



HEALTHCARE SAFETY
INVESTIGATION BRANCH

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WRONG PATIENT DETAILS ON BLOOD SAMPLE

Healthcare Safety Investigation I2019/003

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INVESTIGATION BRANCH

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ABOUT HSIB

The Healthcare Safety Investigation Branch (HSIB) conducts 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 have the potential to cause harm to patients. The recommendations we make aim to improve

healthcare systems and processes in order to reduce risk and improve safety.

Our organisation values independence, transparency, objectivity, expertise and learning for improvement.

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

OUR INDEPENDENCE

We are funded by the Department of Health and Social Care and sponsored by NHS England and NHS Improvement, but we operate independently.

Following recommendations from a parliamentary select committee in August 2018, we expect that a Bill for establishing the Health Service Safety Investigations Body (HSSIB) will be introduced to Parliament soon. The Bill will establish our full statutory independence and enshrine our right to conduct national investigations under protected disclosure. This provision, commonly known as

'safe space', enables staff to share their experience of a patient safety incident without fear of reprisal. It does not prevent us from sharing important details with families, regulators or organisations about an incident or to address immediate risks to patient safety.

The Health Service Safety Investigations Bill will also establish our responsibility for NHS maternity investigations that meet specific criteria. Full information about the draft Bill is available on the **Department of Health and Social Care website**.

OUR INVESTIGATIONS

Our team of investigators and analysts have diverse experience working in 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

Our national investigations can encompass any patient safety concern that occurred within NHS-funded care in England after 1 April 2017. We consider the requirement to investigate potential incidents or issues based on wide sources of information including that provided by healthcare organisations and our own research and analysis of NHS patient safety systems.

We decide what to investigate based on the scale of risk and harm, the impact on individuals involved and on public confidence in the healthcare system, as well as the potential for learning to prevent future harm. We welcome information about patient safety concerns from the public, but we do not replace local investigations and cannot investigate on behalf of families, staff, organisations or regulators.

Our investigation reports identify opportunities for relevant organisations with power to make appropriate improvements though:

- *'Safety recommendations'* made with the specific intention of preventing future, similar events.
- *'Safety observations'* with suggested actions for wider learning and improvement.

Our reports also identify actions required during an investigation to immediately improve patient safety. Organisations subject to our safety recommendations are requested to respond to us within 90 days. These responses are published on our **investigation pages**.

Find out more in the **investigations** section.

MATERNITY INVESTIGATIONS

From 1 April 2018, we became responsible for all patient safety investigations of maternity incidents occurring in the NHS which meet criteria for the **Each Baby Counts programme**.

The purpose of this programme is to achieve rapid learning and improvement in maternity services, and to identify common themes that offer opportunity for system-wide change. For these incidents HSIB's investigation replaces the local investigation, although the trust remains responsible for Duty of Candour and for referring the incident to us.

We work closely with parents and families, healthcare staff and organisations during an investigation. Our reports are provided directly to the families involved and to the trust. The trust is responsible for actioning any safety recommendations we make as a result of these investigations.

We have been operating in all trusts since 1 April 2019. Our longer-term aim is to make safety recommendations to national organisations for system-level improvements in maternity services. These will be based on common themes arising from our trust-level investigations.

Find out more in the **maternity investigations** section.

EXECUTIVE SUMMARY

The reference event

A midwife was working within a maternity triage area. She was the only midwife on duty and was scheduled to work a 12.5-hour shift from 07:45 hours to 20:15 hours. During the afternoon the Midwife collected two blood samples; a sample from Patient A and a sample from Patient B. Both blood samples included a request that the laboratory perform an urgent full blood count¹, liver function tests² and a test for C-reactive protein³.

Records show that the Midwife requested the blood samples for Patients A and B on the Trust's electronic system at 16:00 hours and 16:47 hours respectively. Both samples were collected by a porter and delivered to the Trust's laboratory for testing.

When laboratory staff received the samples they noted that both sets of blood samples had been labelled with Patient A's details, but one set had been sent with Patient B's blood test request form. A test of the blood samples confirmed that only one set of samples belonged to Patient A. Patient B's blood samples had been mislabelled with Patient A's details.

The national investigation

The Healthcare Safety Investigation Branch (HSIB) received a referral from an NHS trust that highlighted wrong blood in tube (WBIT) incidents that had occurred in the Trust's maternity unit.

WBIT incidents can occur when blood samples are taken from patients and are either miscollected (blood is taken from the wrong patient but labelled with the correct patient details) or mislabelled (blood is taken from the intended patient but labelled with the incorrect patient details) (Serious Hazards of Transfusion, 2018).

The Trust had 16 WBIT incidents in its maternity unit in 2017. In response to this the Trust had rolled out a comprehensive training package for staff. All staff had subsequently been retrained in blood sample collection. However, in 2018 the Trust had a further four WBIT incidents in the maternity unit.

HSIB commenced a scoping investigation. The scoping investigation focused on the most recent WBIT incident reported by the Trust. The investigation also evaluated information available to it on the other

reported WBIT incidents in 2018 and carried out observations in a range of clinical areas within the maternity unit.

The findings were considered against HSIB's investigation criteria, and a decision was made to progress to a national investigation.

The investigation utilised a safety science approach to consider staff perspectives on blood sampling and labelling practice. The HSIB investigation aimed to highlight a range of local and national factors that may contribute to WBIT incidents occurring in acute hospitals.

Findings

- *'Work as done'* (what actually happens in the workplace) in blood sampling and labelling practice by clinical staff within health services may vary from *'work as imagined'* by policy makers (assumptions about how it is done).
- Staff are required to adapt their practice in blood sampling and labelling to account for the individual environments and circumstances in which they work.
- There is a risk that current systems that use labels and handwriting on blood samples are open to error induced by work environments.
- Current evidence supports that electronic systems can reduce WBIT incidents and improve efficiencies in blood sampling and labelling practice.
- A lack of suitably qualified staff increases workload, fatigue and the range of distractions in carrying out blood sampling.
- Longer shift patterns may negatively impact on patient safety and make it more likely that WBIT incidents will occur.
- The design of work environments can contribute to staff fatigue and impact on staff's ability to follow end-to-end processes effectively.
- Training is only one of multiple strategies required to address WBIT incidents occurring.

¹ A blood test that can be used to evaluate overall health and detect a wide range of disorders.

² Blood tests that provide information about the health of a patient's liver.

³ A blood test that checks for inflammation in the body.

- Current incident investigations do not always address system-level factors influencing WBIT incidents or seek to understand why blood sampling usually goes right.
- Safety science and human factors methodologies can assist in understanding *'work as done'* and help to identify the necessary adaptations made by staff in local clinical environments.

Local learning for NHS trusts

The HSIB investigation identified local learning that may assist NHS trusts when considering how their own local blood sampling and labelling practices operate:

- Trusts can seek to understand *'work as done'* by staff and take a safety science approach when developing blood sampling and labelling policies.
- Trusts can aim to incorporate human factors thinking and awareness within incident reporting and investigation.
- Trusts should be aware of the increased risk of WBIT incidents occurring where there may be staff shortages and staff fatigue.
- Trusts can ensure that local policies and training on blood sampling account for the challenges posed by different working environments.
- Trusts can aim to understand the range of distractions staff face in different working environments and the compromises staff may have to make to deliver patient care.

- Trusts can optimise the availability, accessibility and usability of appropriate equipment used in blood sampling and labelling (for example: computer terminals, printers, bedside tables, sampling equipment, and that equipment is maintained).

HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATION

Recommendation 2019/46:

It is recommended that NHSX should take steps to ensure the adoption and ongoing use of electronic systems for identification, blood sample collection and labelling.

HSIB MAKES THE FOLLOWING SAFETY OBSERVATIONS

HSIB acknowledges the work of the Serious Hazards of Transfusion scheme in seeking to introduce and evaluate system-level considerations in transfusion incident reporting. Wider NHS incident reporting may benefit from a similar approach that encourages staff to identify and report system-level factors that influence clinical incidents.

NHS organisations may benefit from the input of suitably qualified and experienced human factors specialists in developing, evaluating and reviewing services in addition to the positive role identified for patient safety specialists as outlined in the NHS patient safety strategy.

CONTENTS

- 1 Background and context **9**
- 2 The reference event **12**
- 3 Involvement of the Healthcare Safety Investigation Branch **13**
- 4 Trust policy and local incident response **16**
- 5 Working environment **22**
- 6 Staffing and workload **26**
- 7 Technology solutions **30**
- 8 Adopting a safety science approach to blood sampling and labelling incidents **32**
- 9 Summary of findings, safety recommendation and safety observations **34**
- 10 References **36**

1 BACKGROUND AND CONTEXT

1.1 Blood sampling and testing

1.1.1 Blood sampling is used to collect blood for medical testing. Blood tests are one of the most common types of medical test carried out by the NHS. Blood tests take place in many clinical environments across the NHS, from primary care (for example, GP practices) through to acute hospital care.

1.1.2 Blood samples can be used to carry out a range of tests, including:

- assessing a patient's general health
- assessing for infections
- assessing how certain organs are working
- screening for genetic conditions
- doing the necessary tests before a blood transfusion
- checking the blood group of patients and screening for health conditions during pregnancy.

1.1.3 For the purposes of the Healthcare Safety Investigation Branch (HSIB) investigation it was considered that blood samples fell into two broad categories; transfusion-related blood samples and other blood samples.

1.2 Collection of blood samples

1.2.1 Significant focus has been placed on blood sampling processes for blood transfusion due to the potential for severe harm or death if a patient receives an incompatible blood transfusion. The majority of studies identified by the investigation have focused on transfusion-related blood sampling incidents.

1.2.2 The British Committee for Standards in Haematology guidance (Robinson et al, 2018) states that:

- All patients having a blood sample taken must be positively identified.

- The collection of the blood sample from the patient and the subsequent completion of details on the blood sample tube must be performed as one continuous, uninterrupted event at the patient's (bed)side involving one patient and one trained, competent and locally designated member of staff.

- Sample tubes must be labelled by hand at the patient's (bed)side by the individual who took the blood sample, the exception being labels printed '*on demand*' next to the patient attached to the sample tube immediately at the time blood is taken by the individual who took the blood sample.

- The minimum sample tube information requirements are as follows:

- patient core identifiers (first name, last name, date of birth and unique identification number)
- the date and time that the blood sample was taken
- the identification of the member of staff who took the blood sample.

- Laboratories should have a policy on the acceptance and rejection of blood samples and request forms, which includes acceptable labelling and actions to be taken if minimum requirements are not met.

1.2.3 This guidance only relates to transfusion samples and there is no requirement to follow it when blood samples are taken for any other purpose. Blood samples that are not transfusion-related may be labelled according to local policy and may be labelled with pre-printed labels containing the patient's information.

1.2.4 Further British Committee for Standards in Haematology guidance (2012) states that a second group-check sample should be collected from any patient who has not been grouped before and should be collected at a different time by a different person. This is to try to ensure that the result of the group-check sample could be compared with the result of a historic sample to identify any wrong blood in tube (WBIT) incidents. A second group-check sample is not required where secure electronic patient identification systems are in place.

1.2.5 This guidance only relates to transfusion samples requiring a second group-check sample and there is no requirement to follow it when blood samples are taken for any other purpose.

1.3 The Serious Hazards of Transfusion scheme

1.3.1 The Serious Hazards of Transfusion (SHOT) scheme is the UK's independent, professionally led haemovigilance⁴ scheme.

Its mission is to improve patient safety in blood transfusion. It conducts confidential enquiries into the serious hazards of transfusion and provides an annual analysis and summary of national data associated with blood transfusion incidents.

⁴ Haemovigilance is the set of surveillance procedures covering the entire blood transfusion chain, from the donation and processing of blood and its components, through to their provision and transfusion to patients, and including follow-up.





2 THE REFERENCE EVENT

- 2.1 A midwife was working within a maternity triage area. She was the only midwife on duty and was scheduled to work a 12.5-hour shift from 07:45 hours to 20:15 hours. During the afternoon the Midwife collected two blood samples; a sample from Patient A and a sample from Patient B. Both blood samples included a request that the laboratory perform an urgent full blood count, liver function tests and a test for C-reactive protein.
- 2.2 Records show that the Midwife requested the blood samples for Patients A and B on the Trust's electronic system at 16:00 hours and 16:47 hours respectively. Both samples were collected by a porter and delivered to the Trust's laboratory for testing.
- 2.3 When laboratory staff received the samples they noted that both sets of blood samples had been labelled with Patient A's details, but one set had been sent with Patient B's blood test request form. A test of the blood samples confirmed that only one set of samples belonged to Patient A. Patient B's blood samples had been mislabelled with Patient A's details.



3 INVOLVEMENT OF THE HEALTHCARE SAFETY INVESTIGATION BRANCH

3.1 Notification of the reference event

3.1.1 The Healthcare Safety Investigation Branch (HSIB) was made aware of a safety issue relating to the risk of wrong blood in tube (WBIT) incidents occurring during blood sampling.

3.2 Decision to investigate

3.2.1 Following a scoping investigation, HSIB's Chief Investigator authorised a national investigation. This was because the incident met HSIB's criteria:

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

3.2.2 WBIT incidents can lead to significant physical harm and death. Receiving incorrect test results can also lead to psychological harm for patients. Even where the impact for a patient is limited to the need for a repeat blood sample, this can cause distress and frustration. In addition, substantial efforts are required to resolve such incidents and avoid delays in patient care.

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

3.2.3 Blood sampling takes place in a range of healthcare environments across the NHS. The investigation could not identify any national data to identify the total number of blood samples collected by the NHS.

3.2.4 Incident data collected by the Serious Hazards of Transfusion (SHOT) scheme showed that there were 792 transfusion WBIT incidents reported in 2018 (Serious Hazards of Transfusion, 2019). Public Health England figures that were made available to the investigation also showed that WBIT

incidents accounted for 3% (10) of all incidents reported under its antenatal blood screening programmes in 2018/2019. Studies have suggested that WBIT incidents are underreported (Varey et al, 2013).

3.2.5 Subject matter advisers assisting the investigation estimate that there will be in the region of 100 to 1,000 times more non-transfusion blood samples taken than transfusion blood samples.

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

3.2.6 WBIT incidents are still frequent in the NHS despite a recognition of the risk. Attempts at reducing the risk of these incidents occurring have focused on the development of policies and staff training. An HSIB investigation can provide a whole-system viewpoint to identify broader factors that limit the effectiveness of policies and training in addressing WBIT incidents.

3.3 Evidence gathering and methodology

3.3.1 Bolton-Maggs et al. (2015) found that transfusion WBIT incidents can be seen to occur between one in every 1,986 and one in every 3,448 blood samples collected. This data suggests that the majority of blood samples are collected safely and do not lead to a WBIT incident.

3.3.2 The investigation considered the field of safety science to understand how staff work within the clinical environment and the factors that impact on them when taking blood samples. It considered the challenges faced by staff and how they must use their knowledge, skills and experience to adapt their work to the challenges posed by the system in which they operate. These adaptations could lead to WBIT incidents occurring, but most of the time allowed staff to operate safely and efficiently when collecting blood samples.

3.3.3 Safety scientists currently recognise two approaches relevant to understanding system safety: Safety-I and Safety-II.

Safety-I focuses on the adverse outcome. It seeks to retrospectively identify the causes of incidents with a view to removing factors seen to cause a specific adverse outcome. Safety-II considers how everyday performance is adapted to respond to varying conditions and how these adaptations represent not only opportunities for things to go wrong, but also how these ensure things usually go right (Hollnagel et al, 2015).

- 3.3.4 Safety II is not focused on exceptional practice but seeks to understand how normal or routine performance, which accounts for the majority of clinical interactions, usually results in a safe outcome. This is demonstrated by Figure 1 (Eurocontrol, 2013) which shows how the majority of activity falls within normal, routine performance.
- 3.3.5 Safety-II does not replace the more traditional Safety-I approach and both operate to consider how safety can be improved within the healthcare system. However, there are differences in focus and application between the two approaches.

3.3.6 NHS investigations have traditionally adopted a Safety-I approach to try to identify what may have gone wrong to have led to WBIT incidents occurring. The HSIB investigation instead considered how blood sampling typically takes place within the complex clinical environment of the maternity unit.

- 3.3.7 The investigation considered the challenges faced by staff and how staff must use their knowledge, skills and experience to adapt their work to the challenges posed by the system in which they operate.
- 3.3.8 In order to gain an insight into how best to explore the way staff work in the clinical environment it is important to understand the varieties of human work. Figure 2 shows the varieties of human work described by Shorrock (2016). These show why the healthcare sector needs to adopt different approaches to fully understand healthcare work and incidents.
- 3.3.9 *'Work as imagined'* refers to assumptions that may be made about how work is carried out by staff. However, people making these

FIG 1 SAFETY-II DIAGRAM

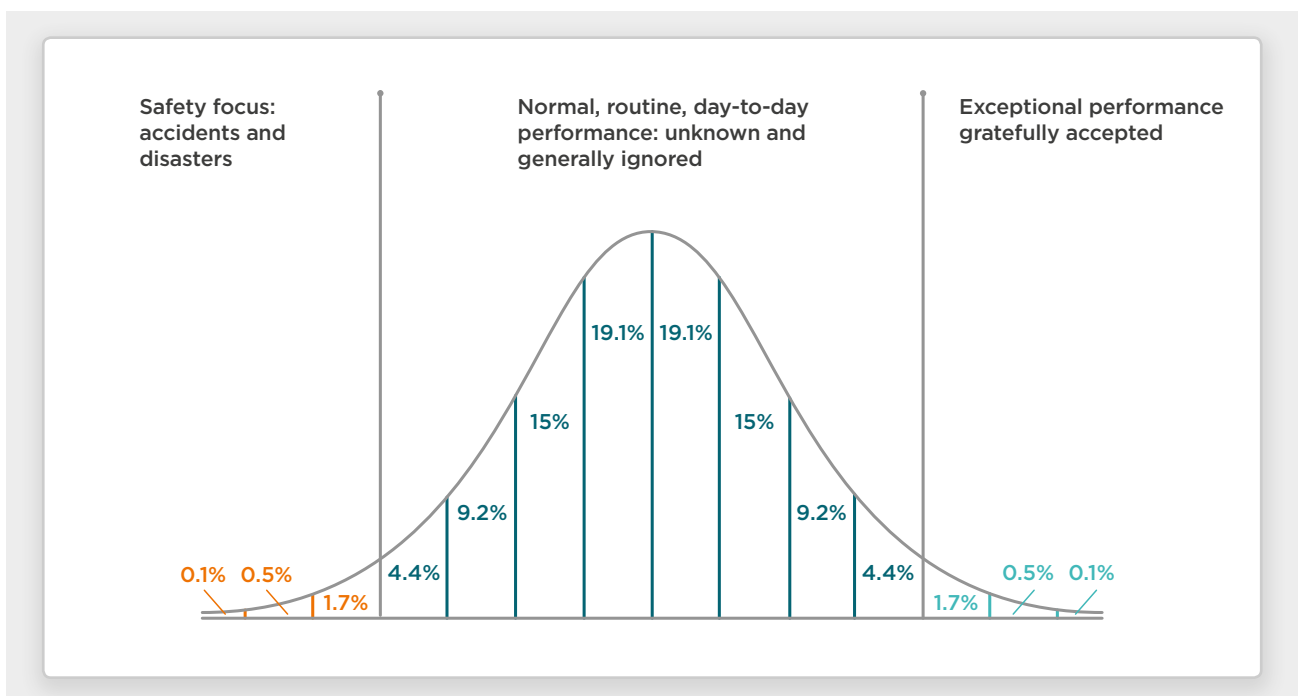


FIG 2 THE VARIETIES OF HUMAN WORK



assumptions may be removed in time and space from the *'front line'* and therefore unable to observe work being carried out in the workplace (Hollnagel et al, 2015).

3.3.10 The imagined way in which people work becomes *'work as prescribed'* when it is set out in policy or processes that frontline staff are asked to follow and adhere to. This is often assumed to be the safest way to work (Shorrock, 2016).

3.3.11 Many traditional incident investigations will place emphasis on taking statements from staff in order to understand their actions. This *'work as disclosed'* may be based on partial or incomplete versions of one or more of the other varieties of human work. Staff may be uncomfortable about, or fearful of, disclosing variations and adaptations made to *'work as prescribed'* if they are worried about the possible repercussions of their actions. Staff may also fail to recognise where adaptations have been made as part of their daily practice.

3.3.12 *'Work as done'* refers to how people actually carry out their work. Understanding *'work as done'* requires a practical focus on understanding and observing work in the environment in which it takes place in order to inform ideas about how work should be planned and managed. Catchpole and Jeffcott (2017) have identified that direct observation of staff within healthcare

usually reveals a difference between what is disclosed and how work is actually done in practice. Without understanding *'work as done'* it is not possible to accurately know how a system is functioning and whether the gap between *'work as imagined'* and *'work as done'* poses a threat to organisational safety or represents the system drifting into an improved state (Shorrock, 2018).

3.3.13 Healthcare is a complex system in which staff are required to adapt and respond to the changing circumstances they are faced with (Woodward, 2019). The ability to make adaptations is understood to be an essential part of work within a complex system. Safety science aims to understand how organisations may be able to utilise adaptive and flexible work processes to deliver safe care (Macrae and Draycott, 2019).

3.3.14 The investigation used the Systems Engineering Initiative for Patient Safety (SEIPS) model (Carayon et al, 2006) to collect and analyse evidence gathered during the reference event site visit. The investigation also took into account academic studies (Pickup et al, 2017; Victorian Managed and Insurance Authority, 2010) into WBIT incidents that used Functional Resonance Analysis Method (FRAM) modelling (Hollnagel, 2012) and Failure Mode and Effect Analysis (FMEA) modelling (Institute for Healthcare Improvement, 2017).

4 TRUST POLICY AND LOCAL INCIDENT RESPONSE

4.1 Trust policy

4.1.1 The policy at the Trust where the reference event occurred described a five-step process for taking blood samples. This was reflected in the Trust blood sampling training package (Figure 3).

4.1.2 The five steps were as follows:

- 1 Complete a blood sample request form on the electronic system and collect the form from the printer.
- 2 Take the printed blood test request form to the patient's bedside and confirm the patient's identity by cross-checking the patient's name band, details on the blood test request form and asking the patient to confirm their identity through the use of open questions.

The printed blood test request form contained the patient's details. Patients were also given an identification wrist band on admission that contained key identification details. Staff were told to ask open questions in order to check that the information contained on the blood test request form and identity band were accurate.

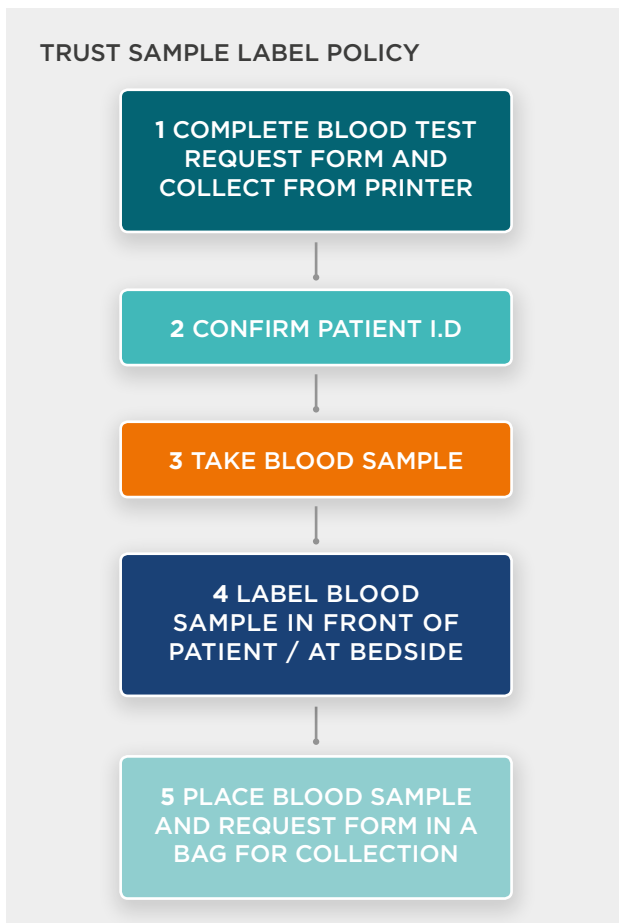
3 Take the blood sample from the patient.

4 Label the blood sample at the patient's bedside. Depending on the type of blood test taken, staff had two options for labelling a blood sample.

For transfusion blood samples, national guidance (British Committee for Standards in Haematology, 2009) required patient details to be handwritten on the blood sample tube. For other blood samples, staff could use pre-printed identification labels from the patient's medical records that were then attached to the blood sample tubes. The details on these labels were to be checked at the bedside against the patient's identification.

5 Place the blood sample and the blood test request form in a sample bag for delivery to the laboratory by the porter service.

FIG 3 THE TRUST'S BLOOD SAMPLING PROCESS

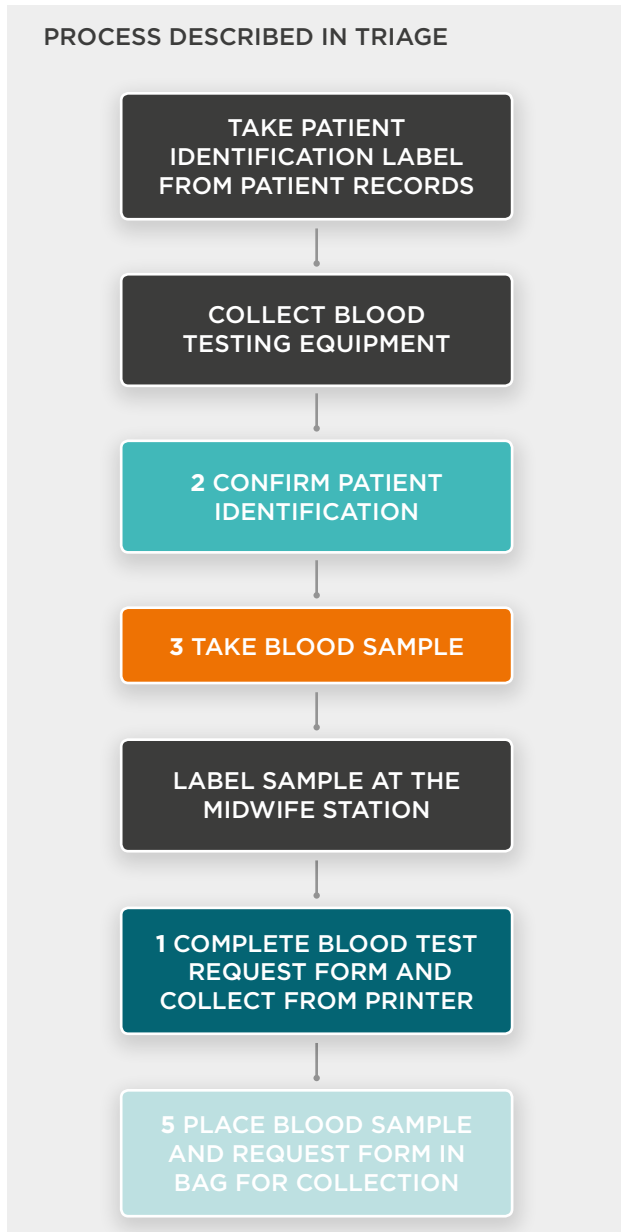


4.1.3 The Trust explained that the process had been agreed by senior members of staff to reflect best practice in blood sampling. Comments made by senior staff indicated that the Trust felt that the blood sampling process was "very clear" and offered a failsafe process against wrong blood in tube (WBIT) incidents occurring. Where errors had occurred, senior staff informed the investigation that this was indicative of staff not following the process; there was "nothing wrong with the system" and it was instead thought that "human error" may be "leading the system to fail".

4.1.4 The investigation carried out interviews with the Midwife and other staff who worked in the maternity triage area. Investigators observed blood sampling taking place and staff were also asked to walk investigators through the blood sampling process.

4.1.5 The investigation identified omissions in the Trust's blood sampling policy and variations in staff's adherence to the policy in the maternity triage area (Figure 4). None of the variations observed in practice by the investigation resulted in mislabelled or miscollected blood samples.

FIG 4 AN OBSERVED BLOOD SAMPLING PROCESS IN MATERNITY TRIAGE

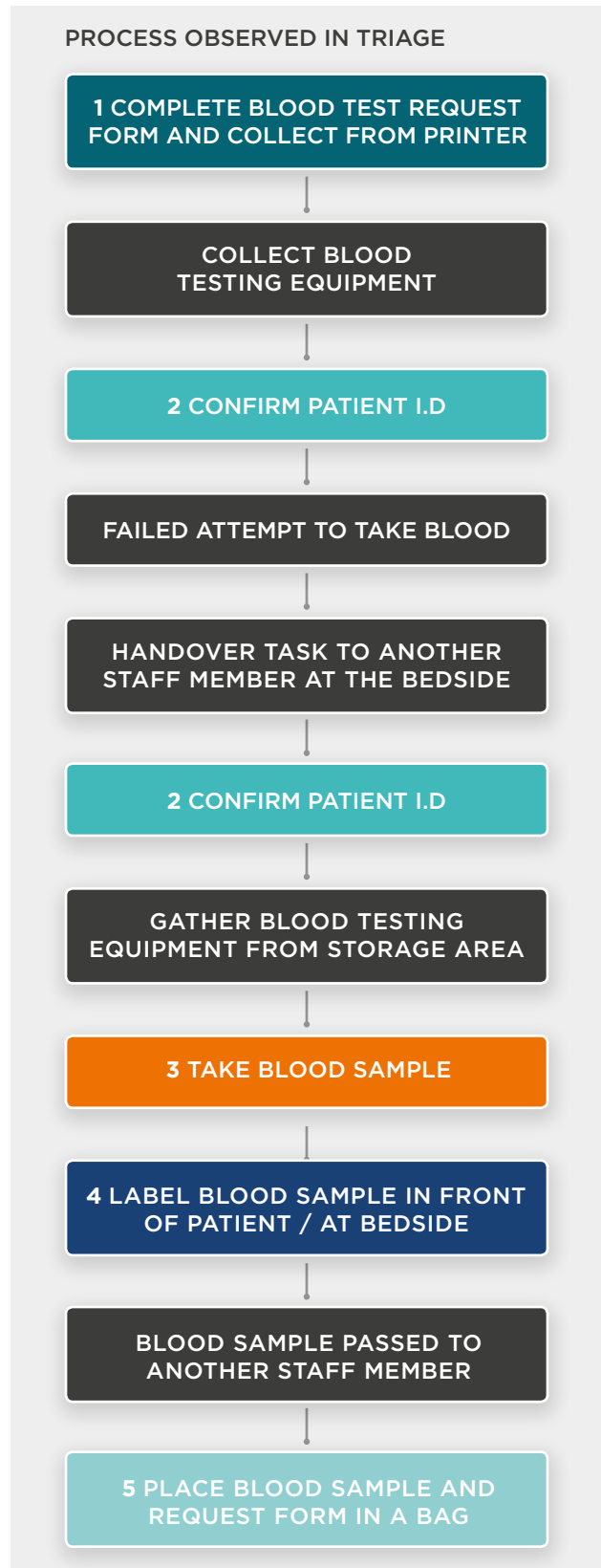


4.1.6 The policy did not describe all the steps taken to complete a blood sample and did not accurately reflect the complexity of the task. For example, the policy did not direct staff to consider at what point they needed to collect the relevant blood sampling equipment from storage areas before the blood sampling process could begin. These steps form an integral part of the blood sampling process and the way staff carried them out varied depending on personal practice and the environment in which they worked.

4.1.7 There was also variation in the order in which the steps identified in the blood sampling policy were followed. The investigation found that the process followed by staff varied depending on personal experience, environmental conditions and the status of the patient. For example, the

investigation observed the following process in maternity triage when staff were having difficulty obtaining a blood sample from a patient in early labour (Figure 5).

FIG 5 AN OBSERVED BLOOD SAMPLING PROCESS IN MATERNITY TRIAGE WHERE THERE WERE DIFFICULTIES IN TAKING A BLOOD SAMPLE

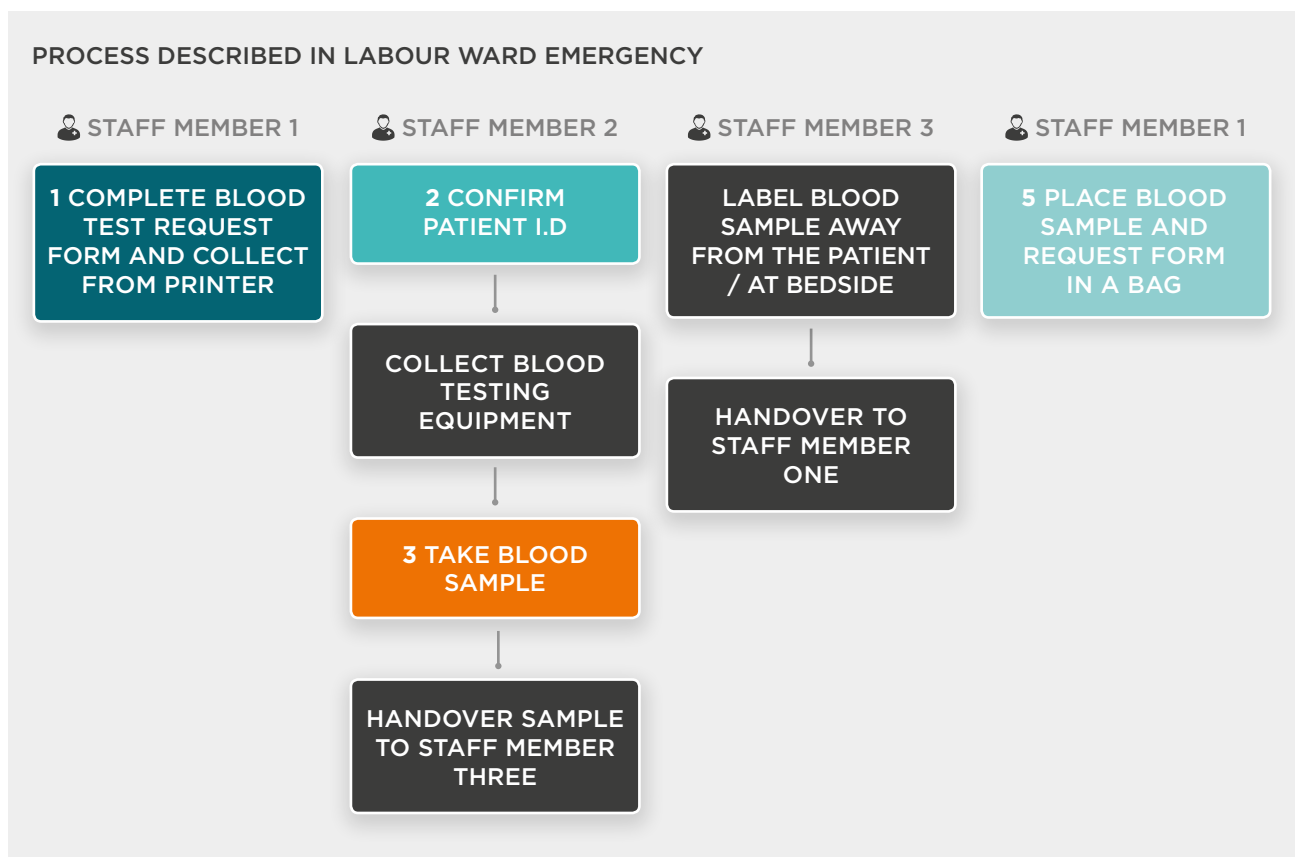


- 4.1.8 Similar variations were observed by the investigation and described by staff in each clinical area. Staff adapted their practice to the realities and challenges facing them due to the physical environment in which they operated and the healthcare needs of their patients.
- 4.1.9 For example, the process in the labour ward differed significantly from the policy because of the scenario in which blood samples would normally be required on that unit (Figure 6).
- 4.1.10 Staff explained that blood samples would be taken in an emergency when a woman was experiencing heavy bleeding. For example, a post-partum haemorrhage (bleeding after giving birth) can result in rapid and significant blood loss and remains a major direct cause of maternal death worldwide (Mavrides et al, 2016).
- 4.1.11 In such a scenario, the clinical environment (the labour suite) would be crowded with a number of staff. Staff told the investigation

that it was not practical for a single practitioner to complete the end-to-end blood sampling process in line with the Trust policy. This was explained as a necessity to expedite the completion of the blood testing process in case a blood transfusion was required.

- 4.1.12 In that scenario, there may be separate clinicians taking, labelling and ordering the blood; a blood sample may be passed to a more junior member of staff to label whilst a senior staff member continued to treat the patient. Another staff member would routinely need to be outside the labour suite ordering the blood test on the computer system, which was located at the midwife station. There would then be a handover of the blood sample from the labour suite to the staff member ordering the blood test. Similar haemorrhage emergencies may also occur in other clinical environments and scenarios, such as intensive care units or during surgery.

FIG 6 AN EXAMPLE BLOOD SAMPLING PROCESS IN A LABOUR WARD EMERGENCY



4.1.13 The range of clinical environments seen within the maternity service at the Trust reflect the broad range of clinical environments in which blood samples are collected within the NHS. Significant variation may exist in blood sampling practice within individual NHS trusts and across the NHS in England as staff adapt their practice to the needs and demands of the physical environment and clinical context in which they work.

4.2 Incident reporting and investigation

4.2.1 Although the blood samples collected in triage by the Midwife were not transfusion samples, the Trust made use of incident reporting guidance available from Serious Hazards of Transfusion (SHOT) when considering the reference incident.

4.2.2 Since January 2016, SHOT has added prompts in its incident reporting to encourage staff who report an incident to be aware of wider issues that may be relevant when WBIT incidents occur. Incident reporters are asked to rate the following questions from one to 10 to indicate the contribution of each of the following factors in a WBIT incident occurrence, with a free text box available for further comment:

- unsafe practice by individual staff member(s)
- unsafe conditions associated with the local environment or workspace
- unsafe conditions associated with organisational or management issues in the trust/health board (for example, staffing levels)
- conditions associated with the government, Department of Health and Social Care or high-level regulatory issues.

4.2.3 The incident reporting form is designed to assist staff in considering any obvious system-wide issues apparent at the point of incident reporting. It also aims to help staff to become aware of the broader factors that may contribute to an incident occurring.

4.2.4 The Trust completed a local incident reporting form that had been developed using the prompts in the online SHOT incident reporting system (Figure 7).

4.2.5 The form helped the Trust to identify some broader factors that may have contributed to the WBIT incident occurring (for example, staffing levels and the lack of bedside tables). However, the scoring used identified that *'unsafe practice'* by the Midwife was the main cause of the WBIT incident.

FIG 7 TRUST WBIT INCIDENT REPORT

<p>1 To what extent is the cause of this incident attributable to unsafe practice by an individual staff member?</p> <p>1...2...3...4...5...6...7...8...9...10</p> <p><i>The midwife is unable to recall exactly what happened but believes it is likely she wrote / affixed the addressograph to the blood bottle at the desk in triage rather than at the bedside of the woman!</i></p>	<p>3 To what extent is the cause of this incident attributable to organisational or management issues in the department e.g. staffing levels?</p> <p>1...2...3...4...5...6...7...8...9...10</p> <p><i>At times of high activity it is recommended that there are two midwives working in triage. This was not so on this occasion. On reflection the midwife would escalate for help in future.</i></p>
<p>2 To what extent is the cause of this incident attributable to unsafe conditions associated with the local environment in the workplace?</p> <p>1...2...3...4...5...6...7...8...9...10</p> <p><i>There is no obvious hard surface / bedside table to facilitate documentation with ease at the bedside in triage.</i></p>	<p>4 To what extent is the cause of this incident attributable to Government, Department of Health and Social Care, or high levels of regulatory issues (i.e. the error was caused by regulatory issues not reportable as regulatory failure)?</p> <p>1...2...3...4...5...6...7...8...9...10</p>

- 4.2.6 This is in line with national data SHOT has collected regarding the reporting of all transfusion errors (Serious Hazards of Transfusion, 2018). The incident reporting system was first introduced by SHOT in 2016 (Serious Hazards of Transfusion, 2017). At that point, 62.6% of incidents attributed scores to individual staff factors.
- 4.2.7 SHOT identified that this may reflect a lack of awareness of system level factors among incident reporters. In response, in January 2017 SHOT introduced a self-learning package for incident reporters showing example scorings for human and organisational factors.
- 4.2.8 SHOT (Serious Hazards of Transfusion, 2019) reported that following the introduction of the training package the number of incidents where scores were attributed to individual staff factors fell from 62.6% in 2016 to 55.8% in 2018. There was also strong evidence to suggest that incident reporters increasingly attributed environmental, organisational and regulatory factors as contributing to an incident occurring.
- 4.2.9 The investigation received comments that human factors considerations identified at the point of incident reporting may not be robust. Without the completion of an investigation it may be possible for factors to be incorrectly identified.
- 4.2.10 SHOT identifies that the training package is aimed at increasing staff awareness of wider system factors at the time of reporting. SHOT acknowledges that scoring may be subjective or based on the available information at the time.
- 4.2.11 The Healthcare Safety Investigation Branch (HSIB) has previously made a safety observation in the report, Implantation of wrong prostheses, during joint replacement surgery (Healthcare Safety Investigation Branch, 2018) reflecting that the current NHS national reporting system does not require the inclusion of data on human factors. Studies have also demonstrated that human factors considerations are not routinely included in NHS incident reporting data (Pickup et al, 2017).
- 4.2.12 Further efforts to prompt staff to consider system-level issues at the time of reporting and the recording of human factors considerations on the completion of incident investigations would be beneficial.

HSIB MAKES THE FOLLOWING SAFETY OBSERVATION

HSIB acknowledges the work of the Serious Hazards of Transfusion scheme in seeking to introduce and evaluate system-level considerations in transfusion incident reporting. Wider NHS incident reporting may benefit from a similar approach that encourages staff to identify and report system-level factors that influence clinical incidents.

4.3 Training

- 4.3.1 In response to the WBIT incident, the Midwife had been asked to undergo further training on the Trust's blood sampling policy. Following WBIT incidents in 2017, the Trust had rolled out regular training to maternity services staff on blood sampling processes. The training reinforced the Trust blood sample policy and sought to raise staff awareness of the potential impact of WBIT incidents. The Trust identified that the training programme had reduced the Trust's WBIT rate by 75% and cited the decreased WBIT rate as evidence of the effectiveness of the blood sampling policy when used correctly. However, the Trust acknowledged that blood sampling processes had not been audited in practice for some time to confirm whether '*work as done*' corresponded to the training being provided.
- 4.3.2 The Midwife had received training on the Trust's blood sampling policy prior to the WBIT incident. Other WBIT incidents had also occurred in the trained staff group since training took place. This was in line with SHOT data that suggests that nationally, the majority of staff members reported to have been involved in a WBIT incident have received training and competency assessment (Bolton-Maggs et al, 2015).
- 4.3.3 A systematic review (Cottrell et al, 2013) of interventions to prevent WBIT incidents showed that a range of interventions were seen to be effective in reducing WBIT incidents in the short term. This included additional staff training, as put in place by the Trust. However, the study identified a lack of research that considered how effective an intervention was in the long-term and which interventions may be seen to be most effective. Although training is part of a solution to prevent WBIT incidents, training alone is not considered to be an effective option.



5 WORKING ENVIRONMENT

5.1 Physical environment

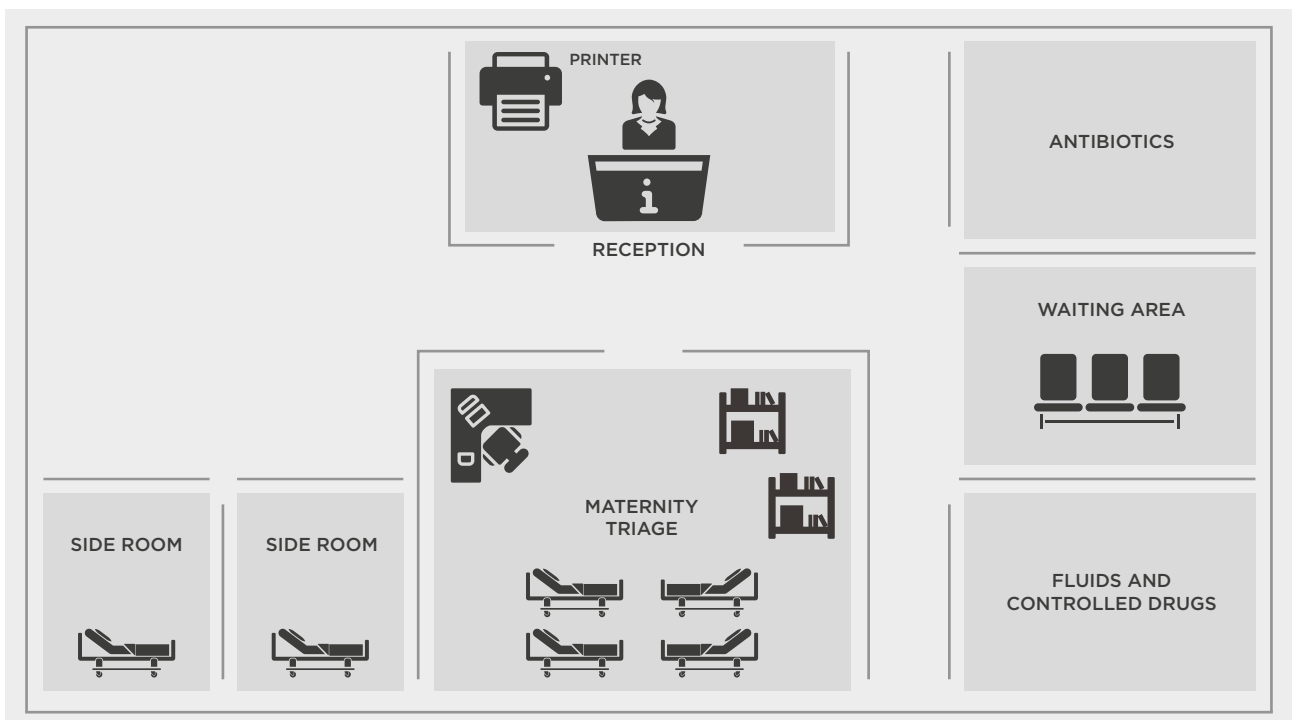
- 5.1.1 The investigation considered how the physical layout of the maternity triage area accommodated the working practices of the Midwife (Figure 8).
- 5.1.2 The maternity triage area consisted of a four-bedded bay with a midwife station. Blood sampling equipment was available from a storage cabinet in the triage bay. In addition to the four beds located in the triage bay, there were also two side rooms available for patients for use if triage was full or for patients with specific needs. Drugs, fluids and antibiotics were not stored in the triage area. These were located in separate store rooms in other areas of the maternity unit.
- 5.1.3 A triage reception and waiting area was also located near to the triage bay. The investigation noted that staff regularly left triage to check on the waiting area and speak with patients. Behind the reception area there was an administration office where the

printer for triage was located. This is where staff had to go to collect printed blood test request forms.

5.2 Access to IT

- 5.2.1 The Midwife explained that her practice in triage was often to print a blood test request form after collecting a blood sample. This was a departure from the Trust's blood sampling process. Staff explained that their ability to follow the blood sampling process may *"depend on whether there was access to the computer"*. Where a blood test was requested by a staff member, staff told the investigation that if the computer could not be accessed, they may begin the blood sampling process without completing the request form.
- 5.2.2 The Trust used an electronic system on which staff were expected to request blood tests. To do so, staff had to log in to a computer, complete a blood test request form online and then print a copy of the request form. The Trust's blood sampling process required staff to print the request form prior to a blood sample being taken, with the intention that the form would be taken to the bedside

FIG 8 LAYOUT OF THE MATERNITY TRIAGE AREA



and used as another reference point for checking patient identification. The form would then accompany the blood sample to the laboratory.

- 5.2.3 The triage area had a single computer located at the midwife station. This was used by the midwife in triage and any medical staff attending to patients. Staff highlighted some further challenges posed by having only one computer in triage. A midwife commented that it was possible to open a patient record with the intention of completing a blood test request. However, if staff became distracted or taken away from the computer it was possible for another staff member to open another patient record. When the midwife returned to the computer to request the blood sample it was possible that they could be working in another patient's record in error.
- 5.2.4 Staff also explained that the need to leave triage to collect print-outs could pose a problem if they were dealing with urgent matters. Staff reported that they would often begin the process of ordering a blood sample based on conversations with clinicians in the triage area whilst they were caring for a patient or where there was an obvious clinical need. In such cases, staff were focused on

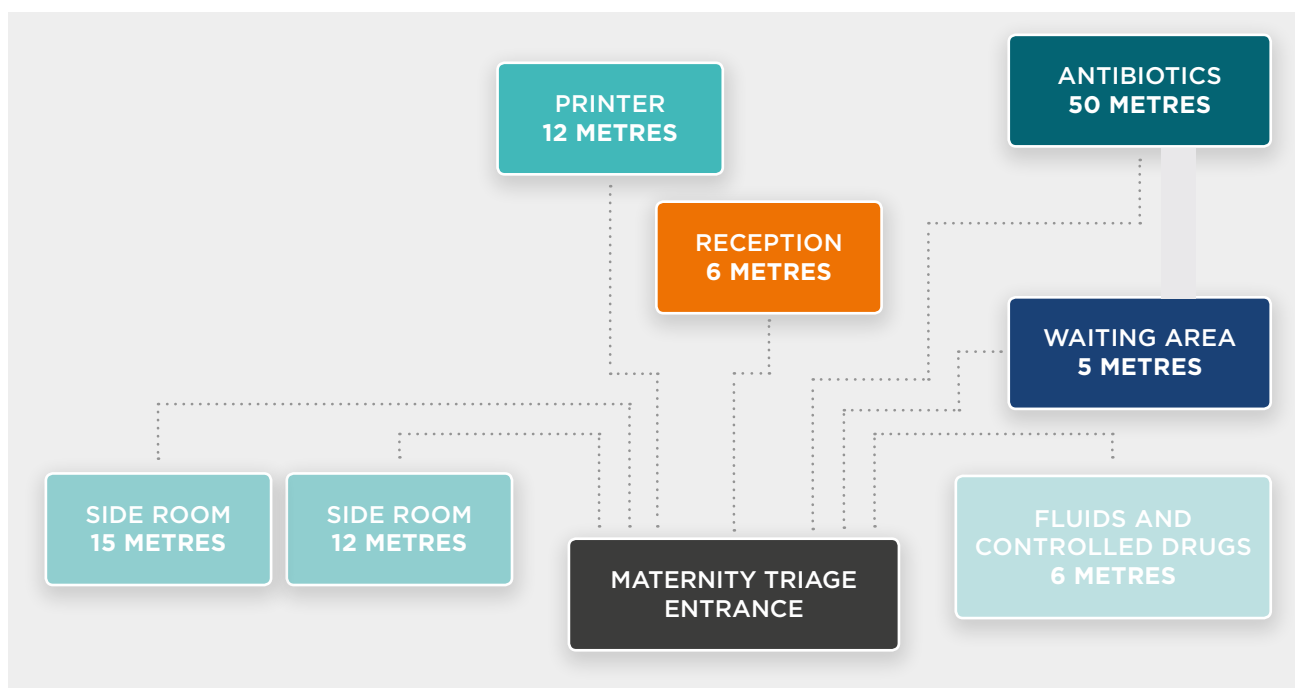
providing care in the triage area and were reluctant to leave to collect a print-out from another area.

- 5.2.5 Some staff told the investigation that to adapt to the need to leave triage to collect blood test request forms, more than one blood test request form could be printed at once in order to avoid separate trips to the printer. Where this occurred there was a risk that the wrong blood test request form could be collected from the printer and confused with another patient's request form.

5.3 Layout of the working environment

- 5.3.1 The Midwife had taken to wearing a pedometer; this showed that she would routinely walk up to 12 kilometres during the course of a 12-hour shift in triage.
- 5.3.2 The investigation mapped out the distances between the areas in the maternity unit that the midwife was required to visit in order to complete her tasks (Figure 9).
- 5.3.3 The investigation observed that there were a variety of reasons why staff were required to travel these distances to complete tasks. The Trust explained to the investigation that

FIG 9 DISTANCES BETWEEN AREAS WITHIN MATERNITY TRIAGE



guidance on lockable medication cabinets (Royal Pharmaceutical Society of Great Britain, 2005) meant that it had not been possible for a lockable cabinet to be located in the triage area in which to store fluids and medications. The printer for triage was also located away from the triage area because of space limitations at the midwife station in triage.

5.3.4 Studies have considered the distance travelled by staff in order to complete tasks, and the time this takes, within other clinical environments (Freihoefer et al, 2019). This approach can offer a valuable insight into how an environment is designed to assist staff to perform tasks. It also allows the time taken to travel to complete tasks, and the distance travelled, to be accounted for and considered in order to make processes more efficient and help reduce staff fatigue. Working environments may be designed to function with full staffing capacity and may not be efficient when not fully staffed.

5.4 Labelling blood samples at the bedside

5.4.1 SHOT data and academic papers (Bolton-Maggs et al, 2015) highlight that a large proportion of near-miss WBIT incidents for transfusion occur when labelling of the blood sample tube is not completed at the bedside.

5.4.2 The Midwife told the investigation that *“for all the goodness of saying you’ve got to do it at the bedside...I hold my hands up and say I can’t always do that, I really can’t”*. This was reinforced by other staff who told the investigation that *“we’re supposed to do blood at the bedside, but this is difficult with the environment that we’re working in”*. The investigation observed and heard from staff about environmental factors that limited staff’s ability to label blood samples at the bedside.

5.4.3 In the reference incident, the Midwife had attached an incorrect identification label to Patient B’s blood sample. The investigation observed that some staff would take these labels to the bedside when completing blood sampling. However, other staff explained, and the investigation observed, that they would return from the bedside with the blood sample before collecting the label from the patient record.

5.4.4 In triage there was no facility for patient records to be stored at the bedside; instead they were stored at the midwife station. These records contained the patient identification labels that could be used to label non-transfusion blood samples. These labels were contained within the patient medical records and formed a printed sheet of adhesive labels.

5.4.5 The investigation observed that the availability of patient records could have an impact on the process of attaching labels. If a patient’s records were in use by another clinician or could not be located at the time a blood sample was taken, then staff were unable to take the labels from the records to the bedside.

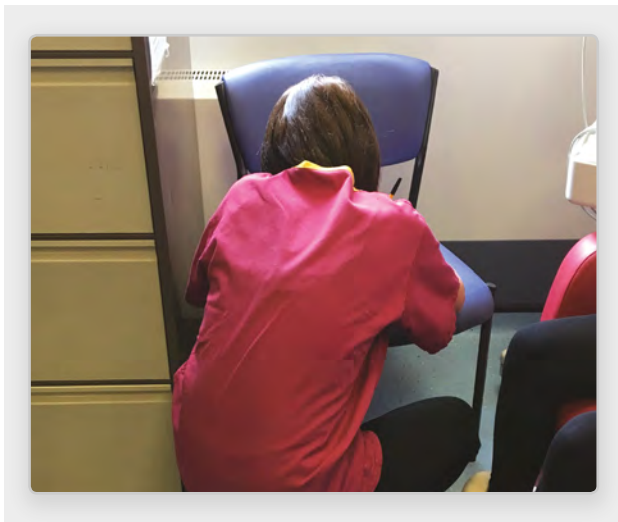
5.4.6 Where labels were affixed at the maternity station, staff acknowledged that there was a risk that an incorrect label could be placed on a blood sample. The station often had a range of medical records open and available and there was a risk of confusion about which label was to be selected.

5.4.7 Staff reported that there were also errors that could occur before the records became available to maternity staff that could lead to incorrect labels being printed or incorrect labels being filed in medical records. A staff member told the investigation about a fault with one of the printers that led to old printing requests being printed in error instead of the labels that had been requested by staff.

5.4.8 There were also no bedside tables or portable trolleys available in the triage area. Staff explained that this could make it difficult for staff to label blood tests or write on blood test tubes as there was nowhere for them to help steady their hands when writing.

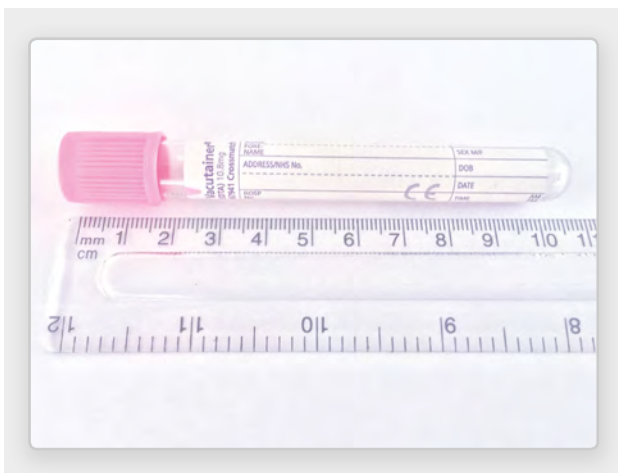
5.4.9 The Midwife explained that in order to ensure that the blood sample could be labelled accurately, her routine practice was to return to the midwife station with the blood sample before labelling it. The investigation observed staff labelling blood samples at the midwife station in areas of maternity, as well as improvising other ways to ensure a steady surface, including crouching to use the seat of a chair (Figure 10) and using a window ledge.

FIG 10 EXAMPLE OF A STAFF MEMBER USING A CHAIR AS A WRITING SURFACE



5.4.10 Staff explained their concerns about accurately labelling blood samples, particularly transfusion samples as these needed to be handwritten. The blood sample tube is cylindrical and staff told the investigation that it could be difficult to write on (Figure 11).

FIG 11 EXAMPLE OF A BLOOD SAMPLE TUBE AND LABEL



5.4.11 Staff explained that they could only use certain types of pen to write on the label as otherwise the writing could smudge. If any smudging or other errors were noted on the label, the sample would be rejected by the laboratory and another blood sample would need to be taken from the patient.

5.4.12 Staff informed the investigation that for patients with longer names, it was difficult to write full patient details on the tubes. Rejected samples created inefficiencies within the system as additional time, cost and resource was required to re-sample and re-test patients. Staff were also anxious to avoid errors wherever possible in order to avoid the additional distress caused to patients by the need to take further blood samples.

5.4.13 The investigation observed that this issue had an impact on the relationship between maternity and laboratory staff. Maternity staff told the investigation that they could become frustrated when samples were rejected. Laboratory staff were clear that rejecting samples with illegible or incorrect labels was necessary to ensure the accuracy of the blood samples being processed and to avoid patient harm. This is supported by academic studies suggesting that blood samples with typographical errors have an increased risk of causing WBIT incidents (Kaufman et al, 2019).

5.4.14 Staff perceived the laboratory as a safety net that was capable of capturing any errors in blood sampling that may occur. However, while this may be possible for transfusion blood samples (where a second blood sample should be available for cross-referencing) such errors may be unlikely to be captured in non-transfusion blood sampling.

5.4.15 The investigation observed a range of environments within the maternity service, each with different environmental conditions that impacted on staff's ability to label samples at the bedside or with a patient present in the clinic room. This reflects the wide range of environments in which blood samples are taken across the NHS.

6 STAFFING AND WORKLOAD

6.1 Triage workload

6.1.1 Staff described triage as an area with varying levels of activity where “*you don't know what is going to come through the door*”. Staff told the investigation that the environment could be “*chaotic*” and that there were a several factors that could add to fatigue and lead to staff becoming distracted from tasks.

6.1.2 The Midwife estimated that during a normal shift in triage she would expect to care for up to 30 patients. Most of these patients would require blood samples to be taken in triage so that appropriate blood testing could take place.

6.1.3 On the day of the reference event, data from the Trust showed that 24 women presented to triage during the Midwife's shift. However, 10 of these patients arrived between 12:45 hours and 16:45 hours. This included one patient who was identified as having more complex needs and requiring additional support.

6.1.4 Staff described this as being a relatively high number of patients given the range of duties the Midwife would need to perform. At around the time of the incident, the Midwife recalled that she was caring for six patients; four patients in the triage bay and two patients in side rooms.

6.1.5 A Trust policy set out a range of duties required of a midwife in the triage area. Midwives also told the investigation about the tasks they routinely performed, which included:

- welcoming women and relatives to the triage area
- taking a clinical history including allergies and current medication
- performing physical observations such as blood pressure and pulse
- carrying out physical examinations such as abdominal palpation (feeling the patient's belly)

- obtaining clinical specimens, including blood samples
- listening to and assessing the heart rate of the foetus
- using their clinical judgement to prioritise patients
- assessing the need for escalation to senior clinicians or colleagues
- assessing the need for admission of women as inpatients
- facilitating discharges from triage
- completing clinical documentation
- monitoring the waiting area and reception
- assisting other clinical and junior staff
- cleaning and administration duties.

6.1.6 In addition, the dedicated triage phone line for patients who required midwife support or advice was located in the triage area. The midwife in triage was responsible for answering these phone calls. The Midwife involved in the reference event estimated that she would expect to receive around 25 telephone calls per shift.

6.1.7 In a single 45-minute observation of the triage area, the investigation saw a midwife engage in two requests for care from women in triage, assist a junior doctor who needed help to log onto the computer system, provide advice to a clinical support worker, answer seven phone calls to the triage telephone line, organise an admission to the ward, consult with senior colleagues, find patient notes for colleagues, record information in the women's clinical notes, order blood tests, collect equipment, attempt to perform venepuncture⁵ and provide emotional support to the patient. The investigation was told by staff that this workload would represent a “*quiet*” period in triage.

6.2 Distraction

6.2.1 The Midwife explained that because of the large number of tasks she was required to complete within triage there were frequent distractions and competing priorities for her attention.

6.2.2 Staff reported that they were rarely able to follow the blood sampling process from end to end without encountering some form of distraction, typically in the form of an interruption from colleagues or a competing patient priority.

6.2.3 Staff gave a range of examples of such distractions, including:

- being interrupted to provide care to another patient in triage
- being interrupted to assist another staff member
- being interrupted to assist with visitors or new patients attending the triage area
- answering the triage telephone line
- attempting to locate a suitable pen to write on a blood sample tube
- attempting to locate patient records
- assisting junior medical staff.

6.2.4 The Institute of Medicine (2000) identified interruptions as a likely contributing factor to medical errors. When staff attention is shifted away from a primary task, the likelihood of an error occurring is increased (Rivera-Rodriguez and Karsh, 2010).

6.2.5 Although distractions have been linked to medical errors, it is important to consider how staff work within a complex sociotechnical system⁶. They are often presented with shifting goals and varying and unpredictable demands (Hollnagel et al, 2015). Within healthcare such distractions and interruptions may be necessary in order for safe care to be delivered. For example, if a staff member was ordering, taking and labelling a blood sample and a patient fainted or had a seizure, staff would be expected to respond to the emergency.

6.2.6 There is a need to distinguish interruption and multi-tasking behaviours that facilitate safe care from those that may be harmful to performance (Westbrook, 2014).

Simulations of process interruptions within replicated clinical environments and direct observational techniques to understand '*work as done*' are suggested to be ways in which the complex nature of such distractions can be better understood (Westbrook, 2014).

6.2.7 There may be circumstances in which interruptions could be limited in clinical practice. Efforts have been made to drive such approaches in other clinical contexts, such as interventions to protect nursing staff from distraction during medication rounds. However, a systematic review of studies into these interventions (Raban and Westbrook, 2014) found limited evidence of the effectiveness of such approaches in reducing distractions or errors. Studies of such measures may also fail to consider the wider complexity and interactions within the healthcare system (Westbrook, 2014).

6.2.8 Staff told the investigation that a dedicated phlebotomist⁷ was used in one area of the maternity service. The investigation observed that the phlebotomist had a side room and would dedicate all their time to blood tests without distraction. A business case had been presented to the Trust to increase the phlebotomy provision within the service but this had not been successful due to the cost of implementation.

6.2.9 Data collected by the Serious Hazards of Transfusion (SHOT) scheme (2019) identifies that medical and midwifery staff may be overrepresented in the number of wrong blood in tube (WBIT) incidents reported. SHOT identifies that for maternity staff this may be because the environment in which they work creates more opportunities for error.

6.2.10 Data collected by SHOT on WBIT rates suggests that the number of WBIT incidents reported is significantly lower for phlebotomy staff when compared with other clinical staff groups (Bolton-Maggs et al, 2014). Studies have demonstrated a reduced error rate when trained phlebotomy staff are used, and the increased use of phlebotomy staff is

⁶ A system in which people and technology interact.

⁷ A person trained to take blood from patients.

identified as a potential way to reduce WBIT incidents (Bolton-Maggs et al, 2015).

- 6.2.11 The investigation aimed to identify whether this could be because phlebotomists are less likely to be distracted from blood sampling by competing clinical priorities. This was supported by comments from midwifery support staff, who said that when they were tasked with completing a blood sampling process they felt better able to complete this task in a linear way without distraction. However, the investigation could not identify any further research that had considered whether this was the case and whether an increased use of phlebotomy staff would result in fewer blood labelling errors.

6.3 Staffing levels

- 6.3.1 The Midwife was the only midwife allocated to work in triage at the time of the incident. This was reflected on the Trust incident report for the reference event, which identified that in periods of high demand it is recommended that two midwives work in triage.
- 6.3.2 The Midwife told the investigation that it was possible to escalate concerns about workload issues with more senior staff and that this was done by contacting the senior midwife on the labour suite. Staff also explained that the response to a request for assistance would depend on the wider activity levels within the maternity unit.
- 6.3.3 The Trust informed the investigation that staffing numbers had fluctuated in recent years. The closure of a local maternity unit had led to the Trust facilitating more than 5,000 births per year. Going over the 5,000-birth threshold had released additional central funding, enabling the Trust to employ more staff. However, the number of births at the Trust had now dropped to just below 5,000 per year. This meant that the Trust could no longer access the additional funding and this had in turn reduced staff numbers.
- 6.3.4 The Trust incident report suggested that the issue of staffing levels could have been escalated by the Midwife on the day of the incident in order to seek additional support. The Trust explained that an escalation
- policy was available to midwifery staff. The escalation policy set out how to escalate patient care when demand on the service led to delays in care being provided. However, the policy did not provide details on how specific concerns about staffing could be escalated where patient care was not delayed but where staff may be working at or beyond capacity. Staff told the investigation that in such circumstances they would raise concerns with the labour ward co-ordinator.
- 6.3.5 Triage formed part of the wider labour ward staff group. Data from the labour ward showed that at the time of the reference event all midwives in the labour ward were occupied caring for women. In addition, wider staffing data from the labour ward for the week the reference event occurred showed that there were 27 out of 40 occasions (68%) when staffing numbers fell below the level required to meet the needs of women giving birth. During the visit to the Trust, Healthcare Safety Investigation Branch (HSIB) investigators noted that senior staff were required to cover clinical duties in order to provide cover for staffing shortfalls.
- 6.3.6 Whilst staff may be able to escalate their concerns, the investigation observed that additional staffing resource may not always have been available to respond to these concerns.
- 6.3.7 Having enough appropriately qualified staff is understood to support patient safety (National Institute for Health and Care Excellence, 2015). Nearly 60% of NHS staff report working additional hours (NHS, 2019) to help fill staffing shortfalls. The Royal College of Midwives (2017) identified that the NHS was facing a shortfall of approximately 2,600 midwives in order to meet the increasing demand on NHS services. The Nursing and Midwifery Council (2017) has also found that an increasing number of midwifery and nursing staff are leaving the profession.
- 6.3.8 Even where local funding may be available to recruit additional midwifery staff, the challenges surrounding local and national recruitment mean that it may not always be possible to recruit the required number of staff.

6.4 Fatigue

- 6.4.1 The Midwife explained that she was often fatigued following a shift in triage. Another staff member told the investigation that staff were “*always tired*” after completing a shift in triage.
- 6.4.2 The Midwife routinely worked a set shift pattern of 34 hours per week over three long days, working a 12-hour shift on Monday, a 10-hour shift on Tuesday, and a 12-hour shift on Wednesday. The Midwife’s Wednesday shift began at 07:45 hours. However, the Midwife explained that she usually arrived and started working at 07:20 hours to give herself time to prepare for the shift and facilitate a handover from other staff.
- 6.4.3 The midwife on triage would then routinely be expected to take their lunch break between 11:30 hours and 12:15 hours. This meant that staff had a further eight hours of work after lunch before their shift finished at 20:15 hours. On the day of the reference event, the Midwife had cared for five patients before her lunch break. Following her lunch break, the Midwife had been required to care for 19 patients. This meant that nearly 80% of the activity she needed to undertake occurred after her lunch break and in the latter hours of her 34-hour shift rotation.
- 6.4.4 Data available to the investigation shows the blood samples were requested by the Midwife at 16:00 hours and 16:47 hours. This is consistent with a study (Pickup et al, 2017) which found that the majority of WBIT incidents occurred during daytime working hours with a peak noted around 16:00 hours. Alertness and fatigue were identified as factors in a significant proportion of the WBIT incidents considered in the study.
- 6.4.5 The maternity unit largely operated on a 12-hour shift rotation for staff working full-time hours. Ball et al. (2015) identify that 12-hour shifts are becoming increasingly common in the NHS; reported data shows that up to 32% of healthcare staff on acute wards in England work day shifts of 12 hours or longer. This may be due to perceived efficiencies for the NHS or an improved work-life balance for employees. However, the study identified that there was currently a lack of evaluation and evidence to support these assumptions.
- 6.4.6 The investigation has been unable to identify significant large-scale studies on this topic relating specifically to midwifery. However, a range of academic literature has considered the impact of longer shifts on nursing performance, safety and staff productivity (Dall’Ora et al, 2019). The National Nursing Research Unit (2015) considered the impact of 12-hour shifts on patient care. It concluded that on balance the academic evidence available suggested that 12-hour shifts had a negative impact on safety, with many of the adverse outcomes noted being related to staff fatigue. In addition, survey data showed that staff working regular 12-hour shift patterns or working over their allotted shift were likely to give lower patient safety scores for their work.
- 6.4.7 Ball et al. (2015) also identified times and circumstances where the risk of staff making errors was greater. These included the time towards the end of a 12-hour shift, after working successive shifts, and an association between working overtime (beyond the set time of a shift) and adverse patient outcomes. Older staff may also be more affected by the impact of long shift patterns (Keller, 2009).
- 6.4.8 The investigation identified studies (Thompson, 2019; Folkard and Tucker, 2003) that have considered the impact of consecutive 12-hour shifts on staff fatigue and performance. The investigation noted that these studies were limited in scope, but have identified greater lapses of attention, a rise in accident rates, and a decrease in vigilance-based reaction time progressively worsening throughout consecutive shift rotations.

7 TECHNOLOGICAL SOLUTIONS

- 7.1 The maternity service within the Trust where the reference event took place had submitted a business case for funding to purchase an electronic blood sampling and labelling system, but this had not been approved. The investigation was told that this was probably due to the significant initial expenditure required to purchase and embed such a system.
- 7.2 Electronic systems are available to aid blood sample request and labelling practice as part of 'end-to-end' electronic blood transfusion systems. Such systems have been accepted for use in the collection of blood transfusion samples and the Serious Hazards of Transfusion scheme (2018) recommended that information technology to support transfusion practice be established as the standard that all NHS trusts should aim to achieve.
- 7.3 A case study published by the National Institute for Health and Care Excellence (2016) demonstrated the safety and efficiency

improvements that can be made by the adoption of electronic blood labelling systems in the context of 'end-to-end' electronic blood transfusion systems. Such systems can provide technological support for staff, from assisting with blood sampling through to ensuring that the correct blood products are dispensed and transfused.

- 7.4 The trust in the case study was also able to evidence significant efficiencies relating to incorrect blood transfusion requests and wasted blood products. By incorporating a trust-wide end-to-end electronic system the trust had made significant net savings of £101,000 per 100,000 patients, generated from reduced blood usage, reduced wastage and increased productivity.
- 7.5 With regard to blood sampling and labelling practice, these systems help staff to correctly identify patients and label blood samples. Figure 10 provides an example of an electronic blood collection process as used by the Oxford University Hospitals NHS Foundation Trust.

FIG 12 EXAMPLE OF AN ELECTRONIC BLOOD SAMPLING AND LABELLING PROCESS

1 Main Menu
Buttons: Collect Samples, Pickup, Transfuse, View Reports, Enable Training Mode
Choose **Collect Samples**

2 Collect Samples
Scan Your Identification
Image: ID card with barcode
Cancel

3 Collect Samples
Scan Patient Identification
Image: Hand with wristband
Cancel

4 Collect Samples
Verbally Confirm Patient ID
Hospital Nr: 123457
Last Name: **Walkhouse**
First Name: **Brad**
Birthdate: 12-Feb-1974
Gender: M
Cancel Next

5 Collect Samples
Complete All Reminders
Wristband details correct?
Patient's first name checked?
Patient's last name checked?
Date of Birth checked?
Cancel Back Next

6 Collect Samples
Select Tests
Group and Save
Crossmatch
Direct Antiglobulin Test
Other
Cancel Back Next

7 Image: Hand holding a PDA with a printer attached
Draw your sample, then attach the **printer** to the PDA

8 Collect Samples
Print Collection Label
Print
Copies: 1 2 3 4 5
Cancel

9 Image: Hand attaching a label to a blood tube
Attach the label to the tube, lining **top of label up with top of tube label**

10 Collect Samples
Print Collection Label
Print
Copies: 1 2 3 4 5
Done

Choose **Done** when finished

- 7.6 Such systems can help to overcome a range of distractions and interruptions identified by the investigation that take staff away from the patient's bedside and may prevent them from following blood sampling policy as prescribed. Electronic systems also eliminate the need to handwrite on blood sample tubes or use pre-printed identification labels.
- 7.7 An international study (Kaufman et al, 2019) found that using electronic patient identification to assist in the collection of pre-transfusion blood samples was associated with approximately five times fewer wrong blood in tube (WBIT) incidents compared with using manual patient identification methods.
- 7.8 Electronic systems may also introduce new complexities into the blood sampling system that need to be understood and evaluated in the procurement process and by observing

how such systems are used in practice. It is important that the adoption of such systems is accompanied by comprehensive education, training, and continued technical support (Murphy et al, 2012).

- 7.9 There is also a need to understand that electronic systems cannot be a single solution to blood sampling errors but can support improved blood sampling practice.

HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATION

Recommendation 2019/46:

It is recommended that NHSX should take steps to ensure the adoption and ongoing use of electronic systems for identification, blood sample collection and labelling.



8 ADOPTING A SAFETY SCIENCE APPROACH TO BLOOD SAMPLING AND LABELLING INCIDENTS

8.1 The Midwife described the day the reference event occurred as being “*no different to any other day*” in triage. The investigation observed that staff were diligent in aiming to provide the best possible patient care; staff told the investigation they were left upset and frustrated when blood sampling incidents occurred.

8.2 A Safety-I approach (see paragraph 3.3.3) had been adopted by the Trust to understand what may have gone wrong on this day to lead to a wrong blood in tube (WBIT) incident occurring. Adopting a Safety-II approach (see paragraph 3.3.3) means not only considering under what circumstances WBIT incidents occur but understanding how staff adapt their practice to ensure that blood sampling usually goes correctly, despite the challenges they may face.

8.3 Blood sample labelling incidents are an example of where a Safety-II approach can assist in focusing on and understanding a process that happens frequently (blood sampling), rather than only focusing on the uncommon scenario where things go wrong (a WBIT incident).

8.4 The Healthcare Safety Investigation Branch’s investigation of the reference event identified a variety of ways in which staff had adapted blood sampling practice to respond to the demands placed on them by the system in which they operated. The adaptations observed by the investigation represented the normal or routine work completed by staff that enabled them to respond to the dynamic needs of patients in a complex healthcare system.

These included:

- labelling samples away from the bedside where equipment to aid staff was not available
- being flexible in adopting a different sample collection and labelling process in clinical emergencies

- re-ordering the blood sampling process where access to computers and printers was limited
- adapting blood sampling practice to the local environmental factors in each clinical area
- purchasing their own pens to ensure they could write on blood sample tubes legibly.

8.5 The practical steps and challenges faced by the Midwife, which led to the reference event, were no different to the steps and challenges that staff faced in the process of successfully collecting many other blood samples in triage that day. Watt et al. (2019) found that the majority of adaptations made by staff are necessary in order to work around or cope with shortcomings in the system.

8.6 Studies have suggested that staff can take action to amend parts of the process they can control, but that this may sometimes involve additional steps or actions to overcome perceived problems in the system (Watt et al, 2019). These ‘*quick fixes*’ highlight where staff may take dynamic action to work around problems encountered in the system without the underlying system problems being clearly identified and addressed (Jefferis et al, 2012).

8.7 However, despite this the majority of blood samples taken by staff using the adaptations identified by the investigation had not resulted in WBIT incidents occurring, instead they often facilitated routine activities.

8.8 The ‘*Efficiency-Thoroughness Trade-Off*’ (Hollnagel, 2009) is understood to operate in complex systems as staff try to consistently balance risk and safety for the patients they care for by trading off thoroughness for efficiency. The adaptations identified by the investigation had an unknown impact on the potential effectiveness and efficiency with which staff were able to carry out a range of other clinical tasks that they were required to complete.

8.9 There is significant learning potential in understanding how activities are normally performed. Where WBIT incidents occur, even where they cause low or no harm to a patient, the accumulated cost and resource implications of dealing with frequent small-scale incidents may be greater than a single serious incident (Hollnagel et al, 2015).

8.10 In practice, the audit and evaluation of staff practices in the workplace can assist in understanding '*work as done*' and where adaptations have been required. Efforts made by NHS trusts to engage in observational studies, such as the '*vein-to-vein*' audit of blood transfusion (NHS Blood and Transplant, 2019), can help to generate knowledge of '*work as done*' relating to blood sampling within the NHS.

8.11 Studies have also demonstrated how clinical simulation can assist in identifying adaptations to working practices (Westbrook, 2014). Simulation is a mechanism by which '*work as imagined*' and '*work as prescribed*' can be compared with '*work as done*' in a protected space away from frontline patient care (Macrae and Draycott, 2019).

8.12 Rules and procedures that are informed by staff and open to adaptation are identified as desirable in complex systems (Hale and Borys, 2013a). Models of policymaking that account for and evaluate how work is done can also help to ensure the gap between '*work as imagined*' and '*work as done*' is closed (Hale and Borys, 2013b). This in turn allows for a fuller understanding of how patient care is delivered by staff, the challenges they face, and action that can be taken to limit unwanted or undesirable adaptations at a system level.

8.13 Watt et al. (2019) identified that managers and colleagues were largely unaware of adaptations that had been made and this resulted in missed opportunities to identify and learn from practices and proactive adaptations that had helped to improve safety and efficiency.

8.14 A greater understanding of safety science and the varieties of human work can help further enhance patient safety (Woodward, 2019). Safety science can assist in understanding

the ways in which WBIT incidents occur and the relative strength of actions that can be taken to address these errors (Pickup et al, 2017; Victorian Managed and Insurance Authority, 2010). This would be helped by an increased awareness and understanding of human factors and safety science within NHS organisations (Chartered Institute of Ergonomics and Human Factors, 2018; Serious Hazards of Transfusion, 2019).

8.15 A failure to understand '*work as done*' and the factors that impact on staff performance make it harder to take effective action to improve processes and reflect the reality faced by staff in clinical environments.

8.16 The new NHS patient safety strategy supports the appointment of patient safety specialists in acute trusts. These staff will receive training in human factors to drive this work and help to increase an understanding of human factors and a safety science approach (NHS England and NHS Improvement, 2019). However, there is also a need to ensure that the NHS can access qualified human factors support when additional specialism and expertise is required in the planning and evaluation of services.

HSIB MAKES THE FOLLOWING SAFETY OBSERVATION

NHS organisations may benefit from the input of suitably qualified and experienced human factors specialists in developing, evaluating and reviewing services in addition to the positive role identified for patient safety specialists as outlined in the NHS patient safety strategy.

9 SUMMARY OF FINDINGS SAFETY RECOMMENDATION, AND SAFETY OBSERVATIONS

9.1 Findings

- ‘*Work as done*’ (what actually happens in the workplace) in blood sampling and labelling practice by clinical staff within health services may vary from ‘*work as imagined*’ by policy makers (assumptions about how it is done).
- Staff are required to adapt their practice in blood sampling and labelling to account for the individual environments and circumstances in which they work.
- There is a risk that current systems that use labels and handwriting on blood samples are open to error induced by work environments.
- Current evidence supports that electronic systems can reduce WBIT incidents and improve efficiencies in blood sampling and labelling practice.
- A lack of suitably qualified staff increases workload, fatigue and the range of distractions in carrying out blood sampling.
- Longer shift patterns may negatively impact on patient safety and make it more likely that WBIT incidents will occur.
- The design of work environments can contribute to staff fatigue and impact on staff’s ability to follow end-to-end processes effectively.
- Training is only one of multiple strategies required to address WBIT incidents occurring.
- Current incident investigations do not always account for and seek to address system-level factors influencing WBIT incidents or seek to understand why blood sampling usually goes right.

- Safety science and human factors methodologies can assist in understanding ‘*work as done*’ and help to identify the necessary adaptations made by staff in local clinical environments.

9.2 Local learning for NHS trusts

The HSIB investigation identified local learning that may assist NHS trusts when considering how their own local blood sampling and labelling practices operate:

- Trusts can seek to understand ‘*work as done*’ by staff and take a safety science approach when developing blood sampling and labelling policies.
- Trusts can aim to incorporate human factors thinking and awareness within incident reporting and investigation.
- Trusts should be aware of the increased risk of WBIT incidents occurring where there may be staff shortages and staff fatigue.
- Trusts can ensure that local policies and training on blood sampling account for the challenges posed by different working environments.
- Trusts can aim to understand the range of distractions staff face in different working environments and the compromises staff may have to make to deliver patient care.
- Trusts can optimise the availability, accessibility and usability of appropriate equipment used in blood sampling and labelling (for example: computer terminals, printers, bedside tables, sampling equipment, and that equipment is maintained).

HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATION

Recommendation 2019/46:

It is recommended that NHSX should take steps to ensure the adoption and ongoing use of electronic systems for identification, blood sample collection and labelling.

HSIB MAKES THE FOLLOWING SAFETY OBSERVATIONS

HSIB acknowledges the work of the Serious Hazards of Transfusion scheme in seeking to introduce and evaluate system-level considerations in transfusion incident reporting. Wider NHS incident reporting may benefit from a similar approach that encourages staff to identify and report system-level factors that influence clinical incidents.

NHS organisations may benefit from the input of suitably qualified and experienced human factors specialists in developing, evaluating and reviewing services in addition to the positive role identified for patient safety specialists as outlined in the NHS patient safety strategy.



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