborn babies can lead to significant harm. Newborn babies have a higher number of red blood cells in their blood which increases their risk of jaundice. Jaundice can cause yellowing of the skin and whites of the eyes; however, sometimes the visual signs of jaundice are not obvious, particularly for premature or newborn babies with brown or black skin.

To explore this issue, the investigation used an example case, referred to as 'the reference event', which involved the delayed diagnosis of jaundice in Baby Elliana, a baby girl of black African ethnicity who was born prematurely.

The investigation's findings, safety recommendations and safety observations aim to facilitate the timely diagnosis of jaundice in newborn babies. Some of the findings and conclusions may also be applicable to other conditions in newborn babies.

The reference event

Baby Elliana was born at 32 weeks and 1 day via a forceps delivery (a type of assisted vaginal delivery). Because Baby Elliana was born prematurely, she was transferred to the Trust's special care baby unit (SCBU).

Baby Elliana was assessed on admission to the SCBU by staff as a clinically stable premature baby. A routine blood sample was taken from Baby Elliana by SCBU staff at approximately 2 hours after her birth to establish a baseline. Analysis of the blood sample indicated bilirubin was present and so the level was measured. This result was uploaded onto the Trust's computer system alongside the results of the blood tests that had been requested by the clinical team.

The bilirubin result was seen by a SCBU member of staff who recognised that the level was high, indicating the possible need for treatment. However, this member of staff was then required to attend an emergency and the bilirubin result was not acted upon.

Another blood sample was taken when Baby Elliana was 2 days of age. The result was uploaded to the Trust's computer system. It is unclear if this bilirubin result was seen by staff; it was not documented in clinical records and was not acted upon.

Over the next 2 days Baby Elliana continued to show no visible signs of jaundice that were detected by staff and she was documented to be developing well.

When Baby Elliana was 5 days of age, a change in her skin colour was observed and visible signs of jaundice were detected. A further blood sample was taken and bilirubin levels were requested by the clinical team. As previously, this confirmed a high level of bilirubin and treatment was started accordingly. Baby Elliana's bilirubin levels returned to within acceptable levels over the next 3 days and she was subsequently discharged home.

The national investigation

High bilirubin levels can cause significant harm including brain damage. It is therefore important that jaundice is diagnosed and treated in a timely way. This relies on visual signs of jaundice being present and observed by clinical staff. It is nationally acknowledged that the recognition and assessment of jaundice can be difficult, particularly in babies with black or brown skin, increasing the risk of delayed diagnosis.

HSIB contacted the hospital where the reference event took place. The Trust welcomed HSIB's involvement and collaborated with information gathering. After initial information had been gathered and evaluated against a set of patient safety risk criteria, HSIB's Chief Investigator authorised a national safety investigation.

Findings

- The assessment of visual signs of jaundice in newborn babies is subjective and more challenging with babies who have black or brown skin.
- Stakeholders have differing opinions about the reliability of visual signs to detect jaundice in newborn babies.
- Some neonatal units have introduced safety measures to mitigate the risk of reliance on visual signs of jaundice.
- National guidance does not recommend routinely measuring bilirubin levels in babies who are not visibly jaundiced.
- National guidance for jaundice in newborn babies maybe more applicable to term babies (those born after 37 weeks of pregnancy) than those born prematurely.
- National guidance does not contain information on how to address the challenges of detecting jaundice in newborn babies with black or brown skin.
- Some universities providing education to NHS students on the detection of jaundice are seeking to ensure that teaching aids and literature represent the diversity of the population.
- Levels of bilirubin can vary according to the gestational age of a baby (how long the baby was in the womb). Laboratory staff do not calculate the gestational age of a baby and therefore whether their bilirubin level is within the expected range.
- Laboratory practice varies in terms of whether they set specific reference ranges for bilirubin in newborn babies; whether they have a defined threshold for communicating results to neonatal units; and whether the telephone alert limit (the level of bilirubin that triggers laboratory staff to report the result to clinical staff by telephone) reflects the thresholds in national guidance.
- Neonatal staff may be unaware that laboratories analyse blood samples to see if they are icteric (indicate jaundice). These staff will not know to look for a comment about this on blood test reports.

HSIB makes the following safety recommendations

Safety recommendation R/2023/208:

HSIB recommends that the National Institute for Health and Care Excellence reviews the available evidence and updates its guidance if appropriate, regarding:

- the reliability of visual signs to detect jaundice in newborn babies, particularly in babies with black and brown skin
- risk factors for jaundice identified by this investigation, including prematurity.

Safety recommendation R/2023/209:

HSIB recommends that the Royal College of Pathologists works with stakeholders to understand current practice and make any appropriate recommendations to promote the adoption of an icteric threshold at which a bilirubin test may be cascaded or reported.

Safety recommendation R/2023/210:

HSIB recommends that the Royal College of Pathologists works with stakeholders to understand current practice and make any appropriate recommendations on neonatal specific reference ranges for total bilirubin and thresholds for direct communication of these results to clinicians.

HSIB makes the following safety observations

Safety observation O/2023/202:

It may be beneficial for regulators of pathology services to consider the findings of the investigation and amend their guidance if necessary.

Safety observation O/2023/203:

It may be beneficial to develop a national standardised Early Warning System track and trigger observation chart for use in neonatal unit settings.

1 Background and context

This section provides information about jaundice and associated risk factors. It also details how jaundice is detected and the impact of ethnicity on this.

1.1 Jaundice

1.1.1 Jaundice is a common, and usually harmless, condition in newborn babies. In medical literature 'newborn' is often defined as the first 4 weeks of life. This investigation focuses on newborn babies, in particular those born prematurely.

1.1.2 Jaundice is a symptom of a condition known as hyperbilirubinemia, in which a person has too much bilirubin in their blood. Bilirubin is a yellow substance produced when red blood cells, which carry oxygen around the body, are broken down (NHS, 2018). High bilirubin levels result from an excessive breakdown of red blood cells. Newborn babies have a higher number of red blood cells in their blood which increases the risk of jaundice.

1.1.3 Bilirubin is broken down by the liver and excreted from the body. A baby's liver is not fully developed at birth and is less effective at removing bilirubin from the blood. A premature baby's liver will be even more immature and, therefore, even less effective.

1.1.4 When there are visual signs of jaundice (see 1.2.1), clinicians request a blood test for bilirubin. In addition, routine (pre-analysis) laboratory checks carried out on blood samples can indicate high bilirubin. When high bilirubin is present the sample is said to be icteric.

1.1.5 If high levels of bilirubin in a newborn baby go undetected and are untreated, a rare but serious complication called kernicterus can occur. Kernicterus is caused by excess bilirubin damaging a baby's brain or central nervous system (NHS, 2018).

1.1.6 If significant brain damage occurs before treatment, a newborn baby can develop serious and permanent problems. These can include cerebral palsy (a condition that affects movement and co-ordination), hearing loss, involuntary twitching of different parts of their body, problems maintaining normal eye movements or poor development of the teeth. Very high levels of bilirubin in newborn babies can be life threatening.

1.1.7 The National Institute for Health and Care Excellence (NICE) has published guidance for jaundice in newborn babies under 28 days of age which covers diagnosing and treating neonatal jaundice (jaundice in newborns). The guidance states that 'Approximately 60% of term and 80% of preterm babies [babies born before or after 37 weeks respectively] develop jaundice in the first week of life'. It recommends clinical staff 'examine the baby for jaundice at every opportunity especially in the first 72 hours' (National Institute for Health and Care Excellence, 2016). It is estimated that 1 in 20 babies have bilirubin levels high enough to need treatment (NHS, 2018).

1.1.8 The NICE guidance aims to 'help detect or prevent very high levels of bilirubin in neonates [newborn babies]' (National Institute for Health and Care Excellence, 2016). The guidance states that detection of jaundice is by visual inspection and that clinicians should:

- check the naked baby in bright and preferably natural light
- examine the sclera (whites of the eyes) and gums and press lightly on the skin to check for signs of jaundice in 'blanched' (paling) skin.

1.1.9 The guidance states 'do not measure bilirubin levels [by taking blood samples] routinely in babies who are not visibly jaundiced' (National Institute for Health and Care Excellence, 2016).

Risk factors

1.1.10 There are a number of factors that increase a newborn baby's risk of developing significant hyperbilirubinemia (National Institute for Health and Care Excellence, 2016). They include:

- gestational age under 38 weeks
- a previous sibling with neonatal jaundice requiring phototherapy (treatment with a special type of light)
- a woman's or pregnant person's intention to breastfeed exclusively (because breastfed babies are more likely to develop jaundice than bottle-fed babies)
- visible jaundice in the first 24 hours of life.

1.1.11 In addition to these risk factors, the Mayo Foundation for Medical Education and Research (n.d.) identified others:

- bruising during birth – newborn babies who become bruised during delivery may have higher levels of bilirubin due to the breakdown of more red blood cells
- blood type – if a woman's or pregnant person's blood type is different from their baby's, the baby may have received antibodies through the placenta that cause abnormally rapid breakdown of red blood cell
- ethnicity – research shows that babies of East Asian ancestry have an increased risk of developing jaundice.

1.2 Detection and treatment of jaundice

1.2.1 Jaundice causes yellowing of the skin and yellowing of the whites of the eyes (sclera) (see figure 1). Other visual signs of jaundice can be yellowing of the palms of the hands or soles of the feet.



Figure 1 A baby with yellowing of the sclera

1.2.2 The signs of jaundice in a newborn baby usually develop 2 to 3 days after birth and tend to get better without treatment by the time a baby is 2 weeks old (NHS, 2018).

1.2.3 A baby will be examined for signs of jaundice within 72 hours of birth by NHS staff as part of the 'newborn and infant physical examination' (NIPE) (NHS, 2018). The aim of a NIPE is 'to spot any problems early so treatment can be started as soon as possible' (NHS, 2021).

1.2.4 Bilirubin levels are measured in two ways. One way is to use a piece of equipment called a transcutaneous bilirubinometer, which measures the yellowness of the skin. A transcutaneous bilirubinometer can be used from 35 weeks gestation and above. The other way is to take a blood sample which is sent to a laboratory for testing or analysed by a machine in the clinical area (known as a point of care machine).

1.2.5 For babies who are having their bilirubin level measured, NICE guidance includes a treatment threshold graph to 'help healthcare professionals assess whether babies should be given phototherapy or exchange transfusion [a complete blood transfusion]' (National Institute for Health and Care Excellence, 2016). The graph defines the thresholds for treatment (phototherapy or the exchange transfusion) by gestational age. There are graphs from 23 weeks to 38 weeks of gestational age (National Institute for Health and Care Excellence, 2010). The position of a baby's bilirubin levels on the graph indicates whether treatment is needed.

1.2.6 Newborn babies on neonatal units are assessed for jaundice in a number of ways:

- examination on admission to the unit
- during a NIPE within the first 72 hours of life
- visual observations during routine care.

1.3 Impact of ethnicity

1.3.1 NICE guidance states that 'clinical recognition and assessment of jaundice can be difficult, particularly in babies with darker skin tones' (National Institute for Health and Care Excellence, 2016). It is not suggested that staff should perform any different or additional checks to those for a baby with white skin (NHS Digital 2021).

1.3.2 There are national initiatives which aim to improve the recognition of clinically significant signs of various conditions in patients with black and brown skin. These initiatives highlight the need for photographic representations of skin tones, and content about skin signs, to be more inclusive (NHS Digital, 2021; Gunowa et al, 2020; Hereford et al, 2021).

1.3.3 A UK clinical handbook of signs and symptoms in black and brown skin was published in 2020 (Mukwende et al, 2020). This aims to highlight the lack of diversity in medical literature and education. The British Association of Dermatologists (BAD) is also working to improve descriptions of clinically significant signs across a range of skin tones and to address the lack of diversity in information about skin conditions (British Association of Dermatologists, 2021).

1.3.4 BAD has also formed partnerships with other groups with similar aims, including the NHS, in response to the issues raised by the Black Lives Matter campaign.

1.3.5 Skin Deep is an international project which also aims to improve education and recognition of medical conditions in all skin tones. It has produced literature to develop an open-access bank of photographs of medical conditions in a range of skin tones for use by healthcare professionals and the public (Skin Deep, n.d.).

1.3.6 Skin Deep has concluded that 'the vast majority of medical textbooks and online resources only contain pictures of children or young people with light skin tones'. In addition, Skin Deep states that 'descriptions of rashes focus on redness or pallor, both of which are more difficult to recognise in darker skin tones or may not be present at all. This means that children with black or brown skin are often not diagnosed correctly or as quickly as those with lighter skin tones' (Skin Deep, n.d.).

1.3.7 A report by the NHS Race and Health Observatory found that Asian babies 'were overrepresented in admissions to neonatal units for jaundice'. The report further noted that previous research has questioned whether some babies could have been 'identified earlier' and

that 'visual estimation of jaundice in babies is highly inaccurate'. The report further notes that visual estimation may also be 'particularly unreliable for babies with darker skin tones'. The report raises the possibility that routine postnatal care practices may 'systematically disadvantage non-White babies by delaying access to care' (NHS Race and Health Observatory, 2022).

2 The reference event

2.1 Baby Elliana's story

The investigation used the following patient safety incident, referred to as 'the reference event', to examine the issue associated with the diagnosis of jaundice in newborn babies.

2.1.1 Baby Elliana was a baby girl of black African ethnicity born prematurely at 32 weeks and 1 days' gestation. She was born at 22:13 hours (on day 0) via forceps delivery (a type of assisted vaginal birth). Because Baby Elliana was born prematurely, she was transferred to the Trust's special care baby unit (SCBU). She was assessed on admission by Clinician 1 at 22:25 hours and was documented as having 'normal [muscle] tone', being 'pink' and as 'clinically stable'.

Day 1

2.1.2 A blood sample was taken from Baby Elliana at approximately 2 hours of age to establish a 'baseline', to help assess her overall condition, and to determine if there were any underlying infections associated with the spontaneous premature birth. The day 1 blood sample was sent to the Trust's laboratory at 02:00 hours.

2.1.3 On receipt of Baby Elliana's blood sample, the laboratory carried out its own internal test to see if the sample was 'icteric' (indicated jaundice, see 1.1.4). This is done routinely for every blood sample as part of the Trust laboratory's processes, as an icteric blood sample can potentially affect the results of requested tests.

2.1.4 Baby Elliana's blood sample was found to be icteric. In line with routine practice, the laboratory then measured the bilirubin level and uploaded the result to the Trust's computer system at 04:37 hours.

2.1.5 At 05:00 hours Baby Elliana's nursing notes (incorrectly) recorded a SBR (serum bilirubin) result of '106' micromoles [actual result was 105 micromoles see 2.1.9]. An SBR of 106 micromoles is outside of the expected range for a baby who has a gestational age of 32 weeks (National Institute for Health and Care Excellence, 2016).

2.1.6 Baby Elliana was examined at 11:30 hours on the ward round by Clinician 2 supported by Clinician 3. A newborn and infant physical examination (NIPE) (NHS, 2018) was undertaken which included an eye examination and a visual assessment for jaundice.

2.1.7 During the NIPE Clinician 2 noted that Baby Elliana had a 'cephalohaematoma' (a bruise on the head) as a result of the forceps delivery. Baby Elliana was documented to be 'stable'.

2.1.8 As a result of their examination, Clinician 2 referred Baby Elliana to the ophthalmology (eye specialists) team due to some inconsistencies in the red reflex (which could indicate eye problems). A repeat blood test was planned for 16:00 hours (not carried out until day 2) to assess Baby Elliana's condition and to check for possible infection.

2.1.9 Baby Elliana's day 1 blood sample results were accessed on the Trust's computer system by Clinician 2. Clinician 2 recalled that they thought the bilirubin level of 105 micromoles was "high" for a baby who has a gestational age of 32 weeks. Clinician 2 entered the received blood results into Baby Elliana's medical notes.

2.1.10 When finalising the review and documentation concerning Baby Elliana, Clinician 2 received an emergency "bleep" alert on their pager device. Clinician 2 left the SCBU immediately to attend to the emergency in another area of the maternity department. There is no further documentation from Clinician 2 regarding Baby Elliana that day.

2.1.11 Baby Elliana's care, including observations such as temperature, heart rate and skin colour, was documented at approximately 2-hourly intervals throughout day 1. No visual signs of jaundice were documented.

Day 2

2.1.12 Clinician 4 received a handover of the babies in the SCBU at 09:00 hours. Clinician 4 examined Baby Elliana at 13:10 hours in the presence of a consultant on the ward round. A plan was made by Clinician 4 to chase up the results of the repeat blood test requested on day 1. This plan was handed over to a junior doctor before Clinician 4 left the Trust that afternoon.

2.1.13 The repeat blood test planned for 16:00 hours on day 1 was taken on day 2 at 17:38 hours and sent to the laboratory. This sample was also found to be icteric. In line with routine practice, the laboratory then measured the bilirubin level. The result, a 'total bilirubin of 363 micromole', was uploaded to the Trust's computer system. This level is outside of the expected range for a baby who has a gestational age of 32 weeks (see 4.1.8).

2.1.14 Baby Elliana's care, including observations such as temperature, heart rate and skin colour, was documented by nursing staff at approximately 2-hourly intervals throughout day 2. No visual signs of jaundice were documented.

Day 3

2.1.15 At 09:00 hours, Clinician 5 received a handover from the night shift regarding the babies on the SCBU. A clinical handover sheet was provided to Clinician 5 which contained Baby Elliana's day 2 blood test results. The day 2 bilirubin result was not detailed on the clinical handover sheet; it only detailed the tests requested by the SCBU clinical team. Clinician 5 saw Baby Elliana on their ward round at 10:15 hours and documented that they did not examine her and that she was 'clinically well'.

2.1.16 As requested following the NIPE (because of the concern about red reflex) an ophthalmologist (Clinician 6) attended the SCBU at 12:50 hours to examine Baby Elliana's eyes. They used a device called a speculum to hold her eyelids open and documented 'no cataract noted', 'clear visual axis', 'no further ophthalmology input needed'. No signs of jaundice were observed during this examination.

2.1.17 Baby Elliana's care, including observations such as temperature, heart rate and skin colour, was documented by nursing staff at approximately 3-hourly intervals throughout day 3. No visual signs of jaundice were documented.

Day 4

2.1.18 Clinician 5 received a handover of all babies on the SCBU from the night shift clinician at 09:00 hours. Clinician 5 examined Baby Elliana at 10:20 hours during the ward round and documented that there were 'no concerns over night' and that she was 'doing well'. Between 10:00 hours and 19:30 hours nursing staff documented that Baby Elliana was 'pink, active and alert'. Baby Elliana's care, including observations such as temperature, heart rate and skin colour, continued overnight. No visual signs of jaundice were observed.

Day 5

2.1.19 At 09:00 hours, a nurse (Clinician 8) undertook a newborn blood spot test (also known as a 'Guthrie check' or a heel prick test). During the ward round, Clinician 9 documented that Baby Elliana was 'not formally examined (examined yesterday)' and their impression that Baby Elliana was 'doing well'.

2.1.20 Clinician 8 carried out observations on Baby Elliana at 12:30 hours and documented 'all ok'. At 15:30 hours Clinician 8 conducted a further set of observations. They documented in the nursing notes 'noticed slight yellowing' of Baby Elliana's skin. Clinician 8 escalated their concerns to a senior nurse. It was agreed to check blood bilirubin levels.

2.1.21 At 16:30 hours, Baby Elliana had an episode of vomiting and holding her breath. Ellen, Baby Elliana's mother, who was with her daughter, pulled the emergency cord to request assistance from staff. Staff attended Baby Elliana who settled without further intervention.

2.1.22 At 18:30 hours the bilirubin level in Baby Elliana's blood was measured using the 'point of care machine' in the SCBU. Results showed that the level was high at 393 micromoles. The result was escalated to a senior clinician and a further, confirmatory blood test showed a level of 384 micromoles. This result was escalated to a doctor (Clinician 9).

2.1.23 Clinician 9 reviewed Baby Elliana and documented that she was found to have jaundice requiring treatment but was 'generally well'. Baby Elliana was examined by Clinician 9 who documented that she was 'well, good [muscle] tone, no abnormal movement'. A plan was made to start phototherapy and to repeat the bilirubin blood tests 'in 1 hour'. Clinician 9 sought advice from the neighbouring specialist neonatal unit which confirmed the treatment plan. Phototherapy was started at approximately 19:30 hours.

2.1.24 Baby Elliana received further treatment over the next 48 hours until her bilirubin levels were within the expected range. She was referred for a magnetic resonance imaging (MRI) scan and a hearing test to assess whether her high bilirubin levels had affected her brain function and hearing. A referral was also made to the children's development centre (a specialist advice and treatment centre for children with potential or actual developmental problems).

2.1.25 The MRI scan was undertaken at 16 days of age and indicated that Baby Elliana's brain had not been affected by her high bilirubin levels. Baby Elliana continued to progress well and was discharged home with her mother 21 days after her birth. Baby Elliana will receive follow-up clinical reviews to confirm that there has been no effect on her long-term development.

3 Involvement of the Healthcare Safety Investigation Branch

This section outlines how HSIB was alerted to the issues associated with the diagnosis of jaundice in newborn babies. It also describes the criteria HSIB used to decide whether to proceed with the investigation, and the analysis methods and evidence used in the investigation process.

3.1 Notification of the reference event

3.1.1 The notification was made by an external organisation which had been contacted by a member of staff at the Trust where the reference event took place.

3.1.2 HSIB contacted the Trust and an initial scoping investigation was undertaken. The purpose of scoping investigations is to explore the identified patient safety risk(s), and to consider the practicality and value of proceeding to a national investigation. The Trust welcomed HSIB's involvement and fully collaborated with information gathering

3.2 Decision to conduct a national investigation

3.2.1 HSIB conducted the scoping investigation which determined that the patient safety concern met the criteria to progress to a national investigation.

Outcome impact – what was, or is, the impact of the safety issue on people and services across the healthcare system?

3.2.2 Rarely, and without timely treatment, jaundice can lead to brain damage. The reliance on visual signs to detect the condition means that there is a risk of delay in diagnosis, compounding the risk of harm.

3.2.3 NHS Resolution reviewed 20 compensation claims for harm secondary to jaundice in newborn babies over a 10-year period. It estimated that these had cost £150.5 million, with future costs likely to increase (NHS Resolution, 2018).

Systemic risk – how widespread and how common a safety issue is this across the healthcare system?

3.2.4 Jaundice is a common condition in newborn babies. National Institute for Health and Care Excellence (NICE) guidance states that 'Approximately 60% of term and 80% of preterm babies develop jaundice in the first week of life' (National Institute for Health and Care Excellence, 2016).

3.2.5 The signs of jaundice usually develop 2 to 3 days after birth. Jaundice usually resolves without treatment by the time a newborn baby is 2 weeks old. However, it is estimated that 1 in 20 babies have bilirubin levels high enough to need treatment (NHS, 2018).

3.2.6 NICE guidance states the 'Clinical recognition and assessment of jaundice can be difficult, particularly in babies with darker skin tones'. It recommends clinical staff 'examine the baby for jaundice at every opportunity especially in the first 72 hours' (National Institute for Health and Care Excellence, 2016).

Learning potential – what is the potential for an HSIB investigation to lead to positive changes and improvements to patient safety across the healthcare system?

3.2.7 Despite the risk associated with the delayed treatment of jaundice being long recognised, this risk has remained. This suggests there are complexities associated with detecting jaundice that need to be understood and acknowledged.

3.2.8 Safety investigations can provide insight into persistent safety risks and make recommendations that stimulate change. In addition, they provide an opportunity to share learning from stakeholders and/or healthcare providers that have made beneficial improvements to positively influence processes and practice across organisations.

3.3 Investigation scope

3.3.1 After initial evidence gathering, it was agreed that the terms of reference were to:

1. identify the system-wide factors that help or hinder the diagnosis of jaundice in newborn babies
2. explore the reliance on visual signs as a means of detecting neonatal jaundice and the impact of ethnicity on this
3. consider the information provided in national guidance to support the diagnosis of jaundice in newborn babies with black and brown skin
4. identify the implications of the findings for mitigating the risk of delayed diagnosis of jaundice.

3.4 Evidence gathering and verification of findings

3.4.1 The evidence was collected between October 2021 and September 2022.

3.4.2 A range of evidence was collected which included:

- a review of Baby Elliana's clinical records
- observation of the clinical setting where Baby Elliana's care was delivered
- interviews with Ellen, Baby Elliana's mother
- interviews with 12 staff members either directly or indirectly involved in the reference event
- a review of relevant local and national guidance and policies
- review of the Trust's internal serious incident investigation report
- review of relevant literature and research
- interviews with stakeholders and subject matter advisors
- responses to surveys sent to neonatal and pathology units (diagnostic test laboratories) across England.

3.4.3 Stakeholders and subject matter advisors across the healthcare system were contacted to provide authoritative comment on systemic issues impacting on the detection of jaundice in newborn babies. These included:

- The Royal College of Nursing
- NHS England and NHS Improvement
- The Royal College of Paediatrics and Child Health
- NHS Race and Health Observatory
- British Association of Perinatal Medicine
- National Institute for Health and Care Excellence
- The Royal College of Pathologists
- The Royal College of Midwives.

3.4.4 The investigation findings were shared with the stakeholders and subject matter advisors. This enabled checking for factual accuracy and overall sense checking. The stakeholders contributed to the development of the safety recommendations based on the evidence gathered.

3.5 Analysis of the evidence

3.5.1 A range of methods were used to collect and analyse evidence during the investigation. These were informed by the Systems Engineering Initiative for Patient Safety (SEIPS) framework (Carayon et al, 2006; Holden et al, 2013).

3.5.2 The evidence gathering process adopted an iterative approach so that as further information was received, additional sources of evidence were identified.

3.5.3 Interview questions were developed to reflect the roles of the staff involved in Baby Elliana's care. Interviews were recorded and subsequently thematically analysed to identify key system factors contributing to either the decisions made or the actions taken.

3.5.4 Surveys were sent to neonatal and laboratory units across England to provide insight into current practice regarding the detection of jaundice. The responses were thematically analysed.

4 Analysis and findings – the reference event

This section describes the investigation's findings in relation to the reference event. It focuses on the factors within the healthcare system as a whole that were found to have contributed to the delayed diagnosis of Baby Elliana's jaundice. They are:

- assessment of jaundice in Baby Elliana
- communication of Baby Elliana's bilirubin results.

In addition, this section includes the issue of care delivered by student nurses. Although this was not found to have contributed to the delayed diagnosis of jaundice, it was raised as a concern by Baby Elliana's mother and so is included here for completeness.

This reference event took place over a period of days. On day 1 of Baby Elliana's life, the special care baby unit (SCBU) was described by staff as "unusually busy". However, days 2 to 5 were described as "normal". Staff involved in caring for Baby Elliana included those permanently employed and student nurses. One member of staff who provided care to Baby Elliana was a clinician employed through an agency who worked at the Trust "once every couple of months"

4.1 Assessment of jaundice in Baby Elliana

Examination on admission to the unit

4.1.1 Baby Elliana was at increased risk of jaundice. She was born prematurely and had a forceps delivery resulting in a bruise on her head (Mayo Foundation for Medical Education and Research, n.d.; National Institute for Health and Care Excellence, 2016).

4.1.2 One of the documents used to record the care given to babies on the SCBU is an Early Warning Trigger Chart (figure 2). Staff record on this chart physiological observations (such as heart rate, temperature and respiratory rate) as well as other clinically significant signs such as skin colour and whether the baby is 'floppy'. The chart has amber and red sections to help identify if the baby's care should be escalated to a doctor or senior staff member. The chart also contains a column for staff to insert serum bilirubin (SBR) readings.

Action:		Action:		Duration of	
1 in Amber = Report to Sister		1 in Amber in Red =		OBS:	
2 in Amber = Report to Sister/Doctor		Immediately to Sister/Doctor			
Date					
Time					
Incubator/ Cot Temp					
Temperature	38 and above				
	37.5-37.9				
	36.6-37.4				
	36.0-36.5				
	35.5-35.9				
BP and Mass					
Heart Rate	180 and above				
	151-179				
	141-150				
	131-140				
	121-130				
	111-120				
	101-110				
	81-100				
Respiratory Rate	<80				
	>80				
	60-79				
	50-59				
	40-49				
	30-39				
	20-29				
	<19				
True Apnoea					
Saturation	<88%				
	88-94%				
	>95%				
NC O2					
Colour					
Grunting	Yes				
	No				
Behaviour	Floppy				
	Jittery				
	Normal				
Jaundice	SBR				
	Phototherapy				
	Bili Bed				
Blood Glucose					
Number of Yellow Scores					
Number of Red Scores					
Sign					

Figure 2 Early Warning Trigger Chart as used on the SCBU to document Baby Elliana's observations

4.1.3 Observations on Baby Elliana were recorded on an Early Warning Trigger Chart by a senior nurse at 01:00, 02:00, 03:00, 05:00 and 07:00 hours on day 1 (see 2.1.2). The nurse documented that Baby Elliana's behaviour was 'normal', and she had 'no signs of respiratory distress' and 'colour pink'. Ellen, (Baby Elliana's mother) told the investigation that she did not "recall Elliana ever looking pink" as she [Elliana] "is a black baby". No observations were in the amber or red sections. No visual signs of jaundice were identified or documented within the medical/nursing records.

4.1.4 There is a section on the Early Warning Trigger Chart called 'jaundice'. This section is used to record bilirubin levels and whether a baby is receiving treatment such as phototherapy. The chart does not prompt staff to inspect areas such as the skin, sclera (whites of the eyes) and gums, or to record whether signs of jaundice are apparent.

Newborn infant physical examination (NIPE)

4.1.5 A NIPE was performed on Baby Elliana at 11:30 hours on day 1 by Clinician 2 and Clinician 3 during their ward round. This examination requires staff to examine a Baby from "top to toe" and included a requirement to conduct a thorough eye examination.

4.1.6 Clinician 2 told the investigation that they found no visual signs of jaundice "in any way shape or form" on their examination of Baby Elliana. However, this clinician said they noted the bilirubin level result on the Trust's computer and thought "gosh that's high". They documented this result in the medical notes but not on a treatment threshold graph (see 4.1.8) as intended because their pager (a small communication device) went off, summoning them to an emergency elsewhere. Clinician 2 carried a pager as their role included attending emergencies in addition to other routine clinical tasks.

4.1.7 After the emergency had been dealt with, Clinician 2 returned to the SCBU. They were aware that two babies had been newly admitted to the SCBU that day and they went to assess them. They forgot to plot the "high" bilirubin level on the treatment threshold graph. Clinician 2 was not scheduled to work in the SCBU for the remainder of that week and did not provide any further care to Baby Elliana.

4.1.8 Figure 3 shows Baby Elliana's bilirubin levels when they were plotted on a treatment threshold graph by the investigation. As indicated by the graph, Baby Elliana's bilirubin level on day 1, and day 2, showed that treatment was indicated as it was above the 'exchange transfusion' line.

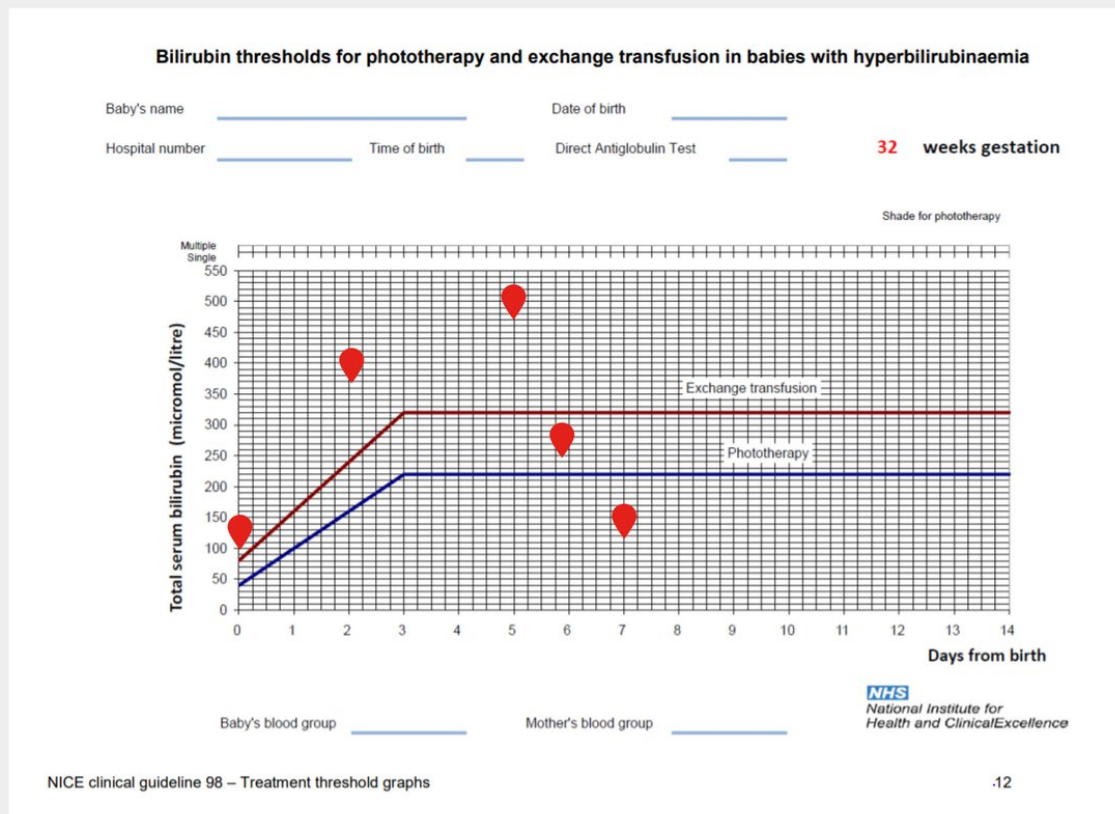


Figure 3 Treatment threshold graph with Baby Elliana's results plotted

4.1.9 The investigation observed staff undertaking a NIPE during a visit to the Trust. The blinds on the windows of the SCBU were noted to be drawn at the time of the observation, restricting the amount of natural light. Staff explained that this is done to protect newborn babies' eyes which are sensitive to daylight.

4.1.10 The investigation observed that newborn babies' eyes, particularly preterm babies', are mostly closed. Examination of the sclera required staff to prise open the eye, disturbing the baby's sleep and sometimes causing distress. In addition, even when prised open, the investigation observed that it can be difficult to see much of the sclera and that this was dependent on where a baby was looking. This observation was confirmed by staff interviewed who said that often "only a tiny amount" of sclera could be seen.

4.1.11 In addition to the difficulties of inspecting the sclera, staff commented on the balance to be struck between frequent intrusive examination and allowing babies adequate sleep to support development. Thus, examining the sclera for signs of jaundice is not a simple task and one that is counter to the need to promote rest.

Visual observations during routine care

4.1.12 Baby Elliana was examined during daily ward rounds and routinely observed by nursing staff (throughout the day and night) during her time on the SCBU. Examinations and observations were documented within the nursing and medical records. During interviews, the investigation was told that routine observations included looking at Baby Elliana's skin colour when giving care such as changing her nappy, commencing her feeds and so on. Baby Elliana's eyes and mouth were observed "when possible", for example when she opened her eyes or mouth when crying or in response to touch. No visual signs of jaundice were identified or documented within the medical/nursing records until day 5.

4.1.13 There was consensus from staff interviewed that jaundice was more difficult to see during observations in newborn babies who have black or brown skin.

4.1.14 Several staff said that they had "learned by osmosis" from colleagues to look for the signs of jaundice in a way that wasn't highlighted in national guidance and had not been emphasised by the training they had received. Staff pointed out that the majority of "information" contained in educational materials was based on babies with white skin.

4.1.15 Staff said that it would be helpful for national guidance to contain information on how to address the challenges of detecting jaundice through visual observation in newborn babies with black and brown skin. Reflecting on Baby Elliana's case, one clinician said that, in their experience, there were some babies who did not exhibit any signs of jaundice despite high bilirubin levels and that national guidance needed to address this (see 5.1.2).

4.1.16 One staff member involved in the reference event said that "they would like the NICE [National Institute for Health and Care Excellence] guidance to be clearer" specifically regarding the reliance on visual detection as the primary method of detecting jaundice. The staff member said that there are "too many graphs, too many gestations". They thought that a recommendation in the guidance to obtain an SBR in babies at increased risk would help prevent a delayed diagnosis in this group.

4.1.17 As stated above (see 2.1.8) Baby Elliana was referred to the ophthalmology team on day 1. The ophthalmologist told the investigation that if signs of jaundice had been apparent during their examination they "would have reflected this" in their documentation.

4.1.18 The investigation interviewed 12 clinicians (doctors, nurses, advanced practitioners, healthcare support workers and students) who provided care to Baby Elliana before her diagnosis of jaundice. Staff recalled that there was a "very low clinical suspicion of jaundice". They said that there were no visual signs of jaundice apparent during routine care or the examinations undertaken. They pointed out that "dark skin might make things more difficult" and that the "whites of the eyes were examined".

4.1.19 The investigation interviewed every doctor who saw Baby Elliana on ward rounds before her diagnosis of jaundice. These doctors explained that routine practice is to ask the nurse caring for a baby if they have any concerns regarding the baby's progress and clinical condition. As the primary care givers, continually observing and interacting with a baby, the nurses' views informed and directed the attention of the doctors. The investigation found that doctors may not examine a baby every day, if there were no concerns raised by nursing staff and if, from their knowledge, the baby was progressing well. Like the nursing staff, doctors explained that examinations disturb sleep and potentially distress a baby so while regular examination was important, it may not be carried out every day.

4.1.20 Doctors said that nursing staff did not raise any concerns about jaundice before day 5. Their comments were reflected in documentation reviewed by the investigation. For example, Baby Elliana was examined at 10:20 hours on day 4 by a doctor who documented 'No concerns [raised by the nursing team] overnight' and 'doing well'. Baby Elliana was assessed by Clinician 9 on day 5 during the morning ward round. It was documented that she was not formally examined as 'examined yesterday' and 'no concerns' over the last 24 hours.

4.1.21 The investigation interviewed five of the nurses allocated to care for Baby Elliana before her diagnosis of jaundice. Comments made by them during interviews, and their documentation in the nursing records, reflect the fact that there were no visual signs or symptoms of jaundice identified prior to day 5.

4.1.22 The investigation interviewed Clinician 8 who detected visual signs of jaundice in Baby Elliana on day 5. This clinician started working on the SCBU the previous day (day 4). On that day, they had observed Baby Elliana being fed by other SCBU staff. They said that "there was no indication of jaundice at this time".

4.1.23 Clinician 8 was allocated to assist with Baby Elliana's care on day 5 (see 2.1.19). Clinician 8 said that Baby Elliana was responding as expected in the morning and was "quite active". At approximately 15:30 hours, Clinician 8 stated that Baby Elliana "opened her eyes briefly and they were very yellow", and they then observed 'slight yellowing' of Baby Elliana's skin.

Summary

4.1.24 Baby Elliana was at significant risk of developing jaundice due to her prematurity and because forceps were used to assist her birth.

4.1.25 A blood test taken on day 1 was tested for bilirubin level. The result was recognised as high by the clinician undertaking the NIPE on day 1 of Baby Elliana's life. The result was not plotted on a treatment threshold graph and a diagnosis of jaundice was not made. The fact that this clinician was called to an emergency during their assessment of Baby Elliana, and had other priority tasks at that time, were seen as contributory to this.

4.1.26 Clinicians caring for Baby Elliana did not detect any visual signs of jaundice until day 5 despite her having high levels of bilirubin in her blood.

4.1.27 NICE guidance states that recognition and assessment of jaundice can be difficult, particularly in babies with black or brown skin. Staff interviewed said it would be helpful for national guidance to contain information on how to address the challenges of detecting jaundice through visual observation in newborn babies with black and brown skin.

4.2 Communication of Baby Elliana's bilirubin results

Laboratory practice

4.2.1 Irrespective of whether bilirubin levels are requested by the clinical team, it is routine practice within the Trust's laboratory to measure this in blood samples found to be icteric (see 2.1.4). Results are uploaded onto the Trust's computer system alongside the results of other blood tests.

4.2.2 The expected level of bilirubin in a newborn baby's blood sample depends on the baby's gestational age. Laboratory staff do not calculate the gestational age of the baby and therefore do not know whether the result is high relative to their age. Accordingly, the result is uploaded in black font as is usual for results found to be in the expected range. Blood results that fall outside of normal limits would usually be flagged in some way – for example, by displaying in red font.

4.2.3 Laboratory staff said that they telephone clinical areas to advise the team that they have tested for bilirubin and to tell them of the result. They used to telephone the SCBU to inform staff of bilirubin results and to facilitate timely intervention if required. The investigation was told that about 18 months before the reference event, the SCBU had asked laboratory staff not to call them regarding these results as the SCBU "had the facility to check bilirubin levels".

4.2.4 Reflecting this, SCBU staff said, "we used to get lots of calls regarding bilirubin levels from the lab". The investigation was told that often staff already knew about these results, because if a baby was suspected of having jaundice a blood test would have been carried out using the point of care machine on the unit. Furthermore, staff said the laboratory would contact them "even if a bilirubin level was low".

4.2.5 The Trust's laboratory policy for telephoning results states that for a baby aged 1 day, a bilirubin level above 100 micromoles would be a 'significantly abnormal' and 'must be communicated directly to a clinician'. In accordance with the agreement between the SCBU and the laboratory, the policy states 'do not phone if SCBU/NICU [neonatal intensive care unit]'.

Day 1 blood sample result

4.2.6 Clinical staff did not request that the blood sample taken from Baby Elliana on day 1 be tested for bilirubin level as staff had not observed any visual signs of jaundice. However, the bilirubin level was measured by laboratory staff because the blood sample was icteric (see 2.1.4).

4.2.7 Blood results are accessible to staff who have completed computer training and been provided with the necessary computer system log-in details. Baby Elliana's bilirubin level from the blood sample taken on day 1 was 105 micromoles. This result was uploaded to the computer system at 04:37 hours on day 1. At 05:00 hours a nurse documented 'SBR [serum bilirubin] of 106' on a feeding chart in Baby Elliana's nursing notes. It is possible that this was a transposition error and referred to the result of 105 micromoles on the computer system. The investigation did not find evidence of any action or verbal communication taken in response to this bilirubin result. In addition, it was not documented in the bilirubin (SBR) column on the Early Warning Trigger Chart (see 4.1.2) or clinical handover sheet which both provide other means of communicating clinical information. The staff member documenting this result was not interviewed as part of the investigation as the investigation only became aware of the feeding chart after interviews were concluded.

4.2.8 The investigation was told about a number of different handover meetings that occur at shift changes in the SCBU. One of these is between medical staff and takes place at 09:00 hours on weekdays. At this meeting information is given verbally and with reference to a clinical handover sheet (see 2.1.15). In addition, the investigation was told that before the COVID-19 pandemic, blood sample results were accessed and reviewed by the paediatric team attending the handover on a large computer screen in the handover room. However, handovers were moved to a different, larger room during the COVID-19 pandemic to support social distancing. The new room did not have the same computer access so one member of the paediatric team was tasked with accessing results and bringing them to the meeting. There was, therefore, a reliance on one pair of eyes noticing results rather than several.

4.2.9 Staff at the meeting at 09:00 hours on day 1 of Baby Elliana's life were unaware that her blood had been tested for bilirubin and that the result was on the Trust's computer system.

4.2.10 Clinician 1 attended the handover meeting and told the day team to 'chase' Baby Elliana's day 1 blood sample results. As Baby Elliana had not exhibited any visual signs of jaundice, staff were not expecting or looking for a bilirubin result.

4.2.11 As detailed above, Baby Elliana's day 1 blood results were accessed on the computer system by clinician 2 during the NIPE but not acted upon (see 4.1.5 to 4.1.7). The investigation found that Baby Elliana's medical notes detailed a plan to repeat a 'full blood count' (FBC) and 'C-Reactive protein' (CRP) at 16:00 hours on day 1; this repeat blood test was not undertaken until day 2.

Day 2 blood sample result

4.2.12 The investigation found that Clinician 4, who took over Baby Elliana's care on day 2, was employed by the Trust on a temporary basis to cover staff shortages. Clinician 4 said that when working on this basis in other NHS trusts, they were provided with a log-in for the trust's computer systems to allow them to access patient information and results. However, in the reference event Trust, they were not given a log-in for access to the Trust's computer systems. They said they relied on colleagues and junior clinicians to access results.

4.2.13 Commenting on this, a governance lead at the Trust highlighted the difficulties of making the Trust's computer systems accessible to temporary staff while protecting patient confidentiality appropriately. Of note, the investigation was told by the governance lead that the Trust was in the process of making all patient records electronic. The project team responsible for this had been made aware of the need for temporary staff to have a log-in and were developing a process to address the issue.

4.2.14 The issues associated with access to computer systems for temporary staff are common to healthcare organisations. A research paper (Jennison, 2013) found that out of 20 hospitals only 4 gave locum (temporary) doctors computer passwords to access medical and administrative computer systems; only 6 of the 20 hospitals gave information on how to use the computer systems.

4.2.15 During the reference event, Clinician 4 asked a more junior clinician to "chase up" the results of the planned repeat day 1 blood tests prior to Clinician 4 departing the Trust. However, the results were not available as a repeat blood sample had not yet been taken from Baby Elliana. A blood sample was taken from Baby Elliana later that day and sent to the laboratory.

4.2.16 As with the previous blood sample, although not requested, the laboratory staff measured the bilirubin level as the blood sample was found to be icteric. The bilirubin level was found to be 363 micromoles. In line with local policy, a telephone call was not made to SCBU staff to inform them of the bilirubin result.

4.2.17 The FBC and CRP results from this blood test were written on the clinical handover sheet and given to the night shift clinicians. The bilirubin result was not documented on the clinical handover sheet. Of note, staff recalled that it was documented on Baby Elliana's clinical handover sheet for day 3 that there were "no pending blood results".

4.2.18 The investigation found no evidence to suggest that the junior doctor saw the bilirubin result. As with the previous bilirubin test on day 1, it was not requested by clinical staff, so they were not searching for this result. Reflecting this, staff interviewed said that "they did not look for results that were not requested". In addition, from visual observations there were no suspicions that Baby Elliana had jaundice and although the bilirubin result was listed just below the 'CRP' result it was not highlighted in red font (see 4.2.2) or visually commanding (see figure 4).

The screenshot shows the Sunquest ICE clinical system interface. On the left is a blue sidebar with icons and labels: 'Patient Search', 'Reporting', 'View Patient Reports', 'View Ward Reports', and 'OpenNet Patient Reports'. The main window has a header with patient details: 'Patient Name', 'Date of Birth', 'Address', 'Hospital Number', and 'NHS Number'. Below this are navigation buttons: '<', '>', 'Back', 'Cumulative', '>', 'Print', and 'Audit Trail'. A yellow banner with a pencil icon and a redacted patient name is visible. Below the banner, a message reads: 'Filed by sunquest (Sunquest Administrator) at 27 Oct 2021 03:00, Reason: Other action'. The test list includes 'Repeat CRP, Neonatal sepsis' and 'Sample 21B20041043 (Blood) Collected 17 Mar 2021 17:38 Received 17 Mar 2021 18:00'. The results table shows:

C-REACTIVE PROTEIN			
CRP	<4.0	mg/L	0 - 9.9
TOTAL BILIRUBIN REFLEX			
Total Bilirubin	363	umol/L	

Below the table, a note states: 'All samples are screened for interfering substances. Bilirubin measured following detection of icterus.'

Figure 4 Result of Baby Elliana's day 2 blood test, including the unrequested bilirubin result

4.2.19 The investigation found that hard copies of all clinical handover sheets (see 4.2.23) were destroyed to "ensure medical confidentiality" once a baby's medical notes had been updated by staff. The investigation learned that blood results would "normally" be updated by staff on to the "green sheet" (SCBU blood results form) held within a baby's medical notes.

4.2.20 Baby Elliana's day 2 blood test results and bilirubin levels were not documented in her medical documents. It is likely that the break in continuity between Clinician 4, who ended their shift at 16:30 hours on day 2, and Clinician 5 who took the handover from the night shift on day 3, contributed to the day 2 blood results not being documented.

4.2.21 Baby Elliana's care continued on the SCBU and no visual signs of jaundice were detected until day 5.

Clinical handover sheet

4.2.22 The investigation found that clinical information about a baby is recorded in multiple places. Key documents are the medical notes (mainly used by consultant nurses and doctors) and nursing notes (primarily used by nursing staff). Additional information is stored electronically, for example test results in the laboratory computer system.

4.2.23 Key pieces of information from all the different sources are captured on a clinical handover sheet, which staff print off to have with them during their working day. This clinical handover sheet provides a quick overview of the significant information pertaining to each baby's care. As such, the clinical handover sheet is a critical document used for the transfer of patient information between clinical staff during handover at shift changes. The sheet is used by the clinician leading the daily ward round to inform their assessment of patients, and supplement information provided by clinical staff involved with a patient's care. The clinician will add to the clinical handover sheet important pieces of information gained during their ward rounds. In addition, required or outstanding tasks (such as blood tests needed or to be checked, procedures to be organised and so on) are added to the sheet. At the end of the shift, an updated clinical handover sheet is electronically generated and printed off to aid handover of the entire SCBU to the incoming clinical team. The daily clinical handover sheets are stored for audit purposes and any paper copies destroyed at the end of a shift.

4.2.24 In the reference event, Baby Elliana's bilirubin level from day 1 was not documented on the clinical handover sheet before day 5 when she was diagnosed with jaundice. The day 1 bilirubin level was documented on the dedicated blood results form (green sheet) and an SBR entry made on a feeding chart contained in Baby Elliana's medical records. The investigation was unable to identify whether either of these documents were looked at during the subsequent ward rounds after day 1.

4.2.25 Evidence indicates that in the context of there being multiple places where clinical information is stored, and given the time pressures on clinicians, there is a reliance by clinicians on the clinical handover sheet. This contributed to the day 1 bilirubin result (and diagnosis of jaundice) being missed until day 5.

Summary

4.2.26 Laboratory practice at the Trust was to measure the bilirubin level when blood samples were found to be icteric. Results were uploaded onto the computer system but, following an agreement with the SCBU, clinicians were not telephoned to advise them of the test and the

result. Furthermore, the laboratory did not calculate whether the result was high for the gestational age of the baby and thus results appeared on the computer system in black font as is usual for results that fall within expected ranges.

4.2.27 The bilirubin result from the day 1 blood sample was documented on a feeding chart on Baby Elliana's nursing notes. The result was also documented by the clinician carrying out the NIPE on Baby Elliana on day 1. This clinician was interrupted during their assessment of the result; it was not plotted on the treatment threshold graph and no action was taken in response to the result.

4.2.28 Due to the COVID-19 pandemic, the location of the morning handover changed which meant that laboratory results were no longer displayed for review by the whole paediatric team. This meant there was one less opportunity for the unrequested bilirubin test and result to be spotted.

4.2.29 The locum clinician caring for Baby Elliana on day 2 did not have access to the Trust's computer systems. They relied on colleagues and junior clinicians to access results.

4.2.30 Clinical information is stored in multiple places. Key pieces of information from all the different sources are captured on the clinical handover sheet. This is a critical document used for the transfer of patient information between clinical staff. Evidence indicates that the reliance on this sheet contributed to the bilirubin result (and diagnosis of jaundice) being missed until day 5.

4.3 Delivery of care by student nurses

4.3.1 Baby Elliana's mother, Ellen, told the investigation that she was concerned that student nurses provided unsupervised care to her daughter. The investigation found that students in their final year of training worked in the SCBU and provided care to Baby Elliana. The investigation was told that student nurses were 'supernumerary'; that is, they were in addition to the number of qualified staff rostered to work each shift. This is in accordance with national standards (Nursing and Midwifery Council, 2019).

4.3.2 The investigation was told that student nurses care for babies under the supervision of a registered nurse. Student nurses carried out 'observational checks and feeding' for Baby Elliana. During interviews, student nurses said that "if there was anything outside of the normal range or if unsure about anything" they would ask staff and they said they "felt really supported and could always ask for help".

4.3.3 The investigation was told that students who provided care to Baby Elliana had received "some awareness training for jaundice". The practical elements of assessing the student's ability to recognise visual signs of jaundice was conducted on a simulation manikin that had

“white skin”. One of the student nurses who cared for Baby Elliana said that during their training they had a question-and-answer assessment which included how they would assess babies with brown or black skin. However, there was no opportunity to practise this element as the manikin used during simulations had white skin.

4.3.4 The investigation found that some universities that deliver training to NHS nursing students recognised that teaching aids, including literature, did not fully represent the diversity of the UK population. These universities were buying additional teaching materials and equipment to “better inform students”.

Summary

4.3.5 Student nurses carried out observational checks and fed Baby Elliana under the supervision of a registered nurse. Some universities providing education are seeking to ensure that teaching aids and literature represent the diversity of the population.

4.4 Actions resulting from the Trust’s internal investigation

4.4.1 The Trust’s internal investigation resulted in several safety actions to reduce the risk of a similar incident happening again. The key actions were:

- SCBU to routinely test the bilirubin level of all babies within 24 hours of admission.
- The clinical handover sheet amended to ascertain that all blood results have been reviewed during the daily ward round.
- Introduce an electronic patient record (planned to be implemented in 2022) to support timely documentation of results and plotting on a chart.

5 Analysis and findings – the wider investigation

This section sets out the findings of the investigation in the context of the wider healthcare system. Evidence was gathered and safety recommendations developed with the reference event scenario in mind. The findings are presented within the following themes:

- reliance on visual signs for the detection of jaundice in newborn babies
- use of a blood test to detect bilirubin.

The investigation recognises that there are challenges with the detection of other conditions where visual signs are an important indicator. These challenges are outside the scope of this report. However, some of the findings may be of relevance in improving diagnosis of these conditions.

5.1 Reliance on visual signs for the detection of jaundice in newborn babies

5.1.1 National guidance recommends that visual signs should be used to detect jaundice followed by a blood test to measure bilirubin when visual signs are present (National Institute for Health and Care Excellence, 2016). The investigation discussed the reliability of visual signs of jaundice with national stakeholders and subject matter advisors (SMAs) (see 3.4.3).

5.1.2 There were differing opinions about the reliability of visual signs to detect jaundice in newborn babies. Of note, the bilirubin threshold level for treatment is lower in preterm babies than term babies, and lower with each week of earlier gestation. Therefore, a preterm baby may have a bilirubin level in the treatment zone but may not be visibly jaundiced. Several stakeholders said that it was possible for a newborn baby to have a high bilirubin level but no visual signs of jaundice, one saying that it was “not that unusual”. Others thought that this was implausible and thought that if looked for in line with the national guidance – that is, ensuring the sclera and gums were inspected as well as the appearance of the skin, in preferably natural light – then signs of jaundice would be visible. In the reference event, Baby Elliana had increasingly high bilirubin levels in her first days of life, but jaundice was not suspected and visual signs, if present, were not obvious or detected.

5.1.3 All stakeholders agreed that the assessment of visual signs was subjective and all agreed that detection was more challenging with babies with black or brown skin. Several stakeholders highlighted the value of inspecting other areas of a baby’s body for visual signs of jaundice in addition to those mentioned in national guidance. For example, an SMA with expertise in neonatal care from the Royal College of Nursing said that looking at the roof of a baby’s mouth (palate) can be very helpful. Other stakeholders mentioned the value of looking at a baby’s lips and the palms of the hands and soles of the feet for visual signs.

5.1.4 While stakeholders agreed that the sclera could be an important visual indicator of jaundice, they raised the difficulty of checking this in newborn babies, particularly those who are premature. Evidence gathered during the investigation’s observational visit confirmed this (see 4.1.10).

5.1.5 In relation to ethnicity, the National Institute for Health and Care Excellence (NICE) guidance states that the visual signs of jaundice can be particularly difficult to recognise in babies with ‘darker skin tones’ (National Institute for Health and Care Excellence, 2016). A neonatal nursing SMA said that this difficulty was compounded by the fact that over the course of a 12-hour shift a nurse can become accustomed to a baby’s skin colour. This means subtle changes caused by the onset of jaundice may not be recognised. The SMA also said that the introduction of a ‘fresh eyes’ approach (NHS England and Improvement, 2022) (asking a member of staff not involved in a baby’s care to assess their skin for visual signs) during a shift

may increase the likelihood of jaundice being recognised. NHS England commented that there is a 'need for a more holistic fresh eyes approach being adopted' to 'ensure all test results are reviewed not just a fresh eyes approach on skin tone'.

5.1.6 Another SMA told the investigation that, in their opinion, a blood sample should be taken from babies with black or brown skin to test for bilirubin if admitted to a neonatal unit rather than relying on visual signs. In essence, this SMA believed that babies with black or brown skin need to be managed differently to ensure jaundice is recognised and treated promptly. However, British Association of Perinatal Medicine (BAPM) said that they would not recommend routine blood testing for bilirubin.

5.1.7 Several SMAs highlighted the role of expertise in recognising visual signs of jaundice. They said that staff working in areas of England that are ethnically diverse are likely to have a heightened awareness of the need to examine areas of the body such as the palate for signs of jaundice. Staff working in less diverse areas are likely to be less aware. The importance of professional training, and the need for this to reflect the diversity of the population, was highlighted in this regard (see 1.3). For example, stakeholders mentioned the need to reflect different skin colours in photographs and descriptions in textbooks, and in the manikins used in practical sessions such as simulations. Reflecting this, some royal colleges, such as the Royal College of Physicians, are introducing new exam questions regarding how clinicians adjust their assessments of patients with different skin colours to aid diagnosis.

5.1.8 The investigation spoke with a representative from the NHS Race and Health Observatory, an organisation that aims to identify and tackle ethnic inequalities in health and care. The representative concurred with the view that if visual signs of jaundice are more difficult to detect in babies with black and brown skin it would be important to review the evidence to see if it indicates an alternative way of testing for bilirubin in these babies.

5.1.9 Several stakeholders said that the NICE guidance seemed more applicable to term babies than those who are preterm. They suggested that it may be helpful for the guidance to contain some additional information to support the detection of visual signs of jaundice in preterm babies. NICE guidance states that prematurity is a risk factor for jaundice; however, the guidance does not recommend what action it might be appropriate to take as a result of this. Similarly, the guidance does not recommend what action should be taken in response to the other risk factors it lists. Evidence from the investigation indicates that it may be helpful for the guidance to include the action to be taken.

5.1.10 One SMA said that NICE guidance should refer to "speciality group guidance" such as that provided by the British Association of Perinatal Medicine (BAPM) when providing national guidance for preterm babies. The SMA further stated that "preterm is different versus term" when considering risks for jaundice and that a preterm baby "may not necessarily follow the

same pathway to that of a term baby as set out in national guidance”. The SMA stated that a test for babies’ bilirubin levels (using whatever equipment a trust had available) on admission to a neonatal unit would reduce the risk of some preterm babies having an undetected bilirubin level that is above the treatment threshold line.

Neonatal survey

5.1.11 The investigation produced a survey to help gain insight into current practice regarding blood testing for bilirubin. BAPM distributed a link to the HSIB survey via their monthly newsletter for UK neonatal units (approximately 165). Given the low number of responses received (2) the survey was again distributed through informal networks by HSIB neonatal clinical advisors. The exact number of neonatal units contacted by this route was not recorded but 36 responses were received. Overall, the evidence showed variation in practice and that some neonatal units have moved away from national guidance and the reliance on visual signs to detect jaundice in preterm babies. For example, one of the questions asked whether units routinely requested bilirubin levels on blood samples taken from newborn babies. The responses are shown in figure 5.

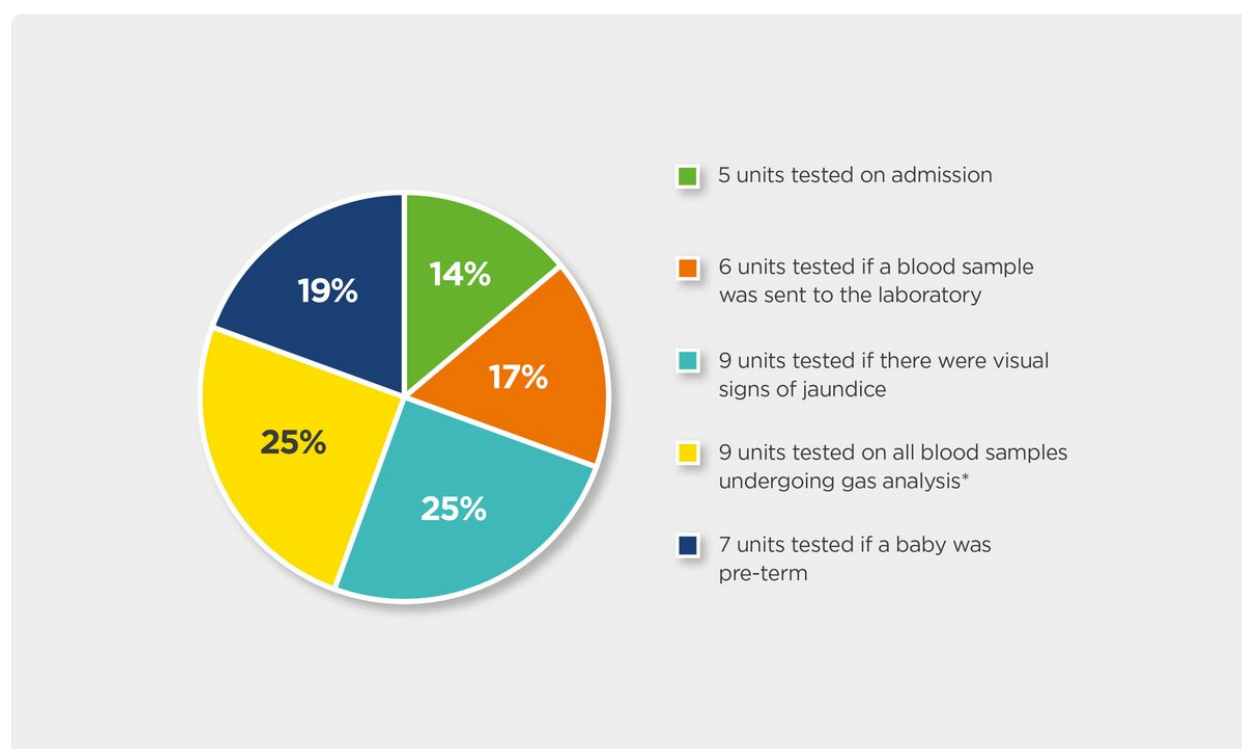


Figure 5 Responses to survey question: 'Do units routinely request bilirubin levels on blood samples taken from newborn babies?'

*Of note, some blood gas analysis machines give a bilirubin result by default without this being requested.

5.1.12 In addition to showing variation, the response to this question demonstrates that the majority of units have introduced additional safety measures rather than relying on visual signs of jaundice as recommended by NICE (National Institute for Health and Care Excellence, 2016).

5.1.13 The survey explored the reasons for units taking this additional safety action despite it not being included in national guidance. The responses evidenced a concern with relying on visual signs of jaundice:

“As clinicians we are bad at assessing level of jaundice. Routinely testing makes sure a level above the treatment line doesn’t get missed (particularly for premature babies).”

“Sometimes high jaundice may not be visual.”

Furthermore, the responses evidenced clinical opinion that because of the increased risk of high bilirubin in preterm babies, this needed to be tested and measured:

“Preterm baby ... any risk factors for jaundice in the history.”

“Preterm or another indication eg significant bruising.”

5.1.14 The response to the question asking whether units were aware of a laboratory pre-analysis check (see 1.1.4) for icterus (evidence of jaundice) showed that most units were not (25 out of 36 units). Thus, they were unaware to look for comment on this on blood test reports and were therefore likely to miss this potentially significant information.

5.1.15 The survey asked units if they thought there was a risk of results being missed if a laboratory tested a blood sample because this seemed indicated by pre-analytical checks. Of the 35 responses to this question, 25 units (71.4%) believed this was a definite safety risk, and 9 units thought it was a possible risk.

Safety recommendation R/2023/208:

HSIB recommends that the National Institute for Health and Care Excellence reviews the available evidence and updates its guidance if appropriate, regarding:

- the reliability of visual signs to detect jaundice in newborn babies, particularly in babies with black and brown skin
- risk factors for jaundice identified by this investigation, including prematurity.

5.2 Blood test to detect bilirubin

Correlation between icterus and bilirubin

5.2.1 The investigation learned that NHS laboratories have been undertaking quality checks on blood samples for more than 60 years. During this period the diversity of the UK population has changed. The investigation found that it is highly unusual practice for laboratories to routinely measure bilirubin level on neonatal blood samples found to be icteric during pre-analytical checks.

5.2.2 To determine whether there was any correlation between icterus and bilirubin levels during pre-analytical checks the investigation sought expert advice. The SMA conducted some additional research to determine whether a bilirubin threshold could be confidently determined during pre-analytical checks irrespective of whether a bilirubin blood test had been requested by the clinical team. Currently neonatal units do not see the data from the pre-analytical checks.

5.2.3 Bilirubin blood sample data (more than 30,000 data points) was taken from two separate laboratories in the south-west of England to ensure consistency. Figure 6 shows a measure of bilirubin levels in the tested samples (Y axis) plotted against the level of icterus measured in each sample (X axis). The results identified a strong correlation between the levels of icterus and bilirubin (98.7%).

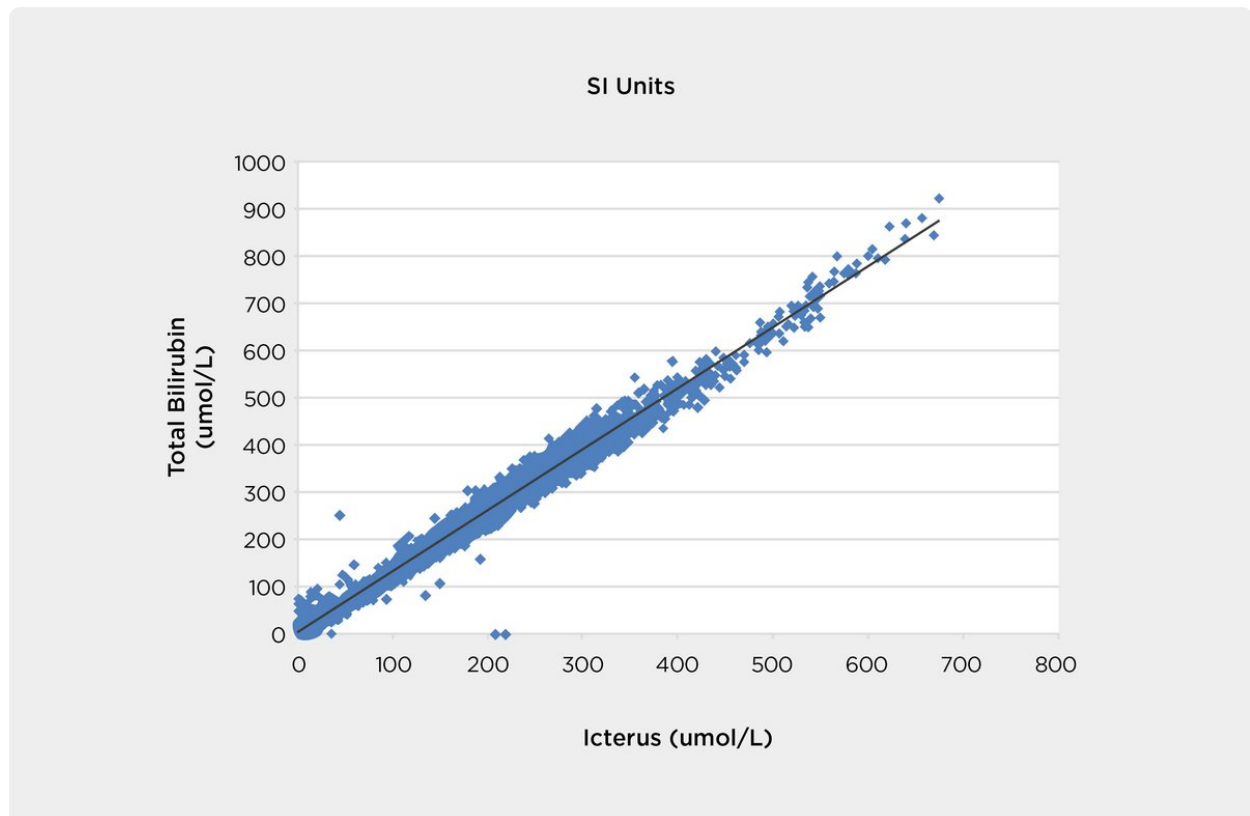


Figure 6 Correlation between icterus and bilirubin levels

5.2.4 Using this data, the investigation learned that the national laboratory network would be able to confidently identify, and cascade results for newborns who were likely to have a bilirubin level that would require immediate intervention.

5.2.5 Based on current NICE guidance the proposal would be to cascade a bilirubin result if it equates to a level of 100 micromoles. This result would be communicated directly to the neonatal unit allowing treatment to be commenced if appropriate. This action would reduce the risk of a baby with high levels of bilirubin in their blood and no obvious visual signs of jaundice from going undiagnosed. As one stakeholder pointed out, given that the need for treatment depends on the gestational age of a baby, consideration would need to be given to the number of phone calls that might be generated to a neonatal unit before this practice was adopted. This stakeholder said it would be important to balance the risk of unnecessary telephone calls to neonatal units versus the benefit of early diagnosis and treatment of hyperbilirubinemia.

5.2.6 The investigation learned that the use of the correlation between bilirubin and icterus could be used elsewhere to actively monitor patients and inform clinicians in other clinical scenarios, irrespective of whether a blood test had been requested.

Laboratory survey

5.2.7 In collaboration with the national pathology network, the investigation distributed a survey through the 29 pathology network leads in England. The survey asked about laboratory practice in relation to samples from newborn babies that are found to be icteric. Specifically, it asked if laboratories measure bilirubin levels directly on such samples if this test has not been requested by the clinical team caring for the baby.

5.2.8 The investigation received responses from 26 laboratories. Of those, 20 laboratories (76.9%) received blood samples from neonatal units (SCBU/Local neonatal unit/NICU). Twenty (76.9%) of the 26 units said that they performed pre-analytical checks which included whether a blood sample was icteric. Five units did not answer this question and 1 said it did not carry out such checks. Of the 20 units who said they tested whether a sample was icteric, there was variation in whether this result was communicated: 5 units said they would communicate this result and 10 said they would not. Four of the 5 units said that they reported that a sample was icteric on the electronic reporting system and 1 unit did not provide a response.

5.2.9 There were 19 responses to the question of whether a laboratory would routinely go on to measure the bilirubin level in a blood sample found to be icteric; 18 of the 19 units would not do this. There is a risk that these samples may contain high bilirubin levels without neonatal jaundice having been diagnosed, potentially contributing to a delay in treatment. One unit said it might go on to measure bilirubin, stating: "It depends on the icteric index of the sample." Thus, this practice (which was found in the reference event) appears to be highly unusual.

5.2.10 The survey asked laboratories if they had defined neonatal reference ranges for bilirubin. There were 20 responses that showed variation in practice (see figure 7).

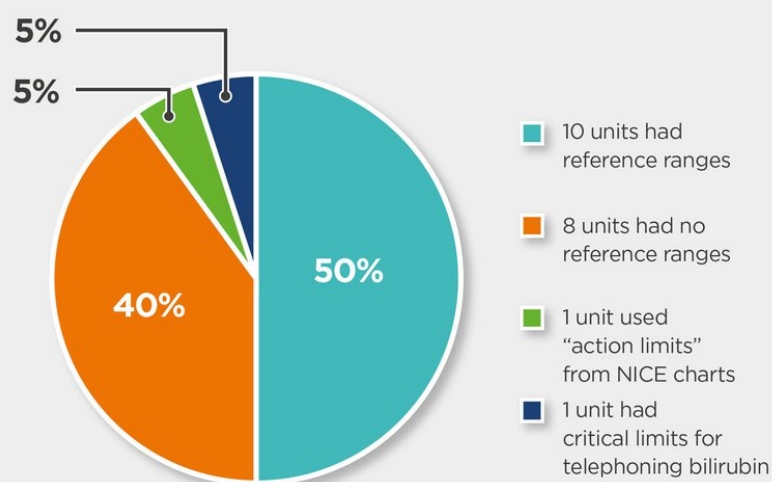


Figure 7 Responses to the survey question 'Does the laboratory have defined neonatal specific reference ranges for bilirubin?'

5.2.11 Another survey question asked about the communication of the bilirubin levels to neonatal units. Of the 20 responses, 16 said they had a defined level for communicating bilirubin levels to neonatal units; 4 did not. The survey also asked whether the level for telephoning reflected the threshold levels in NICE guidance. There were 15 responses of which 7 said that it did, 5 said that it did not and 3 reported other thresholds (1 referred to Royal College of Pathology guidance, 1 said they had a single level and 1 said they used the phototherapy threshold for a newborn aged 36 hours).

Safety recommendation R/2023/209:

HSIB recommends that the Royal College of Pathologists works with stakeholders to understand current practice and make any appropriate recommendations to promote the adoption of an icteric threshold at which a bilirubin test may be cascaded or reported.

Safety recommendation R/2023/210:

HSIB recommends that the Royal College of Pathologists works with stakeholders to understand current practice and make any appropriate recommendations on neonatal specific reference ranges for total bilirubin and thresholds for direct communication of these results to clinicians.

Safety observation O/2023/202:

It may be beneficial for regulators of pathology services to consider the findings of the investigation and amend their guidance if necessary.

Observational early warning systems

5.2.12 Observational charts designed to act as early warning systems (EWS) are used in healthcare to support staff with the timely recognition and response to the deterioration of a patient's condition. With regard to newborn babies admitted to neonatal units, there is no nationally mandated observation/trigger chart or EWS to use, so different units may have different charts in use. This inconsistency in EWS affects clinical staff who may work in different units.

5.2.13 As in the reference event, most neonatal observation charts include a section on jaundice. The section is used to record bilirubin level and whether a baby is receiving treatment such as phototherapy. The chart does not include a prompt to staff to inspect areas such as the skin, sclera and gums or to record whether visual signs of jaundice are apparent. Inclusion of this would provide a means of formalising the expectation that these areas are inspected rather than relying on the diligence and vigilance of staff for this aspect of care.

5.2.14 The investigation distributed a survey to neonatal units across England looking at aspects of care. One of the questions asked whether staff thought that neonatal EWS trigger charts should include a prompt to staff to check a baby's sclera and other areas of the body during routine observations for visual signs of jaundice. Of the 36 units who responded to the survey, 19 said yes, 10 said no and 6 said maybe. This indicates that staff recognise that the inclusion of a prompt will increase vigilance to focus on any change in a baby's appearance that would indicate whether jaundice was present. National guidance currently only provides staff with treatment threshold graphs to plot bilirubin levels once jaundice is detected for premature babies; no associated observation chart is provided to aid in early detection of jaundice.

5.2.15 An SMA told the investigation that "staff fall into a pattern" when they are undertaking observational checks and a prompt within a trigger chart may assist staff in identifying "trends" that may indicate jaundice was present and that further confirmation via a blood test was required.

5.2.16 The investigation met with SMAs from the British Association of Perinatal Medicine (BAPM) who were involved in the development of a standardised newborn early warning trigger chart (NEWTT 2) for use in postnatal care settings – that is, in delivery suites, postnatal wards and transitional care units (British Association of Perinatal Medicine, 2022). The SMAs were asked about the possibility of including a prompt to staff to check areas such as a baby's eyes and gums for signs of jaundice. The SMAs highlighted the risk of overloading the chart with additional information. However, they agreed to strengthen the wording regarding visual checks for jaundice in the draft Deterioration of the Newborn framework (British Association of Perinatal Medicine, 2022) which incorporates NEWTT 2.

5.2.17 The SMAs said that NEWTT 2 was not designed for neonatal unit settings (SCBU/Local neonatal unit/NICU). Thus, variability remains in EWS track and trigger observation charts used in neonatal units.

Safety observation O/2023/203:

It may be beneficial to develop a national standardised Early Warning System track and trigger observation chart for use in neonatal unit settings.

6 Summary of findings, safety recommendations and safety observations

6.1 Findings

- The assessment of visual signs of jaundice in newborn babies is subjective and more challenging with babies who have black or brown skin.
- Stakeholders have differing opinions about the reliability of visual signs to detect jaundice in newborn babies.
- Some neonatal units have introduced safety measures to mitigate the risk of reliance on visual signs of jaundice.
- National guidance does not recommend routinely measuring bilirubin levels in babies who are not visibly jaundiced.
- National guidance for jaundice in newborn babies maybe more applicable to term babies (those born after 37 weeks of pregnancy) than those born prematurely.
- National guidance does not contain information on how to address the challenges of detecting jaundice in newborn babies with black or brown skin.
- Some universities providing education to NHS students on the detection of jaundice are seeking to ensure that teaching aids and literature represent the diversity of the population.
- Levels of bilirubin can vary according to the gestational age of a baby (how long the baby was in the womb). Laboratory staff do not calculate the gestational age of a baby and therefore whether their bilirubin level is within the expected range.
- Laboratory practice varies in terms of whether they set specific reference ranges for bilirubin in newborn babies; whether they have a defined threshold for communicating results to neonatal units; and whether the telephone alert limit (the level of bilirubin that triggers laboratory staff to report the result to clinical staff by telephone) reflects the thresholds in national guidance.
- Neonatal staff may be unaware that laboratories analyse blood samples to see if they are icteric (indicate jaundice). These staff will not know to look for a comment about this on blood test reports.

6.2 Safety recommendations and safety observations

HSIB makes the following safety recommendations

Safety recommendation R/2023/208:

HSIB recommends that the National Institute for Health and Care Excellence reviews the available evidence and updates its guidance if appropriate, regarding:

- the reliability of visual signs to detect jaundice in newborn babies, particularly in babies with black and brown skin
- risk factors for jaundice identified by this investigation, including prematurity.

Safety recommendation R/2023/209:

HSIB recommends that the Royal College of Pathologists works with stakeholders to understand current practice and make any appropriate recommendations to promote the adoption of an icteric threshold at which a bilirubin test may be cascaded or reported.

Safety recommendation R/2023/210:

HSIB recommends that the Royal College of Pathologists works with stakeholders to understand current practice and make any appropriate recommendations on neonatal specific reference ranges for total bilirubin and thresholds for direct communication of these results to clinicians.

HSIB makes the following safety observations

Safety observation O/2023/202:

It may be beneficial for regulators of pathology services to consider the findings of the investigation and amend their guidance if necessary.

Safety observation O/2023/203:

It may be beneficial to develop a national standardised Early Warning System track and trigger observation chart for use in neonatal unit settings.

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