HSIB

HEALTHCARE SAFETY INVESTIGATION BRANCH

WWW.HSIB.ORG.UK

The use of an appropriate flush fluid with arterial lines

Independent report by the
Healthcare Safety Investigation Branch NI-000832

August 2022

Providing feedback and comment on HSIB reports

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

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

About HSIB

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

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

Considerations in light of coronavirus (COVID-19)

A number of national reports were in progress when the COVID-19 pandemic significantly affected the UK in 2020 and 2021. Much of the work associated with developing the reports necessarily ceased as HSIB's response was redirected.

For this national report, the investigation was initially paused, but then restarted due to its association with COVID-19. The processes HSIB used to engage with staff and families had to be adapted. Changes are described further in this report.

A note of acknowledgement

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

About the patient

The picture on the shelf in the family lounge shows Keith at the heart of a large extended family. Keith was married for 44 years and has three daughters and three grandchildren who describe him as a "fun family man".

Keith worked and volunteered as a marshal at the Silverstone racecourse, where he shared a love of motor racing with his family.

He was well-known and well-loved within his community with a reputation for his ability to fix everything and anything from cars to cupboards. He had a particular love for wood, which he collected and stored wherever he could find space at home. He was a man people turned to with their everyday problems and he was always willing and equally very able to lend a hand.

About this report

This report is intended for healthcare organisations, policymakers and the public to help improve patient safety in relation to the use of a flush fluid and blood sampling from an arterial line in people who are critically ill in hospital. For readers less familiar with this area of healthcare, medical terms are explained in **section 1** and throughout the text.

Our investigations

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

We undertake patient safety investigations through two programmes:

National investigations

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

Maternity investigations

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

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

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

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

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

Executive Summary

Background

This investigation aimed to understand the risks for patients associated with blood sampling from arterial line systems used in adult critical care. An arterial line is a system used to continuously monitor a patient's blood pressure and intermittently monitor blood glucose levels by taking a blood sample from the arterial line. A thin tube called a cannula is inserted into an artery, usually in the person's forearm, and tubing is used to attach a device called a transducer. This is connected to a bag of fluid (the flush fluid) and the pressure change of the fluid within the connecting plastic tubing transmits to an electrical monitoring device. This device displays the blood pressure within the artery as a continuous wave line on the monitoring screen. Arterial lines are used in other areas of healthcare and the findings of this investigation may also be relevant to these areas.

The selection and attachment of the incorrect flush fluid is a recognised risk in the use of arterial lines. When a flush fluid contains glucose rather than saline (0.9% sodium chloride) and a blood sample from an arterial line is contaminated, a false high blood glucose is recorded. This will mislead the clinician who may start the patient on insulin, which controls blood sugar levels. This may lead to unrecognised and dangerous levels of hypoglycaemia (low blood glucose levels), which can lead to the patient going into a coma. Careful monitoring of blood glucose levels has become established practice for critical care patients. It provides the information clinicians need to understand whether treatment is appropriate to correct an imbalance in blood glucose levels. Blood glucose monitoring using an arterial blood sample is recommended in critical care environments.

As an example, which is referred to as 'the reference event', the investigation reviewed the care of a patient named Keith. Keith received treatment to drain his gallbladder but then became very unwell. He was admitted to a critical care unit with significantly low blood pressure and sepsis (a reaction to infection that causes a person's body to damage its own tissues and organs). An arterial line was inserted, and the incorrect flush fluid was connected to the transducer. The use of the incorrect flush fluid led to the contamination of the blood samples taken from the site of the arterial line, which consequently misled clinicians to give Keith an unnecessary and potentially harmful treatment.

This investigation's findings, safety recommendations and safety observations aim to demonstrate the risk associated with the set-up of the arterial monitoring line and use of the correct flush fluid and to improve care for patients across the NHS.

The reference event

Keith was 66 years old and was recently retired. After feeling unwell for 25 days and attending medical appointments to investigate his gallbladder, he was admitted to hospital. Following an investigation and the drainage of his gallbladder his condition deteriorated. He was admitted to the critical care unit late in the year of 2020 with sepsis and very low blood pressure. Keith was medically unstable and required numerous medications and devices to be attached to him to enable accurate monitoring of his condition.

The insertion of the arterial line was completed around 16:20 hours. The doctor inserted a cannula into an artery in Keith's arm, while a nurse went to look for the correct equipment, an arterial line (marked red) and a 500ml bag of saline (sodium chloride 0.9%) flush fluid. Saline is the recommended flush fluid for an arterial line and other fluids should not be used for this purpose. The nurse looked first within the 'lines' drawers at the bedside (intended to include all necessary equipment for the insertion of an arterial line). When unable to find the correct arterial line transducer set, the nurse looked in two other areas of the critical care unit. They also collected the bag of saline flush fluid from the drug cupboard. The nurse was aware that the cannula had been inserted and the blood would clot and block the line without the arterial line and saline flush fluid attached. They returned to the bedspace with a blue line central venous transducer set. The line and bag of flush fluid were checked and attached. The risk of attaching a blue transducer line was recognised by staff, as a blue transducer line is intended to be connected via a vein and can indicate it is safe to administer medication, which would not be safe through an arterial transducer line.

The need to change the line was prioritised by staff but the nature of Keith's condition created several competing tasks. Keith's blood glucose levels were found to be low. A different nurse went to retrieve a bag of glucose so that a glucose infusion (where glucose in a liquid solution is delivered via a patient's vein) could be commenced to increase Keith's blood glucose levels. Unable to locate the required strength of glucose, the nurse returned with two alternative strengths for the doctor to select for treatment. While collecting the glucose the nurse also found and returned with the correct red arterial transducer line. The red arterial transducer line and remaining bag of glucose were left together by the bed. The other nurse interrupted their current task and collected both items to replace the blue transducer line that was in position with the correct red arterial transducer line. They replaced the central venous transducer set (blue line) and the correct saline flush fluid with the arterial transducer set (red line) and the incorrect bag of fluid containing glucose as the flush fluid.

Subsequent blood samples taken from Keith's arterial line were contaminated with the flush fluid containing glucose. This led clinicians to conclude that Keith was suffering from high blood glucose levels and at risk of further harm. An infusion of insulin, the required treatment for high blood glucose, was administered for approximately 8 hours. This treatment reduced Keith's blood glucose levels to below the recommended limit. The incorrect fluid was identified the next day, during morning safety checks completed by the nurse taking over Keith's care. The treatment of insulin was stopped, and glucose administered to correct the blood glucose levels.

Keith had a brain scan on the same day, which concluded at that time there was no neurological damage associated with the abnormal blood glucose levels. He was discharged from the critical care unit 15 days after his admission following care for his underlying condition. Sadly, Keith died of COVID-19 later during his hospital stay.

The national investigation

HSIB was contacted by the Department of Health and Social Care in response to receiving a prevention of future deaths notice from a coroner's investigation into the death of a woman aged 57 years. The investigation was completed on the 7 September 2020 and concluded that the use of a solution containing glucose instead of saline, the recommended fluid to flush an arterial line, contributed to the patient's death.

HSIB identified Keith's case as a similar patient safety incident. Although the event did not result in the death of a patient, it involved a similar sequence of events and the same error was identified.

Findings

The key findings from the investigation include:

- The physical layout and design of the clinical and storage areas will influence how reliably staff are able to select and collect similar-looking equipment and medication.

- The labelling of bags of fluids, similar looking medications and manufacturers' packaging reduce the reliability of selecting the correct flush fluid in the context of a critical care unit with time pressures and high workloads.

- The procurement and design of arterial transducer line equipment, the pressure infusion bags and transducer, do not assist in the identification of the incorrect flush fluid or prevent contamination from the flush fluid of a blood sample taken

from the arterial line. Alternative equipment, for example transparent pressure infusion bags and closed arterial transducer lines, are currently available to the NHS. These may reduce the risk but are not routinely in use.

- Challenges in the provision of a consistent suitable workforce and high workloads have a detrimental effect on the safety controls currently relied upon to avoid or identify the risk of using the wrong flush fluid. Safety checks and training lack resilience to organisational pressures regularly experienced within critical care units.

- There can be a delay in identifying the contamination with glucose of an arterial line blood sample due to a normalisation and acceptance that critically ill patients may have altered blood glucose levels and require insulin treatment, and a perceived low risk associated with the use of a flush fluid.

- The design of systems to record and monitor information relevant to the arterial transducer line system and blood glucose levels do not easily alert staff to the potential use of the wrong flush fluid.

- Recommendations issued over the last 14 years by national safety bodies and professional healthcare organisations to address the safety of blood sampling associated with arterial lines have not been effectively implemented.

HSIB makes the following safety recommendations

The intention of this safety recommendation is to provide design guidance for manufacturers to manage the risk associated with fluid selection. All aspects of label design should be considered this recommendation is broader than the judicious use of colour as the approach to increasing label safety.

Safety recommendation R/2022/200:
HSIB recommends that the Medicines and Healthcare products Regulatory Agency [Head of Metabolic Disorders and Renal Systems] engages with other national regulators and relevant stakeholders to develop design guidance on labelling and packaging specific to fluids to reduce selection errors.

The intention of this safety recommendation is to ensure fluid labels can be consistently read from all directions at all times when the pressure infusion bag is inflated.

Safety recommendation R/2022/201:
HSIB recommends that the Medicines and Healthcare products Regulatory Agency [Head of Metabolic Disorders and Renal Systems] reviews and acts on the available evidence to regulate for the use of pressure infusion bags that allow fluid labels to be read when inflated.

The intention of this safety recommendation is to increase awareness of and action on known risks related to the design of the medical devices.

Safety recommendation R/2022/202:
HSIB recommends that the Medicines and Healthcare products Regulatory Agency [Head of Metabolic Disorders and Renal Systems] communicates to all relevant stakeholders and acts on the available evidence concerning the management of the risks associated with arterial transducer line sets.

The intention of this safety recommendation is to assure appropriate action is taken to manage the known risks related to the design of the medical devices.

Safety recommendation R/2022/203:
HSIB recommends that the Department of Health and Social Care [Director of Medical Technology], once post-market surveillance data is available, involves relevant stakeholders including the Association of Anaesthetists' review and determine appropriate actions that could be taken to further mitigate the risk of blood sample contamination by the flush fluid when using arterial transducer line systems.

The intention of this safety recommendation is for the Association of Anaesthetists to revise existing national guidance in collaboration with all relevant healthcare professionals including the following clinical areas: critical care, theatres and emergency departments.

Safety recommendation R/2022/204:
HSIB recommends that the Association of Anaesthetists [President] works with relevant professional organisations to revise existing national guidance to manage the risks of contamination by the flush fluid when using an arterial line to take a blood sample.

The intention of this safety recommendation is to provide assurance that NHS providers have implemented the future national guidance.

Safety recommendation R/2022/205:
HSIB recommends that the Care Quality Commission [Chief Executive] reviews the recommendations from the Association of Anaesthetists on how to manage the risks of contamination by the flush fluid when using an arterial transducer line and determines any appropriate actions for the oversight of governance and assurance arrangements within NHS providers following.

HSIB makes the following safety observations

Safety observation O/2022/179:
It may be beneficial to recognise that safety risks are not reliably reported and therefore that the likelihood and level of harm may not be accurately reflected through existing reporting systems.

Safety observation O/2022/180:
It may be beneficial to recognise that workload and fatigue will influence the reliability of safety controls dependent on staff time and attention.

Safety observation O/2022/181:
It may be beneficial, to undertake product essential specification development with end users as part of any NHS procurement framework renewal.

Safety observation O/2022/182:
It may be beneficial for future reviews of the design of storage space within critical care units to consider the engagement of expertise in physical workspace design.

Safety observation O/2022/183:
It may be beneficial to increase the speed of implementation of the use of technology to support closed-loop medicines administration systems.

Safety observation O/2022/184:
It may be beneficial to review the unintended consequences associated with the use of pre-populated prescriptions for arterial flush fluid and also insulin.

Safety observation O/2022/185:
It may be beneficial if regulatory bodies remain alert to and encourage the adoption of alternative approaches to continuous glucose monitoring.

Safety observation O/2022/186:
It may be beneficial to consider how the design processes and guidance for blood glucose recording can support identification and early warning of a potential blood sample contamination by flush fluid.

HSIB notes the following safety action

Safety action A/2022/053:
The Association of Anaesthetists has started to identify relevant stakeholders for the development of guidance on blood sampling when using arterial transducer line systems.

Contents

1 Background

1.1 Adult critical care

1.1.1 Critical care refers to a specialist area of healthcare that cares for seriously ill patients with complex medical needs. Critical care patients may have single or multiple organ failure and require close observation and medical interventions.

1.1.2 Critical care service specifications indicate that one nurse may care for two patients, except for patients that may require advanced respiratory (breathing) support and additional equipment to manage multiple organ failure. For these patients a ratio of one patient to one nurse is required (NHS England, 2019; The Faculty of Intensive Care Medicine and Intensive Care Society, 2019).

1.1.3 The guidance for the provision of critical care services highlights the infrastructure and design of the physical environment as essential to support safe and effective care (The Faculty of Intensive Care Medicine and Intensive Care Society, 2019). This guidance reflects common challenges for existing critical care units which include good visibility of patients, adequate storage, provision of space and natural light.

1.2 Management of blood glucose levels

1.2.1 The amount of sugar in the blood is known as the blood glucose level. The blood glucose levels of a healthy person should be between 4 and 8 millimoles per litre (mmol/litre) (Diabetes.co.uk, 2022). Blood glucose levels may fluctuate during a severe illness (Kerr et al, 2017). It is recognised that control of blood glucose levels is associated with better patient outcomes (Mesotten et al, 2015).

1.2.2 Hypoglycaemia is when the blood glucose level is less than 4mmol/litre (National Institute for Health and Care Excellence, n.d.). This will occur in approximately 2 to 3% of critical care patients (Badawi et al, 2012). Hypoglycaemia can inhibit the nervous system and prolonged periods of hypoglycaemia may cause brain damage or death (Association of Anaesthetists of Great Britain and Ireland, 2014).

1.2.3 Mild hyperglycaemia (blood glucose levels between 10.0 and 12.2mmol/litre) is common in critically ill patients and is a stress response to the severity of an illness (Marik and Egi, 2014). The clinical implications of hyperglycaemia are poor clinical outcomes, higher death rate and longer stays in critical care units (Stapleton and Heyland, 2022).

1.2.4 Careful monitoring of blood glucose levels has become established practice for critical care patients. It provides the information clinicians need to understand whether treatment is appropriate to correct an imbalance in a patient's blood glucose levels. Blood glucose monitoring using an arterial blood sample is recommended to avoid inaccuracies associated with more commonly used blood glucose tests obtained by pricking the person's finger (known as a capillary blood test) (Mesotten et al, 2015).

1.3 Arterial line equipment and taking blood samples

1.3.1 An arterial line is a system used to continuously monitor a patient's blood pressure and to monitor blood glucose levels. It has five separate components (see figure 1):

- a cannula (a plastic tube inserted over a sharp needle)
- arterial transducer set (short and stiff plastic tubing)
- 500ml bag of saline flush fluid (0.9% sodium chloride)
- a pressure bag to inflate over the bag of saline flush fluid
- a transducer (which transmits the blood pressure recording).

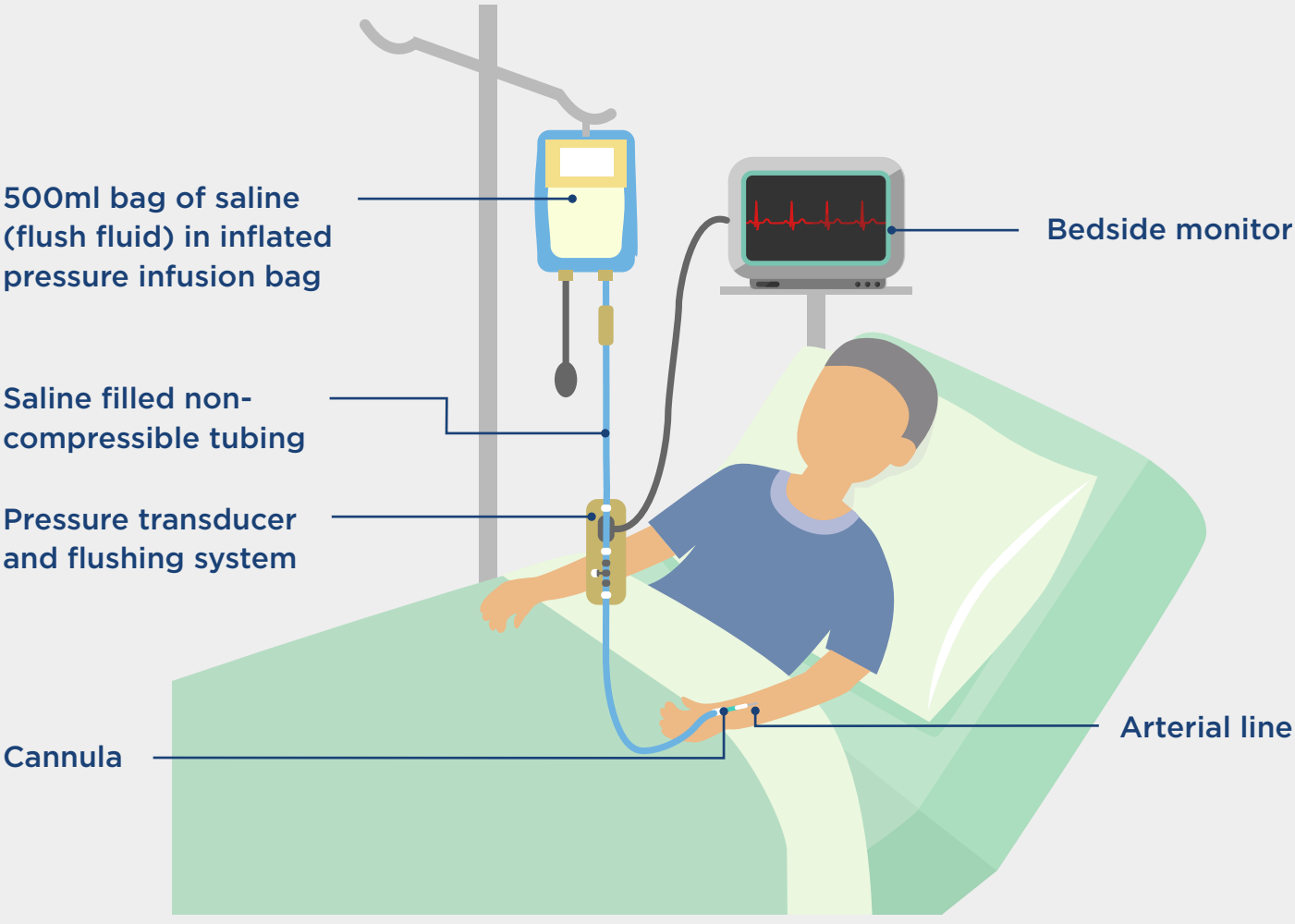
1.3.2 The 500ml bag of saline (0.9% sodium chloride) is often referred to as the 'flush' fluid as its function is to maintain the patency (openness) of the tubes, prevent blood from clotting and flush the arterial tubing. Clinical staff will also draw the flush fluid through the system to prevent clotting of residual blood when taking an arterial line blood sample.

1.3.3 The transducer records the pressure change of the saline flush fluid within the plastic tubing. This change in pressure is transmitted to an electrical monitoring device, which reflects the blood pressure within the artery as a continuous wave line on the monitor. The use of an arterial line is considered the 'gold standard' for the monitoring of a patient's blood pressure. This enables regular blood tests to obtain an accurate and real-time continuous monitoring of a patient's vital signs (Plowright and Sumnall, 2022).

1.3.4 There are several steps to setting up an arterial line (Plowright and Sumnall, 2022). Depending on local policies, these steps may be completed by one or two members of staff, including a doctor and a nurse. The process for setting up an arterial line includes (but may not occur in this order):

- insertion of the arterial cannula into the patient's artery in the forearm
- collection of transducer and tubing, 500ml bag of saline (flush fluid) and pressure bag
- connecting a 500ml bag of saline to the tubing extending from the transducer
- hanging the 500ml bag of saline covered by a pressure bag, which is inflated to 300 millimetres of mercury (mmHg)
- attaching the transducer cable to the transducer tubing and the bedside monitor
- attachment of tubing and transducer to arterial cannula site and labelling to identify as arterial line
- checking the measurement of arterial blood pressure via the bedside monitor.

Figure 1 The equipment and set up of an arterial line



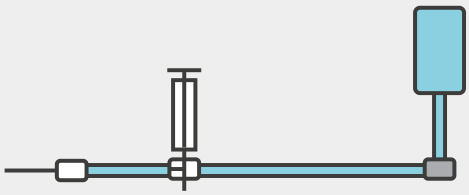
1.3.5 The process for taking a blood sample from an arterial line will vary depending upon the type of transducer system used. There are two main types of transducer systems: 'open' and 'closed'. The difference between these is the length of tubing between the cannula and the access point, known as a 'port', where a blood sample can be taken. This distance is referred to as the 'dead space' and described in more detail below.

1.3.6 An 'open' system (see figure 2) has a '3-way tap' as a port close to the arterial catheter site. Staff attach a syringe to the port to remove residual flush fluid and will then take a blood sample from the same port using a blood sampling syringe. Guidance recommends that an amount of blood equivalent to three times the volume of the dead space be removed to reduce the contamination of a blood sample with the flush fluid (Medicines and Healthcare products Regulatory Agency, 2014a). Other guidance highlights that even taking five times the dead space, contamination from the flush fluid is still possible when using an 'open' system (Association of Anaesthetists of Great Britain and Ireland, 2014).

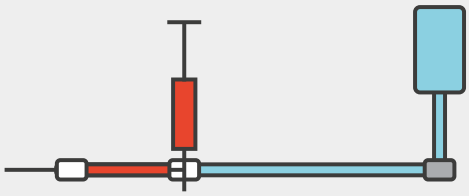
1.3.7 A 'closed' system (see figure 2) has a port beyond a separate sampling site (from which blood can be taken). This enables staff to remove the residual flush within the dead space, while conserving the patient's blood. A closed system is reported to reduce the chance of contamination of a blood sample (Association of Anaesthetists of Great Britain and Ireland, 2014).

Figure 2 Illustration of open and closed systems, (Association of Anaesthetists, 2014)

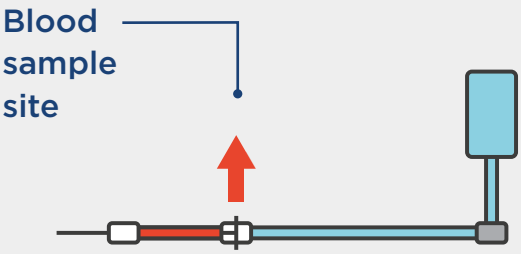
Open systems



1 Attach a syringe to port

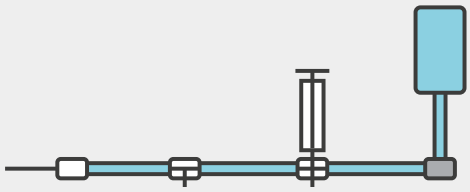


2 Draw back blood 3 times the volume of dead space. Discard blood safely

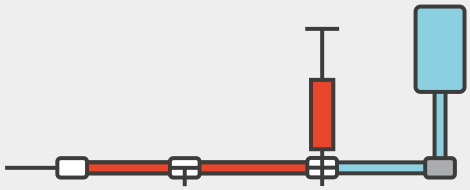


3 Withdraw a sample of blood for testing from the blood sample site

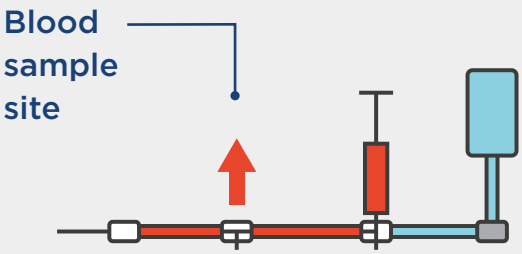
Closed systems



1 Attach a syringe to port furthest from cannula site



2 Draw back blood 3 times the volume of dead space. Conserve the patient's blood



3 Withdraw a sample of blood for testing from the blood sample site

4 Replace the conserved blood back into the closed system

Key

Flush fluid **Blood** **Port** **Syringe** **Cannula**

Inflated pressure infusion bag

Dead space – remaining fluid between cannula and blood sample site

1.4 Risk of the wrong flush fluid in arterial lines

1.4.1 The selection and attachment of the wrong flush fluid is a recognised risk in the use of arterial lines. When a blood sample from an arterial line is contaminated with flush fluid that contains glucose, a false high blood glucose is recorded. This will mislead the clinician who may initiate treatment in the form of insulin. The inappropriate administration of insulin to a patient may lead to unrecognised and dangerous levels of hypoglycaemia. Arterial lines are used in other areas of healthcare and the findings of this investigation may also be relevant to these areas.

1.4.2 Public awareness of this safety concern has been raised by the reporting of the death of Susan Warby (who was mistakenly given glucose instead of saline through an arterial line) and the subsequent prevention of future deaths report issued to the Department of Health and Social Care. This report identified systemic issues (that is, issues inherent to the healthcare system as a whole rather than isolated problems) that warranted change to protect the public (Courts and Tribunals Judiciary, 2020).

1.4.3 There is a large body of further evidence of the multiple systemic factors believed to contribute to the risks associated with the wrong flush fluid used in conjunction with arterial transducer line systems. These include:

- look-alike labelling and packaging of intravenous fluids (National Patient Safety Agency, 2008a)
- storage, clarity and ease of selection of flush fluids from working environment and storerooms (Association of Anaesthetists of Great Britain and Ireland, 2014; Gupta and Cook, 2013)
- the physical environment including lighting and ability to see text within labels (Gupta and Cook, 2013)
- inadequacy in checks of flush fluids (Association of Anaesthetists of Great Britain and Ireland, 2014; Gupta and Cook, 2013; National Patient Safety Agency, 2008a)
- staffing and caseload may influence adherence to local procedures (Gupta and Cook, 2013)
- obscured labelling of intravenous fluid because of the need to cover with a pressure bag (Association of Anaesthetists of Great Britain and Ireland, 2014; Gupta and Cook, 2013; National Patient Safety Agency, 2008a)

- blood sampling contaminated by inadequate flushing (Gupta and Cook, 2013; National Patient Safety Agency, 2008a)

- design of the arterial line may increase the likelihood of the contamination of a blood sample with glucose-based flush fluid (Gupta and Cook, 2013; National Patient Safety Agency, 2008a)

- presentation of data and glucose levels within medical records may inhibit the detection of the wrong flush fluid as the cause of altered blood glucose levels (Gupta and Cook, 2013; National Patient Safety Agency, 2008a).

Existing recommendations to address the known risks

1.4.4 There have been three key national attempts to address the risk of the wrong flush fluid used with arterial lines. These stem from the National Patient Safety Agency (NPSA) in 2008 (National Patient Safety Agency, 2008a), the Medicines and Healthcare products Regulatory Agency (MHRA) in 2014 (Medicines and Healthcare products Regulatory Agency, 2014a) and the Association of Anaesthetists of Great Britain and Ireland in 2014 (Association of Anaesthetists of Great Britain and Ireland, 2014).

1.4.5 In 2008 the NPSA issued a rapid response report to highlight the risk associated with the use of the wrong flush fluid with arterial lines. This document states 'sampling from arterial lines is risky'. This report asked healthcare providers for an immediate response which included:

- increased awareness of the risk

- clearly labelled arterial lines

- assurance of the prescription and checking of infusion (a volume of liquid given to a patient through a vein) fluids

- only saline to be used as an arterial line flush fluid

- visibility and clarity in the labelling of fluid bags irrespective of the use of a pressure bag.

A national review of previously issued safety alerts, published in 2022, confirmed that this NPSA rapid response report was an enduring standard which remained valid, is unlikely to change in the immediate future and 'should already be embedded systematically across NHS provider organisations' (NHS England and NHS Improvement, n.d.).

1.4.6 The MHRA issued a drug safety update in 2014 stressing the risk associated with the use of glucose solutions compared to saline in arterial lines (Medicines and Healthcare products Regulatory Agency, 2014a). It recommended the use of saline as the solution of choice and that staff 'remain vigilant' when selecting solutions as similarities between glucose and saline bags of fluid means that 'confusion may occur'. When drawing a blood sample, a minimum volume of three times the dead space of the cannula (tubing) should be discarded first to avoid contamination in the event of the wrong flush fluid being used.

1.4.7 The Association of Anaesthetists developed a working party to address the incorrect use of arterial flush fluids (Association of Anaesthetists of Great Britain and Ireland, 2014). It recognised that the NPSA guidance and good sampling practices were insufficient to prevent patient harm or death due to the consequence of sample contamination. The working party completed a robust systems analysis and issued a comprehensive set of system-wide recommendations which included:

- guidance to store saline separately from other infusion fluids
- double checking of prescribed saline fluids on setting up an arterial line, and checking at least once during a shift
- pressure bags to have a fully transparent front panel, and use of 'closed' arterial transducer line systems
- vigilance to glucose thresholds – an unexpectedly high glucose level should trigger a medical and equipment review
- starting or increasing an insulin infusion based on samples taken from an arterial line must require a medical review
- trends in blood glucose levels over time are more easily identified from a graphical representation.

1.4.8 The NPSA and the Association of Anaesthetists both conclude that manufacturers should develop a universal safer system to address this problem. This would require consideration of potential engineered solutions (that is, solutions built into the design of the equipment) to prevent or minimise the risk.

2 The reference event

This investigation used the following safety incident, referred to as the 'reference event', to examine the issue of the wrong flush fluid used with arterial transducer lines. This section describes the care that a patient named Keith received up to the point that the use of a wrong flush fluid was identified.

2.1 Keith was 66 years old and had recently retired. After being unwell for 25 days and attending medical appointments to investigate his gallbladder, he was admitted to hospital.

2.2 Keith's family called an ambulance on a night late November 2020, as he had acute stomach pain and was unable to pass urine. He was admitted via the emergency department to a gastroenterology ward (a ward for patients with conditions relating to the digestive system, liver and pancreas).

2.3 He remained in hospital and on the following day his Wife was contacted and asked to come to the hospital at 09:30 hours the following day. Keith and his Wife were informed that he was seriously ill and he would be receiving a scan and treatment.

2.4 Keith was diagnosed as having acute inflammation and an infection within his gallbladder. He received treatment to drain his gallbladder, but he developed sepsis (a reaction to infection that causes a person's body to damage its own tissues and organs) and became very unwell. His blood pressure was severely low and he had metabolic acidosis (his blood fluids contained too much acid).

2.5 At 15:38 hours on the day Keith was admitted to the adult intensive care unit (AICU) he was medically 'unstable' and so unwell that his Wife was called in from home. He required multiple interventions to enable healthcare staff to monitor his vital signs (important measurements that reflect the essential body functions) and deliver medication to stabilise his condition.

2.6 In the AICU each patient was allocated one-to-one care by a nurse who is qualified and assessed competent based on the Trust's training programme. An additional nurse may be rostered on duty who can provide support for the patient's allocated nurse, referred to as the 'float' nurse. A float nurse was available when Keith was admitted to the AICU.

2.7 The nurse allocated to Keith (nurse 1) was also supervising another qualified nurse who was undertaking additional training to become competent in critical care nursing.

2.8 During Keith's admission to the AICU, the float nurse (nurse 2) arrived at his bedside to offer support to nurse 1. Nurse 2 volunteered to support the doctors to complete two interventions: the insertion of an arterial line and a central line (the placement of a flexible tube into Keith's central vein to allow blood to be taken, fluids and medication to be given). The insertion of the arterial line was completed at around 16:20 hours. The doctor inserted a cannula into Keith's arm, while nurse 2 went to look for the correct equipment – an arterial (marked red) transducer line and a 500ml bag of saline fluid. Nurse 2 first looked within the 'lines' drawers at the bedside, which are intended to include all necessary equipment for the insertion of an arterial line. When unable to find the correct transducer they looked in two other areas of the unit. They also collected the bag of saline fluid from the cupboard. Nurse 2 was aware that the cannula had been inserted and would clot without a transducer line and flush fluid attached. They returned to the bedspace with a central venous transducer set (a 'blue line' set).

2.9 Nurse 2 attached the blue transducer line to the cannula and recalls checking the name and expiry date of the fluid with the doctor who had inserted the cannula. The fluid was placed inside an opaque white pressure bag with transparent front panel, which was inflated to provide the required pressure and hung from a metal stand.

2.10 Both nurses recognised that the connection of a blue transducer line posed a risk to the patient; the blue transducer line usually indicates insertion into a vein where medication may be delivered, which would not be safe via an arterial line. Nurse 2 recalls asking a care support worker (staff designated to assist nursing care) to look for a red line arterial transducer set.

2.11 At 16:24 hours a blood test was taken and analysed within the AICU. This revealed that Keith had a low level of blood glucose (3.5mmol/litre), classified as hypoglycaemia. This required immediate treatment in the form of a glucose infusion and nurse 1 went to retrieve a bag of glucose.

2.12 Nurse 1 went to the drug cupboard, a locked room situated next to Keith's bedspace, with the intention of retrieving a bag of glucose 20%. Nurse 1 was unable to locate 20% glucose so retrieved 500ml bags of 50% and 10% glucose to allow the medical team to decide, which should be used.

2.13 At 17:00 hours a doctor selected the bag of 50% glucose and 75ml was delivered to Keith intravenously (directly into a his vein). The remaining 500ml bag of 10% glucose was left by the computer terminal at the end of Keith's bed to be returned to the cupboard. The use of 50% glucose was recorded retrospectively at 17:32 hours within the IT system; this included an explanation that the 20% strength of glucose was unavailable.

2.14 In parallel, nurse 2 supported a consultant to insert the central line. A senior nurse, with the role of unit co-ordinator, stood at the end of the bed and saw a blue transducer line had been used. They instructed the team to replace the line and to complete an incident report as soon as possible.

2.15 A red arterial transducer line was brought to the bedside and left next to the bag of 10% glucose by the computer terminal. Nurse 2 noticed the red transducer line and in a "rush" went to collect it along with the bag of fluid (10% glucose) next to it. Nurse 2 used both items to replace the original bag of saline and the blue transducer line, then returned to the work they were completing to support the management and stabilisation of Keith's condition.

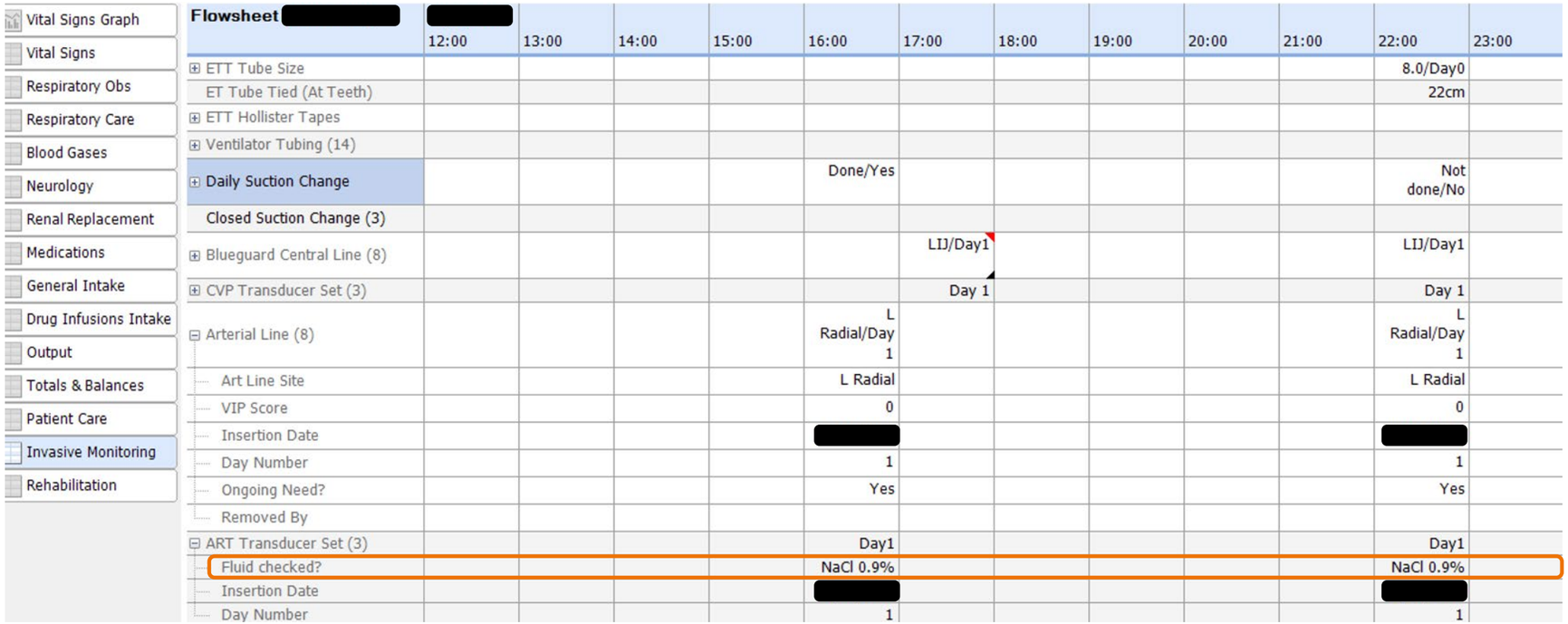
2.16 Further blood tests were taken and analysed at 17:25 hours and 18:34 hours, which revealed that Keith had blood glucose levels of 19.95 and 11.1mmol/litre respectively. These and subsequent blood tests were taken from the arterial line and contaminated with glucose from the flush fluid (10% glucose), which was now obscured by the pressure bag.

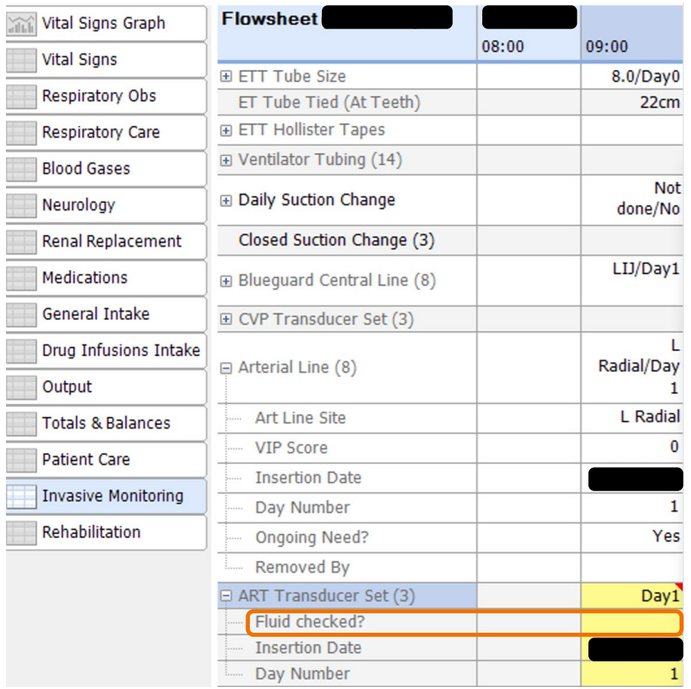
2.17 At 18:45 hours Keith's condition deteriorated, and additional medication was required to stabilise him.

2.18 At 19:30 hours the night shift nurse arrived and received a handover from nurse 1. Nurse 1 provided information on the Keith's medical condition and walked through the information that had been recorded on the IT system. The daytime medical team handed over to the night-time medical team at 20:00 hours and due to a further deterioration in Keith's condition the night-time medical team decided to intubate (that is, to put a tube down his throat and into his windpipe to help him breathe). A nasogastric tube (a flexible tube that carries food and medication into a person's stomach through the nose) was also inserted and an X-ray completed to check its position. A further blood test indicated that Keith's blood glucose level was 10.2mmol/litre at 21:17 hours.

2.19 The intubation and insertion of a nasogastric tube created a high level of activity for the night nurse. This resulted in interruptions and delays to the completion of safety checks due to be completed at the start of a shift (see figure 3). Immediately following the insertion of the nasogastric tube, more patients were admitted to the same area of AICU as Keith. The night nurse provided support to colleagues to receive these patients. The night shift did not have a float nurse to provide additional assistance to the nurse allocated to individual patients.

Figure 3 Safety checks recorded





2.20 The night nurse recorded the safety checks as having been completed at 22:00 hours. This included a check of the arterial transducer line set ('ART Transducer Set' in figure 3) and the field for 'Fluid checked?' (highlighted in figure 3) was completed at 22:00 hours with 'NaCl 0.9%', the abbreviation for saline fluid.

2.21 Blood tests and glucose levels were checked at intervals, at 21:17 hours, 22:37 hours and 01:03 hours, and these recorded increasing levels of blood glucose (**see table 1**). The increase in time intervals between samples occurred as the night shift nurse covered staff breaks and the care for other patients. The team agreed to start treatment for hyperglycaemia and an insulin infusion was started at 02:00 hours on the second day by the night nurse.

2.22 At approximately 06:00 hours the doctor was concerned and requested a review by the consultant. The consultant instructed to start Keith on renal replacement therapy (a machine to assist the kidney function of filtering the blood) and a junior doctor (qualified to complete this) inserted a temporary renal dialysis line (a connecting tube from a dialysis machine to a patient to allow their blood to be filtered). Once this was in place the night nurse asked the junior doctor if they wished for a blood sample to be taken for the purpose of checking that the renal dialysis line was positioned correctly in a vein (a low reading of oxygen implies venous blood). The blood gas was completed and at 07:21 hours the night nurse returned with a paper printout of the blood gas results. The doctor, still within a sterile environment, was unable to read the results as the nurse was positioned at the end of the bed. The night nurse read out the oxygen levels recorded, as requested by the doctor, which indicated the renal dialysis line was correctly positioned in a vein.

Table 1 Keith's blood glucose levels

Day 1

	15.00	16.00	17.00	18.00	19.00	20.00	21.00	22.00	23.00
Blood glucose (mmol/litre)		3.5	19.9	11.1			10.2	14.4	

Day 2

	00.00	01.00	02.00	03.00	04.00	05.00	06.00	07.00	08.00	09.00	10.00
Blood glucose (mmol/litre)		15.1				6.0	7.0	1.4			0.7

2.23 The shift handover occurred at 07:30 hours and at 09:00 hours the nurse on duty completed a number of bedside checks that revealed the presence of the 10% glucose flush fluid under the pressure bag. At 09:04 hours the flush fluid containing glucose was swapped for the correct saline flush fluid. Further blood gases were taken once the glucose flush fluid had been replaced with a saline flush fluid; these indicated Keith's blood glucose level to be 0.7mmol/litre.

2.24 At 10:13 hours the insulin infusion was stopped and at 10:30 hours the medical records indicate that 100ml of 20% glucose was administered intravenously (directly into Keith's vein). Four further administrations of 100ml of 20% glucose were administered until Keith's blood glucose levels rose to 8.2mmol/litre.

2.25 Keith had a brain scan on the same day and the Trust concluded at that time there was no neurological damage associated with the abnormal blood glucose levels. He was discharged from the critical care unit 15 days after his admission following care for his underlying condition. Sadly, Keith died of COVID-19 later during his hospital stay.

3 Involvement of the Healthcare Safety Investigation Branch

This section outlines how HSIB was alerted to the issue of the use of a wrong flush fluid in an arterial transducer line system. It also describes the criteria HSIB used to decide whether to go ahead with the investigation, and the methods and evidence used in the investigation process.

3.1 Notification of the reference event and decision to investigate

3.1.1 The Department of Health and Social Care contacted HSIB following a prevention of future deaths notice from a coroner's investigation into the death of Susan Warby (Courts and Tribunals Judiciary, 2020). The coroner's investigation was completed on the 7 September 2020 and concluded that the use of a solution containing glucose instead of saline contributed to the patient's death.

3.1.2 HSIB identified Keith as a man aged 66 years who experienced a similar patient safety incident while being treated in an NHS critical care unit. Although the event did not result in Keith's death, a similar sequence of events occurred and the same error was identified.

3.2 Decision to conduct a national investigation

3.2.1 HSIB conducted an initial scoping investigation which determined that the patient safety concern met the criteria for investigation (see below). HSIB's Chief Investigator authorised a national investigation.

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

Arterial transducer line systems are routinely used for patients admitted into the critical care environment. They are essential to ensure accurate and continuous monitoring of a patient's vital signs, which informs clinical decision making and the management of the patient's condition.

An arterial transducer line requires the use of a saline flush fluid to ensure the connecting tubes remain open. If an incorrect flush fluid containing glucose is used, the contamination of any blood sample taken from the arterial transducer line may falsely indicate that the patient has high levels of blood glucose. Subsequently, clinicians may judge that the patient is suffering from hyperglycaemia (high blood glucose) and deliver treatment in the form of an insulin infusion. This will reduce the patient's blood glucose levels causing hypoglycaemia (low blood glucose), which can cause fatal neuroglycopenic brain injury (Association of Anaesthetists of Great Britain and Ireland, 2014).

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

A review was performed of the National Reporting and Learning System (NRLS) (a database of patient safety incidents reported by the patients, the public and healthcare professionals in England and Wales) (see appendix 1). A search was undertaken for historical incident data reported on and between 1 September 2016 until and including 31 August 2021, using the search term 'arterial' which returned 39,543 results. The search was filtered to focus on adults by removing those where the patient's age was reported to be aged 17 years or less. This returned 32,132 results. A total of 447 relevant reports involving the wrong flush fluid were identified in this 5-year period. This supports the view that this remains a systemic problem and glucose is not the only incorrect flush fluid that might be used; reports also included the use of water for irrigation, mannitol (used to manage tissue swelling) and potassium chloride infusion (used to replace potassium in the blood).

Patel et al (2020) suggest that despite multiple recommendations and guidelines, cases of incorrect treatment of falsely elevated blood glucose levels from arterial line blood sampling continues to occur. Patel et al reports data obtained between 2005 and 2015 from the NRLS, which recorded 299 incidents of this type of error. The investigation completed a similar analysis of the data between 1 September 2020 and 31 August 2021 and concluded on average there was an increase in the number of incidents reported per year between 2005 and 2021. This may be due to an improved culture of reporting these incidents. However, of note there were more episodes of hypoglycaemia reported in the detailed analysis between 1 September 2020 and 31 August 2021 than reported between 2005 and 2015 (18 compared with 6 respectively) (**see appendix 1**).

A survey of UK adult critical care units in 2013 highlighted 30% reported errors involving the use of glucose solution attached to an arterial line (Gupta and Cook, 2013). This suggests a greater number of incidents may be occurring than formally reported.

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

Despite safety alerts (National Patient Safety Agency, 2008a), academic reviews (Patel et al, 2020; Gupta and Cook, 2013) and national guidance (Association of Anaesthetists of Great Britain and Ireland, 2014; Medicines and Healthcare products Regulatory Agency, 2014a), the risk of harm and fatal brain injury caused by low blood sugar levels, associated with the use of the wrong flush fluid with arterial lines, continues to exist.

The existing body of evidence concludes that engineered solutions and national changes need to be considered to address this safety risk. There have been many attempts for improvement which include training, procedures and modification to the task of blood sampling. These have been unable to avoid ongoing harm and in some cases contributed to patient death (Association of Anaesthetists of Great Britain and Ireland, 2014) (Gupta and Cook, 2013), (Patel, et al, 2020).

HSIB has explored the reference event to consider the potential for existing safety measures to manage the risk associated to the wrong flush fluid being used with arterial transducer line systems. HSIB has identified that a national investigation would be beneficial to understand and learn how, despite a focus on the improvement of this issue, patient harm continues to occur.

3.3 Evidence gathering

3.3.1 The investigation was completed between March 2021 and March 2022.

3.3.2 The investigation was delayed in starting as it took account of the ongoing demand and effect of the COVID-19 pandemic on NHS critical care resources.

3.3.3 The HSIB investigation team included the following expertise:

- healthcare leadership
- healthcare investigation
- human factors and systems engineering
- clinical subject matter advisors.

3.3.4 The investigation collated and reviewed evidence from Keith's family, clinical staff from the reference event Trust, and staff supporting the storage and procurement of supplies for the critical care unit. Information sources included:

- patient medical records
- interviews with Keith's Wife and three daughters
- interviews with staff who cared for Keith at the time of the incident
- interviews with operational staff supporting the critical care unit
- interviews with staff in governance roles and involved in the Trust's internal investigation into the incident.

3.3.5 The adult critical care unit was observed to understand the layout and physical characteristics of the environment in which Keith was cared for. This provided the opportunity to observe the storage of arterial transducer line equipment and fluids, and Trust staff demonstrated how an arterial transducer line would be set up, checked and recorded in the medical records.

3.3.6 Stakeholders with national influence on the safe management of arterial transducer lines were identified. These stakeholders informed the investigation team on the current level of safety and potential terms of reference for a national investigation.

3.3.7 A period of engagement with relevant stakeholders included one-to-one conversations with representatives of pharmacy and clinical professional bodies along with commercial and national organisations. These conversations ensured representation of the professional colleges and regulatory bodies with the greatest influence and knowledge of arterial transducer line systems in the UK.

3.3.8 Three workshops were held to facilitate discussions on recognised safety issues and the implementation and reliability of safety controls. These considered where future controls should be focused. **Appendix 2** summarises the organisations present at the workshops. The final workshop focused on where HSIB safety recommendations could be directed to increase future safety of arterial transducer line systems.

3.4 Methods used to analyse the evidence

HSIB adopts a no-blame approach to all investigations. The healthcare system is considered in its entirety, including the equipment, physical space, tasks, human capabilities, organisational culture, to understand the factors most likely to have contributed to the outcome. The analysis of the data collated considers principles and evidence relevant to the science of design, engineering and psychology and relies heavily on the safety science of human factors. This section describes in more detail how the investigation was carried out.

3.4.1 Before completing interviews or a site visit, the investigation team familiarised themselves with the equipment and task of attaching an arterial line and the necessary flush fluid. Relevant HSIB clinical staff were interviewed to walk through the task and training videos were consulted. This informed the development of a hierarchical task analysis to assist the investigation (Kirwan and Ainsworth, 1993). The investigation undertook interviews and observations at the Trust to understand how each task was completed, the equipment required and factors which may contribute to how staff complete the tasks.

3.4.2 The investigation team visited and interviewed Keith's family to understand their recollection of events and perceptions of the incident.

3.4.3 The combination of family and staff interviews informed the development of a timeline for the reference event. The timeline was verified and added to following a review of electronic documentation.

3.4.4 The investigation process was iterative; as further information was gained, additional interviews or data sources were identified.

3.4.5 Interview and observation data were either digitally recorded or notes taken, which were then thematically coded and analysed, based on the Systems Engineering Initiative for Patient Safety (Carayon et al, 2006). This informed the investigation of the factors interacting and contributing to the outcome from the wrong flush fluid being used.

3.4.6 Several approaches were applied to the analysis of the evidence to consider a top-down perspective of the wider system. Finally, analysis was completed to understand how the context of the adult intensive care unit influenced the reliability and accuracy of tasks required to set up and take a blood sample from the arterial transducer line. This analysis was based on the Systematic Human Error Reduction and Prediction Approach (SHERPA) (Embrey, 2014), completed with a clinical subject matter expert. The findings were visualised for sharing using a Bowtie analysis (Chartered Institute For Ergonomics and Human Factors, 2016). This described the threats to the safe use of arterial lines and the sufficiency of existing safety controls. This enabled a shared understanding across multiple stakeholders within the healthcare system to address the threats and develop safety recommendations.

4 Analysis and findings – the reference event

This section describes the investigation's findings in relation to the reference event.

The findings are described under three key headings to explain how factors in the wider healthcare system may have influenced the performance of staff and the delivery of Keith's care. These are: the organisational context and working environment, clinical care involving Keith's arterial line; and the influence of the design of equipment.

4.1 Organisational context and working environment

Organisational context relative to COVID-19 pandemic

4.1.1 The Trust provides adult critical care at two sites. Nursing staff are rostered to work at either site and are required to call on the day of their shift to find out which site they will work on. The adult intensive care unit (AICU) is the larger unit compared to the critical care unit (CCU). The incident occurred within the AICU. The AICU has 16 beds, and the unit is divided into three sections. Nurse 1, who admitted Keith, explained she was more familiar with working at the CCU.

4.1.2 In November 2020, the second wave of the COVID-19 pandemic was just starting in England. On the day of Keith's admission there were nine patients on the AICU and a further three admitted overnight. Acuity (a high number patients requiring a high level of care) was rated as high, and staff at the Trust reported that three night-time admissions were unusual.

4.1.3 The investigation heard that the COVID-19 pandemic had resulted in several months of high levels of workload for staff. A senior nurse explained there had not been enough of staff to accommodate the need for staff to isolate if they were in contact with or confirmed as having COVID-19. Subsequently, staff not affected by COVID-19 were encouraged to work additional duties. The investigation heard that generally staff were suffering a certain degree of burnout and fatigue, with breaks not always protected, and a greater reliance upon bank (temporarily contracted) staff was necessary around the time of the incident.

4.1.4 Before the pandemic, the Trust had found it a challenge to ensure nursing staff were consistently available with the correct skill sets to cover all shifts. COVID-19 had exacerbated this staffing issue further.

Staff wellbeing and fatigue

4.1.5 The investigation explored staff wellbeing and the Trust's approach to the managing the risk of staff fatigue. Appendix 3 summarises the typical shift patterns and hours of work for some staff involved in the incident. This suggests examples of staff completing regular shifts and then being rostered on to complete additional bank shifts during scheduled days off. In the month of November 2020, this included a member of staff completing seven consecutive 12.5-hour night shifts. In some weeks there were examples of staff working consecutive weeks of 87.5, 70 or 62.5 hours. Cumulative fatigue and extended periods of being awake are both well recognised as influencing human performance including memory recall and attention to information (Dawson and McCulloch, 2005).

4.1.6 Nursing staff said that both night and day 12.5-hour shifts were often started earlier or finished later; therefore, typically these became 13.5-hour shifts. These additional hours are unpaid unless a specific request is made and felt necessary by staff to ensure the effective sharing of information between shifts. The working time directive states a worker should not exceed, including overtime, an average of 48 hours for each 7-day period. They also should not exceed 8 hours of nightwork within 24 hours. The duration of working hours is calculated as an average over 17 weeks (The Working Time Regulations, 1998).

4.1.7 The investigation spoke with the AICU wellbeing lead. They recognised the Trust's approach to managing staff fatigue was reactive, which had become increasingly apparent during the COVID-19 pandemic. This finding was reiterated by a member of staff who suggested a reluctance to highlight fatigue to senior staff at the risk of being perceived badly. They suggested that knowledge on the impact of fatigue and the need to report on fatigue was not well understood. This reflects the wider NHS culture which is highlighted in a recent publication by the Royal College of Nursing, which quotes the Health and Safety Executive recommendation to avoid shifts longer than 8 hours and where 12-hour shifts are implemented these should be limited to three consecutive shifts (Royal College of Nursing, 2021). This report recognises the risk associated with staff fatigue to both patient safety and staff wellbeing. There is currently no regulatory requirement to prevent excessive working hours for nursing staff.

4.1.8 The rostering of shifts, in the context of the recent COVID-19 pandemic, was described as challenging by staff at the Trust. Senior staff are made aware of the availability and competence level of nursing staff through the IT rostering system. This enables senior staff to create a staff roster and to cover AICU duties that can fall outside of the working time directive.

4.1.9 The Trust and NHS Professionals (NHSP) (a service that contracts with staff who are often already employed within the organisation) agreed over the winter period to offer a financial initiative for staff; on completing five shifts with NHSP they would be paid for six. This may have had the unintended consequence of encouraging a norm where staff work a high number of hours. The IT system is limited in its ability to alert managers when staff are working excessive cumulative hours across shifts completed through the Trust and NHSP. Senior nursing staff suggested the only time they may look at an individual's historical shift pattern was retrospectively, if staff showed signs of fatigue or reduced levels of performance. There were various factors behind staff members' motivation to work additional shifts. Some staff suggested a concern for their peers and patients if a shift was inadequately staffed; others highlighted the high cost of living in the local area and a need to increase their earnings.

4.1.10 The investigation found there had been a normalisation and acceptance of staff working extended shifts and additional hours during the start of the COVID-19 pandemic. The concept of fatigue management is yet to become an established process in healthcare, as applied in other industries (International Civil Aviation Organisation, n.d.). Staff at the Trust reported that the current approach to managing NHS staff wellbeing was not prospective in managing the associated risk of fatigue.

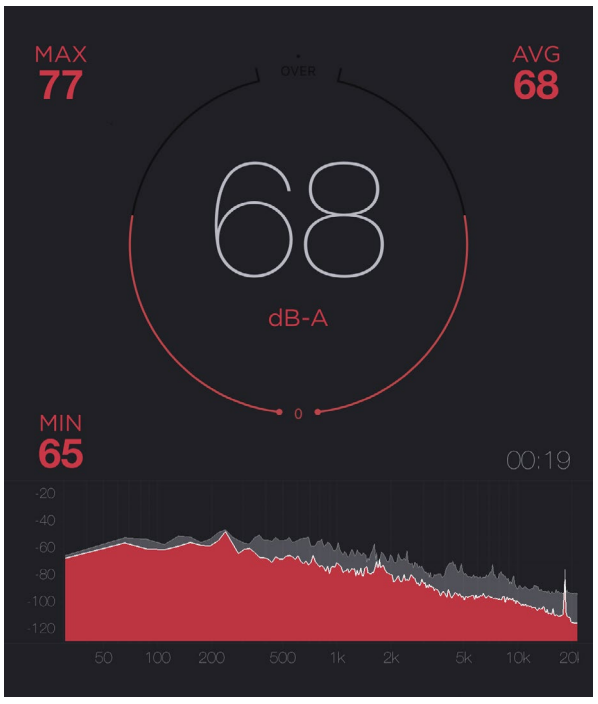
Physical characteristics of the clinical environment

4.1.11 Many of the staff interviewed reported that the AICU bedspaces and the physical environment were noisy, with poor lighting and insufficient space to work. The investigation heard terms used to describe the bedspace during the time of the incident as "messy", "cluttered" and "chaotic". The Trust is aware that due to the unit's age the physical design of the bedspaces does not comply with the existing recommendations (Department of Health, 2013). The investigation was shown plans for the new larger AICU currently under construction, intended to comply with these recommendations.

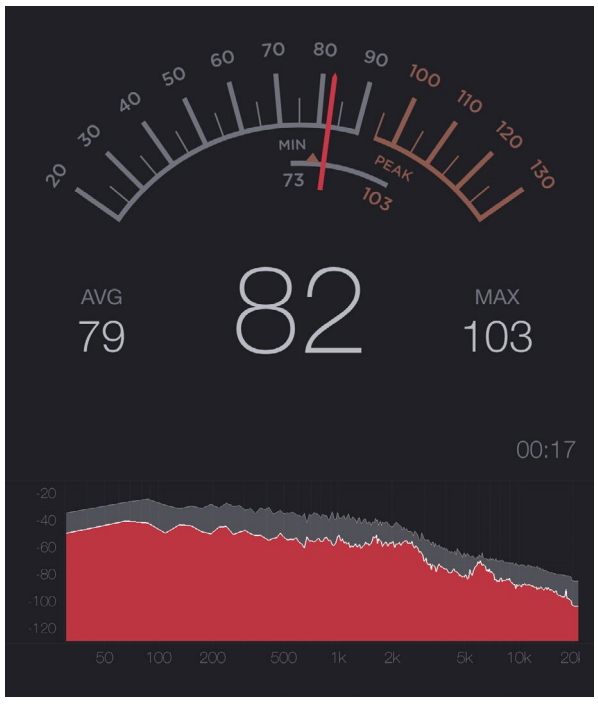
Noise

4.1.12 During the observation visit, the investigation noted high levels of background noise from an industrial-sized ventilation system. The ventilation system had recently been introduced in response to the risk of airborne infection recognised during the COVID-19 pandemic. This had the unintended consequence of making communication more challenging (made worse by the need for staff to wear face masks) and created a working environment that affected people's level of comfort and stress (see figure 4).

Figure 4 Additional ventilation system in the AICU and relative noise levels



Keith's bedspace area in the AICU



Bedspace directly next to ventilation in the AICU

Noise levels in the CCU

4.1.13 The level of noise within the AICU created challenges for patients, relatives and staff. Considering the Healthcare Safety Executive risk analysis of daily noise exposure (Health and Safety Executive, 2020), people exposed for 12 hours to the level of noise at Keith's bedspace have the potential to fall above the recommended noise exposure level. At a bedspace closer to the ventilation system a 12-hour exposure would meet this criterion. The Trust was alerted to these findings and completed its own risk assessment. In comparison, the level of noise in the CCU was much lower (**see figure 4**).

4.1.14 Keith's family highlighted to the investigation that Keith suffered with hearing loss and used a hearing aid. On their first visit to see Keith he immediately asked for his hearing aid.

4.1.15 The impact of remaining or working in prolonged high levels of noise includes stress and distractions, which may affect individual attention, judgement and decision making, which could contribute to increased errors (Institute of Occupational Safety and Health, n.d.).

Layout and storage of medication

4.1.16 The physical layout and storage of medication and equipment influenced the time and reliability with which staff collected the required equipment. Nurse 1 went to collect a bag of 20% glucose fluid from the drug cupboard. They looked for the appropriate bag of fluid but, unable to find the appropriate strength, they returned to the bedside with two 500ml bags of glucose fluid, one of 10% glucose and the other of 50% glucose. The investigation observed inconsistency in the way fluids were stored within the AICU and between the AICU and CCU, between which the staff rotated. A lack of standardisation in medication storage introduced a risk for staff to accommodate different layouts as they collect or return medication to the cupboards at two different workplaces.

4.1.17 The storage of medication is guided by the Trust's medicines management policy. The policy requires medication to remain in the manufacturer's original box until used. The investigation observed similar looking bags of fluids being stored closely together. Several staff described the risk of selecting glucose rather than saline due to their proximity in the storage area. In other units within the same Trust, staff explained that saline may be stored separately from other clear fluids as recognised by the Royal Pharmaceutical Society (Royal Pharmaceutical Society, 2018). As the infusion fluid box labels are not easy to read, or sufficiently different between products, additional coloured labels have been added to the storage shelves since this incident. The national best practice guidance suggests the need to risk assess the storage of fluids, with a need for 'clear quality labelling' (NHS England and NHS Improvement, 2021b).

4.1.18 The Trust staff, particularly pharmacy staff, clearly understood the risk and had considered storage of medications. However, staff told the investigation they were limited by the physical space available to them in the current AICU. This is due to be addressed with the construction of the new unit, but some staff felt there had not been an appropriate level of consultation on the storage space within the new unit to ensure medication safety.

4.1.19 The investigation spoke to non-clinical staff responsible for the ordering and restocking of the medications and all AICU equipment. They described how the COVID-19 pandemic had required additional storage space and reorganisation to accommodate the high level of additional supplies required. They expressed some concern relating to new responsibilities as they recognised that they had limited knowledge of the risks that could be created by the storage of medications and equipment.

4.1.20 The physical space, layout, and organisation of the existing AICU presented a challenge for staff to ensure the working environment minimised recognised risks. The design of the work and storage space presented a challenge for staff to facilitate the collection of the right equipment and medication at the right time.

4.2 Clinical care involving Keith's arterial line processes

This section considers factors that influenced how the team completed the work and activities required to manage Keith's deteriorating condition. This section will consider how opportunities arose for the incorrect flush fluid to be used at different points of Keith's care.

Management of Keith's admission to the AICU

Staff perceptions

4.2.1 Staff described Keith's admission to the AICU as an emergency as he was clinically very unstable. The description used by two clinical staff reflecting on Keith's admission was "firefighting", suggesting there were multiple simultaneous clinical challenges. The handover received on admission identified an urgency for staff to treat Keith's very low blood pressure. The need to insert an arterial line was prioritised by a consultant to enable effective blood pressure monitoring.

4.2.2 During Keith's admission there were at least five staff working around the bedspace, under time pressure to complete competing tasks to stabilise

his condition. Nurse 2 recalls offering assistance and took on the role of supporting the doctor with the insertion of the arterial and central line, to enable nurse 1 to continue to set up the bedspace and administer medication as required.

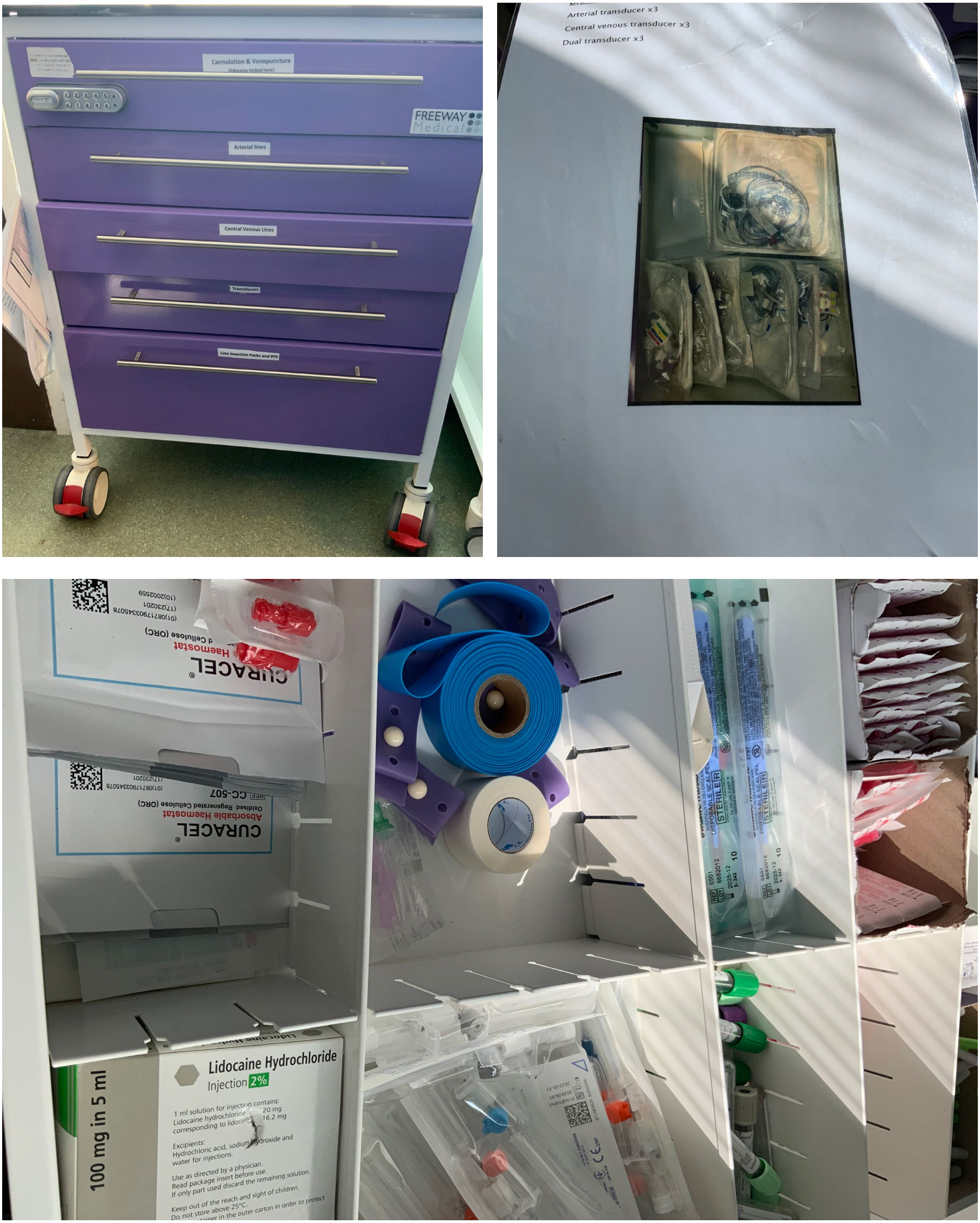
4.2.3 Nurse 1, who was allocated to receive Keith on admission, had been away from work for 5 weeks on leave and usually worked at the CCU. They were conscious of constant changes to the work environment in the AICU and had regularly checked their emails while on leave to keep up to speed with the changes. This was their first shift back and they also had the responsibility of supervising a nurse undertaking specialised training. These factors were described by nurse 1 to the investigation as creating feelings of being "overwhelmed". The lack of familiarity with staff and equipment storage systems (modified during the COVID-19 pandemic) were specifically identified as adding to their stress.

Setting up the arterial line

4.2.4 Nurse 2 was on duty as part of the NHS Professional bank service. Nurse 2 explained that setting up an arterial line was a daily task for them. They also described differences in the way equipment was stored compared with the work environments they were more familiar with; the CCU and operating theatres.

4.2.5 The storage of arterial line equipment in the CCU and operating theatre environment was suggested as being clearer and more consistent compared to the AICU. In the AICU it was described as regularly changing, with different types of stock being contained within the unit's three clinical areas. Both nurses reflected that this had improved since the incident, with allocated and labelled drawers (see figure 5) containing the arterial line equipment, except the flush fluid.

Figure 5 Lines drawer with drawer content labelled and visually presented



4.2.6 The doctor completed the insertion of the cannula, to start effective monitoring of Keith's deteriorating condition. Nurse 2 worked under time pressure to find a red arterial transducer line, which was not located where expected. The investigation heard that it was the responsibility of the care support workers (CSWs) (rostered on to a shift to support nursing duties) to ensure bedspaces were equipped with the necessary equipment. Nurse 2 explained to the investigation that the time pressure was associated with their concern about losing the patency (opening) of the cannula, which by now had been inserted by the doctor. They made the decision to connect the only available line, a blue venous transducer line, asking the CSW to continue to look for the correct equipment.

4.2.7 The investigation heard from doctors and nurses familiar with inserting arterial lines. The findings suggest there is variability in how the specific tasks of inserting, collecting and installing an arterial line is completed. Typically, there is an implicit understanding in AICU that the doctor will insert the cannula and the nurse will collect and connect the remaining equipment, including the checking and connection of the flush fluid. On some occasions or in different clinical areas the doctor may complete all the tasks.

4.2.8 The division and completion of different tasks by the different job roles placed a time pressure on the collection of equipment. This division of tasks spreads the responsibility for the reliability and safety of the whole task. The organisation of equipment and the organisation of the timing of the task across team members appeared to influence how the arterial line was set up. The process of connecting the transducer to the cannula and connecting a flush fluid had to be undertaken twice, as a consequence of the correct transducer set not being available at the time of the cannula being inserted.

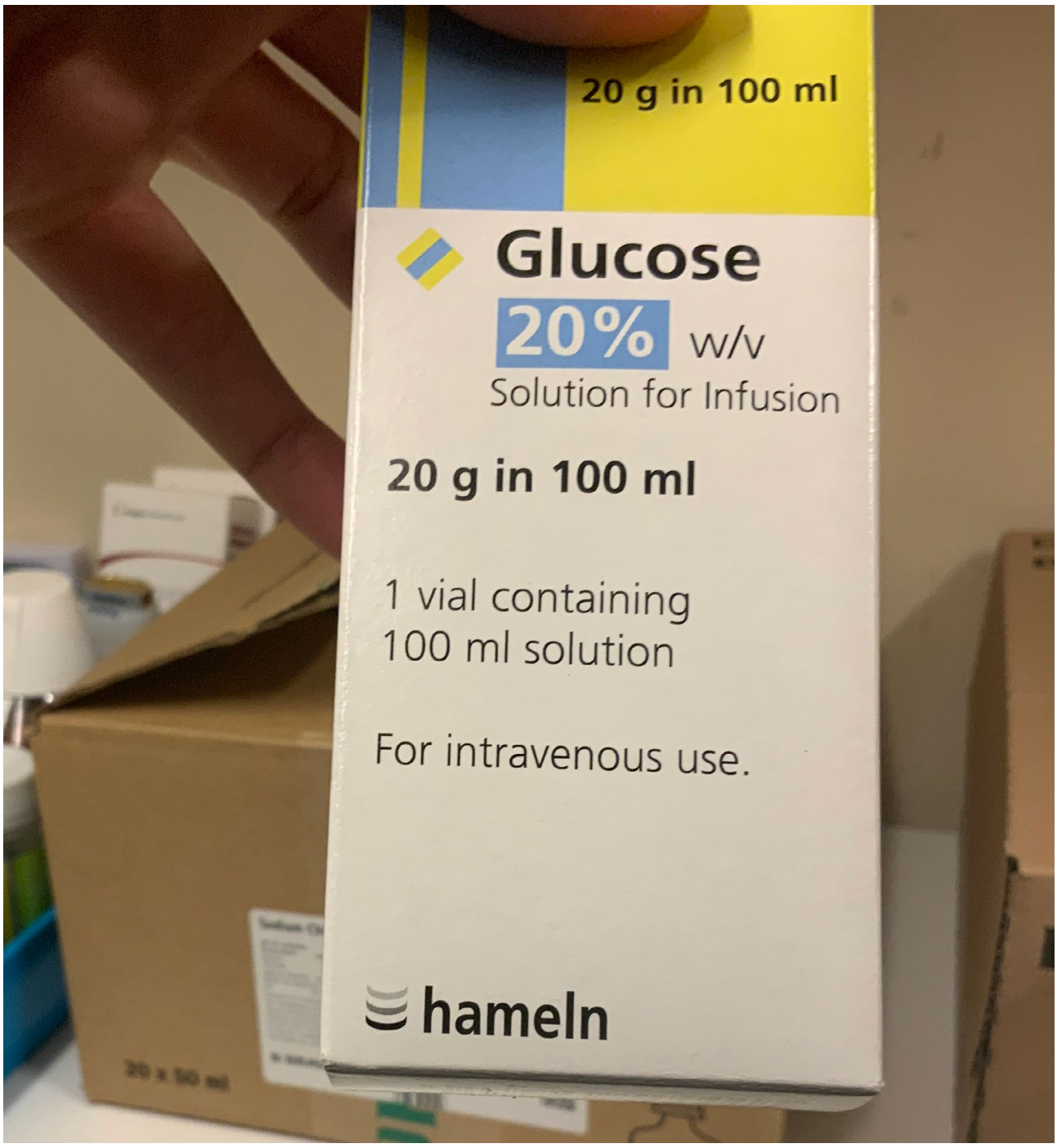
Management of episode of hypoglycaemia (low blood sugar)

4.2.9 At 16:24 hours, as the arterial line was being inserted, a blood test identified that Keith's blood glucose level was 3.4mmol/litre and he was diagnosed with hypoglycaemia. Nurse 1 spoke with the doctor and treatment with glucose was advised. The Trust policy for treatment of hypoglycaemia in adult inpatients depends upon the level of alertness of the patient. On every ward, including the AICU, there is a 'hypo box' which contains a 100ml vial (glass bottle) of 20% glucose and treatment would require the delivery of 75ml of the glucose as an infusion. Within critical care units, glucose is readily available to staff within the drug cupboard, hence staff explained to the investigation the 'hypo box' was never used. The location of the hypo box within the AICU reflected this, as it was stored at a far point of the unit obscured by equipment.

4.2.10 The nurse went to the drug cupboard to look for 20% strength glucose (see figure 6). They were only able to locate 500ml bags of glucose at 10% and 50% strength. The investigation heard from the critical care lead pharmacist at the Trust that the stock of infusion bags provided to the AICU only included 5%, 10% and 50% glucose strengths. An infusion of 20% glucose was only available in the AICU as a 100ml vial (glass bottle) (see figure 7). The investigation observed that such vials were stored on shelves opposite the bags of fluid, which nurse 1 would have had their back to when looking for glucose.

Figure 6 Shelves where infusion fluids are stored, including glucose and saline on separate shelves (labelling added after the incident)

Figure 7 100ml vial of 20% glucose stocked within AICU



4.2.11 The investigation visited the CCU, the other unit in which nurse 1 was more familiar with working. Due to the nature of CCU patients' healthcare needs, the investigation heard from the critical care lead pharmacist and later observed, that 500ml bags of 20% glucose were routinely stocked and stored in the CCU's drug cupboard (see figure 8). Four staff working in both the AICU and CCU were asked by the investigation how they would treat hypoglycaemia for their patients. All staff (of different grades and job roles) described the use of a 500ml bag of 20% glucose as an infusion. None suggested they would access the 'hypo box' or use the 100ml vial of 20% glucose. The use of a 500ml bag of 20% glucose was also described in the Trust's incident report as the accepted approach to managing hypoglycaemia on the AICU. A senior member of staff reflected that the current local hypoglycaemia policy does not reflect typical management of critical care patients, where intravenous access is easily achieved to deliver intravenous fluids.

4.2.12 The investigation found the accepted work practices within the critical care units were not reflected by the current local policy, evidenced by the AICU not stocking 500ml bags of 20% glucose. As nurse 1 did not find the glucose in the AICU drug cupboard in the form they expected, it appears they concluded it was out of stock, rather than looking for an alternative volume of 20% glucose. The nurse selected 10% and 50% strengths of glucose to bring to the bedspace to allow the doctor to select a suitable alternative. This suggests a mismatch between Trust staff tasked with developing safety policies and those providing the medication with those working every day in this clinical area.

Figure 8 500ml saline bags of 20% glucose stocked within CCU drug cupboard

Checking and recording of medication

4.2.13 At 19:30 hours the night shift nurse arrived and received a handover from nurse 1. This involved both nurses viewing Keith's record on the IT system. At the start of a shift this verbal handover would usually be followed by a walk around the bedspace with a visual check of all equipment and medication attached to the patient. This is supported by a safety checklist, which at the time of the incident did not include a reminder to check the arterial transducer line fluid; this has since been added. These visual checks were not completed by the night nurse until 22:00 hours and were also delayed the next morning at 09:00 hours. The IT system has two interfaces to record medications: the 'medication administration record' and 'flowsheet'. There were gaps and inconsistencies in how the arterial flush fluid was recorded and delays and incompleteness of the safety checks (**see figure 3** in section 2).

4.2.14 Keith's Wife arrived at about 19:00 hours. Keith's condition was deteriorating, and she recalls there was a lot of activity by staff around the bedside. The night nurse commenced the visual checks but was interrupted on several occasions. The interruptions were necessary to respond to Keith's deteriorating condition and the need for him to be intubated and for a nasogastric (NG) tube to be inserted; there were some challenges with putting the NG tube in the correct position. Further interruptions occurred when two new admissions were received onto the unit. The staffing levels on the night shift did not allow for a float nurse and the night nurse was required to support other nurses in receiving new patients. The night nurse described how multiple competing tasks and time pressures influenced the reliability of the checking and documentation completed. The intensity of the nurse's workload was commented on to the investigation by Keith's Wife and by one of the doctors arriving for the medical handover at 20:00 hours.

4.2.15 The delay of safety checks the following morning was also suggested to be a result of staff workload. The nurse on duty that morning had the additional responsibility of co-ordinating the staff and tasks within that section of the unit. This nurse did raise concerns that these additional responsibilities may not be compatible with providing the attention required by Keith due to the seriousness of his illness. They were informed that, because of a lack of additional senior nurses, there was no alternative.

4.2.16 Nursing and pharmacy staff described how the arterial flush fluid, although a relatively harmless fluid, is considered a medication and as such requires a prescription, which should be signed by clinical staff once they have completed safety checks: check of name and strength of medication on the bag, the expiry date, and the name of the patient for whom it is intended.

A collection of medications regularly given to patients in the AICU have automatically pre-populated prescriptions; this includes insulin and saline for a flush fluid. This reflects how frequently these medications may be given by either a nurse or doctor in a critical care setting.

4.2.17 One member of staff told the investigation that flushes may not be consistently signed for by clinical staff. There was a consensus across staff that the arterial flush was considered a "low-risk" medication, as its function is to maintain the patency of the arterial transducer line, rather than being therapeutic for the patient. Staff also suggested to the investigation there was a belief that there is a low probability of the flush fluid being incorrect. This suggests the awareness and perceived risk associated with the administration of the flush fluid may differ between staff.

4.2.18 Checking is often added as a safety measure in healthcare, without strong evidence to reflect its effectiveness in avoiding errors (Koyama, et al, 2020). The challenge of multiple checks being used as a reaction to a safety concern or incident was suggested to the investigation: "... you find a problem, so you add it to the checklist and the next thing you know your checklist takes you an hour." This was highlighted to explain how the duration of time required to complete long lists of checks may compromise the reliability and quality of checks. In this situation, the competition for the nurse's attention disturbed the sequence of checks. The checks the following morning, although again delayed, were successful in identifying 10% glucose as the flush fluid.

Blood sampling and management of hyperglycaemia (high blood sugar)

4.2.19 At 17:25 hours a blood test was completed from the arterial line and returned a blood glucose reading of 19.9mmol/litre. This inferred Keith had moved from a state of hypoglycaemia to hyperglycaemia. It was documented on the 'flowsheet' that an insulin infusion was started at 02:53 hours; this is not recorded in the 'medication administration record'. The initials entered in the 'flowchart', to indicate delivery of insulin, were not those of the night nurse and the investigation heard they were the initials of another AICU nurse, likely to be covering the night nurse's break. The last dose of insulin is recorded at 11:12 hours on the second day.

4.2.20 The treatment of hyperglycaemia in the AICU is outlined in a local protocol. This indicates that if a patient's blood glucose levels are above 8mmol/litre on two consecutive occasions then insulin should be started and blood glucose initially monitored hourly. Once blood glucose levels fall within the range of 4mmol/litre to 7mmol/litre then monitoring of blood glucose should be continued every 2 hours.

4.2.21 In Keith's case, five entries of blood glucose at a level greater than 8mmol/litre were recorded between 17:25 hours and 02:00 hours before he was given insulin. The investigation heard that a nurse spoke with one of the doctors who agreed to starting the insulin. Once the insulin had been started Keith's next blood glucose recording was at 05:17 hours and was below 8mmol/litre. The night nurse suggested to the investigation the intensity of the workload influenced the lack of blood samples taken as indicated in the protocol.

4.2.22 The first increase in blood glucose was from 3.5mmol/litre to 19.9mmol/litre between 16:24 hours and 17:25 hours. The investigation considered the significance in the size of the increase. Staff explained in hindsight this is "a big jump". However, this could be explained in response to the recent administration of 50% glucose and the deterioration of Keith's condition, as hyperglycaemia is a recognised response to sepsis in critical illness. Two further opinions from staff suggested that on reflection an episode of hyperglycaemia would be unusual in a patient with impaired liver function, which Keith had been diagnosed with.

4.2.23 The impact of the 10% glucose flush fluid in place was considered by the investigation. The investigation heard from staff that this can contaminate the blood sample taken from the arterial line to give an erroneously high level of glucose in blood test results. Reflecting on the significant change in Keith's blood glucose levels, a nurse and doctor both suggested that a capillary blood test would have been the only way to confirm whether this reflected a true record of Keith's blood glucose levels. Capillary blood tests are not usually undertaken for patients in the AICU because there is a high level of confidence placed on the reliability of arterial blood test results.

4.2.24 The combination of workload, the context of the AICU, where hyperglycaemia and the administration of insulin is common, and the result of the blood sample all influenced the decision to administer insulin to Keith. The risk of a contaminated blood sample was not suggested to the investigation as a likely consideration for staff, because of the familiarity of the pattern of events, namely a patient with severe sepsis becoming hyperglycaemic. This reflects a well-recognised approach and limitation to real-world decision making in the context of experienced people, where either information or time is limited (Kahneman and Klein, 2009). The absence of information to contradict the assumptions or 'mental model' held by an individual about a situation, may cause them to not consider alternative explanations for the information they are presented with.

4.2.25 An opportunity to identify the 10% glucose and its contribution to providing inaccurate blood glucose levels occurred when a blood sample was taken from another site on Keith's body. This opportunity arose when the temporary

renal dialysis line (central line for renal replacement therapy) was inserted by a doctor and, although it was not standard practice, the nurse offered to test the blood the doctor had removed during the procedure. The doctor told the investigation that they were mindful that they were at the end of their first night shift and aware of the level of fatigue they were experiencing. They explained to the investigation that moving to a nightshift can make it difficult to sleep the day before, so by 07:00 hours they estimated they may have been awake for almost 24 hours. Remaining awake beyond 17 hours has been demonstrated to reduce performance levels to those seen in a person at the legal blood alcohol limit for driving (Dawson, 1997). The doctor's awareness of their fatigue motivated them to adopt a high level of vigilance to their tasks and they agreed to the blood tests to be sure the temporary renal dialysis line was positioned in a vein. The blood test result was read with the motivation to check the oxygen level and this reduced the attention given to the remainder of the results by either the doctor or the nurse.

4.2.26 The situation and reason for the blood test being taken, combined with how the blood results were presented was not sufficient to alert staff to the significance of blood glucose being outside the expected range. Staff fatigue may also have reduced the amount of attention given to all the available information.

4.3 Equipment and design issues

This section considers how the design of the equipment used within the AICU influenced the reliability of the use of the correct flush fluid and potential opportunities to identify the use of the incorrect flush fluid.

Arterial line system

4.3.1 The Trust told the investigation that open arterial line systems (**see figure 2** in section 1) are used within the AICU. The pressure infusion bag used was opaque on one side, which obscured the flush fluid bag's label (**see figure 9**).

Figure 9 Opaque pressure bag (facing forward and away)

4.3.2 Pressure bags with different designs were used in the AICU. Several types were observed during the investigation (see figure 10), with only one type providing full visibility of the flush fluid bag label. Since the incident the Trust had removed pressure bags that obscure the label. The investigation observed this was difficult to control as patients arrive from other parts of the hospital with different pressure infusion bags. Staff told the investigation that once the flush fluid was in position some pressure infusion bags made it difficult to read the label and notice an incorrect flush fluid. They explained to the investigation that the lack of distinct labelling may also contribute to the selection of the wrong fluid.

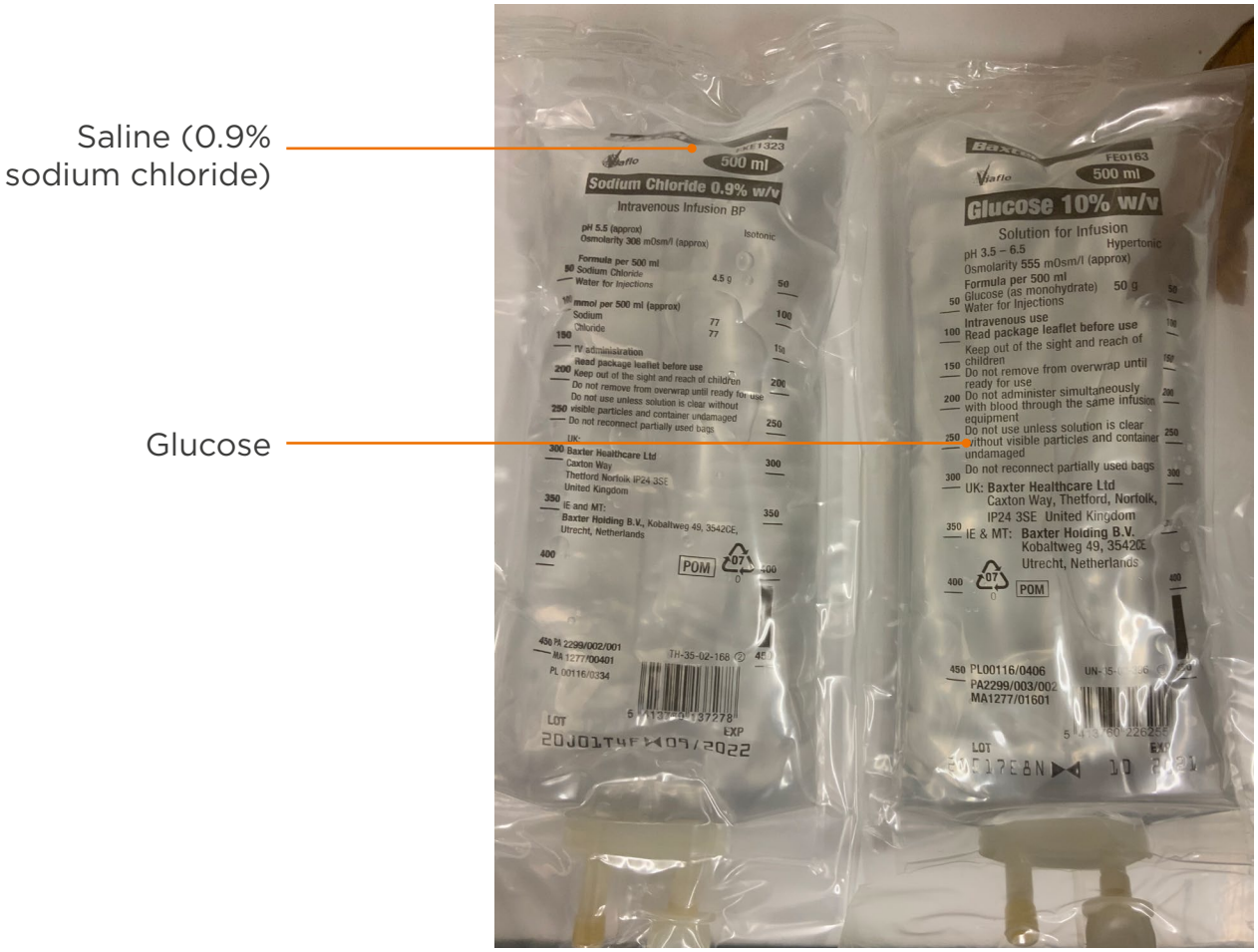
Figure 10 Selection of pressure infusion bags, only one of which ensures full visibility of its contents

4.3.3 The labelling of medication is a recognised problem in healthcare, with packaging that looks similar for different medication types or strengths, making it harder to avoid the risk of medication errors (Medicines and Healthcare products Regulatory Agency, 2020a). The Medicines and Healthcare products Regulatory Agency (MHRA) best practice guidance on labelling of medication highlights the prominence of critical information. This includes:

- text style and size
- colour used
- space on packaging
- use of graphics.

4.3.4 The similarity between the bag of saline fluid and the one containing glucose (see figure 11) influenced the incorrect selection and identification of the bag of 10% glucose at the bedspace. Education and checking by healthcare staff are the current safety controls to manage the risk created by packaging design (**see sections 5.3.13 to 5.3.18**).

Figure 11 Similarity in packaging design



4.3.5 Once the incorrect fluid was in place, the risk of contamination with glucose of a blood sample became likely and increased the risk of staff concluding Keith was hyperglycaemic. AICU staff education advises on the need to accommodate this known risk in the design of arterial transducer line. This informs staff to remove a certain volume of blood (**see section 1.3.6**) from the line before taking a blood sample. Education is often used as a safety control to compensate for the procurement or design of equipment with a known safety issue. Designing safety into equipment is recognised as a more sustainable and effective approach, particularly in the context of a task with the potential for a high level of harm (Karsh, et al, 2006).

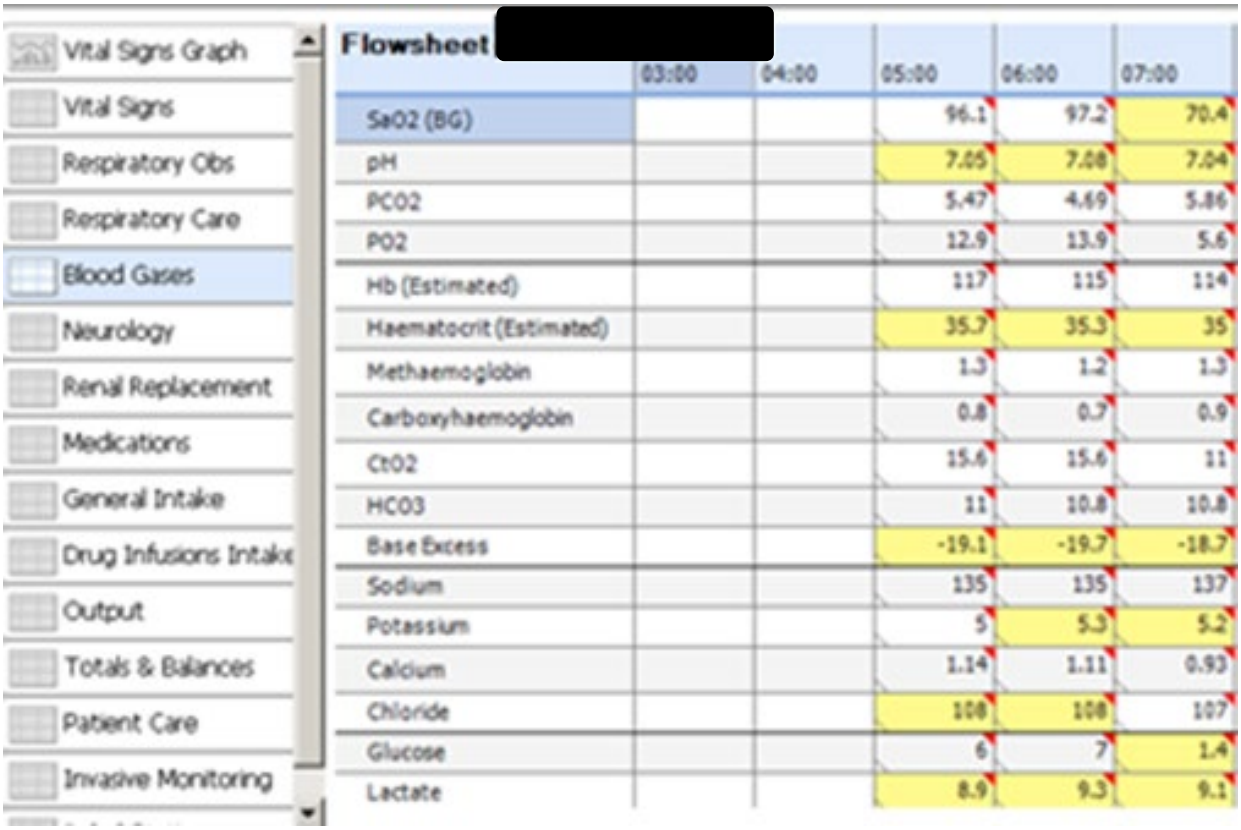
4.3.6 The impact of using the wrong flush was compounded by the use of an 'open' arterial transducer line system. Blood sample contamination with glucose is a known risk and the safety controls became compromised by time pressure and high workloads. The reliance on arterial blood sampling to monitor blood glucose impeded earlier identification of the reason for Keith's blood glucose results.

Presentation of clinical information

4.3.7 The IT systems relied upon by staff to record clinical information have two key functions; to record the delivery of care and medication and to present information to inform clinical decision making. The design and layout of information may influence how visible critical information is, the inferences made from the information and level of alert provided to the clinician. The investigation found that the current design of information relied upon by staff does not facilitate the interpretation of, or convey the significance of, clinical information.

4.3.8 The investigation found episodes where Keith's blood glucose levels increased significantly and then remained high for extended periods of time. Two members of staff commented on the presentation of this information; they suggested that the current interface does not "capture attention". Any finding from a blood test that is outside of an expected range will be highlighted in yellow. The critically ill patient in the AICU may have many readings outside of this range and staff described being presented with "a sea of yellow" (**see figure 12**). The use of colour is a recognised approach to designing alerts in IT systems. However, the ability of the system to draw the clinician's attention to information and flag the need for urgent action is also a requirement of IT interface design (International for Standardisation Organisation, 2021).

Figure 12 The clinican's view of the blood gas results



4.3.9 Good interface design should apply the principles of how people process information to increase attention and reduce the demand on the user's memory, while enhancing the interpretation of information to inform clinical decision making. This can assist in the display and organisation of information to optimise sense making and minimise identified risks (International for Standardisation Organisation, 2021).

4.3.10 The investigation found inconsistencies in the presentation of information and initials within the IT system. This suggested variability in the recording of second checks of the flush fluid. There are two interfaces within the IT system to record the delivery of medication; signing on one screen to indicate a medication has been delivered as prescribed does not automatically populate the other screen. Signing for the same medication twice, in the context of a high workload, was not consistently adhered to. The IT system requires staff to record the presence of an arterial line. The system does not alert staff to the contradiction in the entries made across the two interfaces. For example, if an arterial line is in place and a saline flush has not been signed for there is no alert to warn staff of this omission and prompt the need to check and sign for the flush fluid in the medication section.

4.3.11 The impact of the presentation of information was not limited to the IT system. The blood test completed during the insertion of the temporary renal dialysis line was an unforeseen opportunity to alert staff to a significantly low blood glucose level. Levels significantly outside of the normal range were not emphasised within the paper blood gas report.

4.3.12 The design and functionality of the IT and paper-based systems do not support staff to reliably complete documentation, prompt critical changes in information, or minimise the risk of omitting checks in the context of the care of a critically ill patient.

5 Analysis and findings – the wider investigation

This section describes the investigation's findings which focused on understanding the safety issues relating to the selection of the correct flush fluid (saline also known as 0.9% sodium chloride) and the taking and interpreting of a blood sample from a patient using an arterial transducer line system. The investigation focused on the care of adults within a critical care context but recognised that critically ill patients may be moved to, or received from, other areas, for example the emergency department and operating theatres.

The investigation's findings are presented in three key areas to explain the existing risks and the implementation and effectiveness of nationally used safety controls. This includes a summary of the reported evidence on the related safety issues from national and professional bodies, the understanding from the reference event and the findings from three stakeholder workshops.

5.1 Reporting on wrong flush fluid incidents

Medicines and Healthcare products Regulatory Agency (MHRA)

5.1.1 The MHRA is the regulatory body responsible for the safe and effective use of both medication and medical devices in the UK. It operates the 'Yellow Card' reporting system which collects and monitors voluntarily reported information (by health professionals and/or patients) on suspected safety concerns with healthcare products.

5.1.2 The investigation asked the MHRA for details of any Yellow Card reports associated with the use of the wrong flush fluid used with an arterial line. The MHRA responded following a search of its database between 1 September 2020 until and including 31 August 2021. This did not identify any reports relating to the investigation.

5.1.3 The investigation identified several considerations regarding the reliability of using the National Reporting and Learning System (NRLS) (**see 3.2.1**) and MHRA Yellow Card reports to establish the frequency of incidents and associated level of harm. These are:

- There is variability in how information is entered into the systems and therefore how it can be searched and reported.
- It is mandatory to report serious incidents, but voluntary for other patient safety incidents (NHS England and NHS Improvement, 2021a).

- Yellow Card reporting by the public and healthcare professional is promoted but reporting is not compulsory.

- Medical device manufacturers are obliged to report certain types of incidents directly to the MHRA; this is influenced by the robustness of their post-market surveillance processes (the monitoring manufacturers are required to undertake to evaluate the safety and performance of their products).

- The number of reports submitted reflects the reporting culture, not how often incidents happen (NHS England and NHS Improvement, 2021a).

- Reporting rates were lower during the COVID-19 pandemic (NHS England and NHS Improvement, 2021a).

5.1.4 The absence of reports on medical devices or medicines through the Yellow Card reporting system has been highlighted as an issue in previous HSIB investigation reports (**Healthcare Safety Investigation Branch, 2018**) (**Healthcare Safety Investigation Branch, 2019**). Issues relating to staff awareness and effective communication with manufacturers have been highlighted in a recent study (Tase et al, 2022). This study indicates that evaluation of the risks related to medical devices does not consider the actual environment and context in which they are used, and recommends improvements in medical device reporting and the communication between end users and manufacturers.

Investigation survey

5.1.5 The investigation was aware that the reporting system may not reflect the likelihood of the risks associated with blood sampling from arterial lines. Furthermore, in the context of the COVID-19 pandemic the safety concerns may have changed. Two professional bodies, the British Association of Critical Care Nurses and College of Operating Department Practitioners, offered to issue a brief anonymous electronic survey to their membership in December 2021. The survey included questions on whether staff had experienced, or were aware of, the selection and use of the wrong flush fluid in an arterial line, the likelihood of this happening and the consequences of taking a blood sample from the arterial line when an incorrect flush solution had been used.

5.1.6 Replies were received from 138 members, 101 (73%) of whom had experienced or heard about incidents with the wrong flush fluid being used within an arterial line. Several respondents commented that this “occurs only infrequently”. It was recognised that the consequences of taking a

blood sample from the arterial line when the wrong flush fluid was used may lead to false results and inappropriate treatment decisions. Some commented that the sampling method should minimise contamination from the flush fluid.

5.1.7 Where a solution containing glucose had been inadvertently used, respondents reported the actual impact on the patient ranged from none, as the wrong fluid was found before it was used, through to insulin treatment initiated for hyperglycaemia and the death of patients.

5.1.8 There was a wide range of responses about the likelihood of selecting and using a wrong flush solution in the arterial line. These included:

- "Quite likely, the bags are stored together, look similar and packaging is similar."
- "Should be unlikely but it does happen."
- "This is rare, but an ongoing potential hazard on a daily basis."

5.1.9 Staff highlighted the importance of taking a systemic view of the risk, especially the impact of contextual factors such as the COVID-19 pandemic. Staffing numbers and the impact on the ratio of qualified nurses available on a unit were thought to influence the reliability of checks.

HSIB makes the following safety observation

Safety observation O/2022/179:
It may be beneficial to recognise that safety risks are not reliably reported and therefore that the likelihood and level of harm may not be accurately reflected through existing reporting systems.

5.2 Known risks relevant to blood sampling via an arterial line

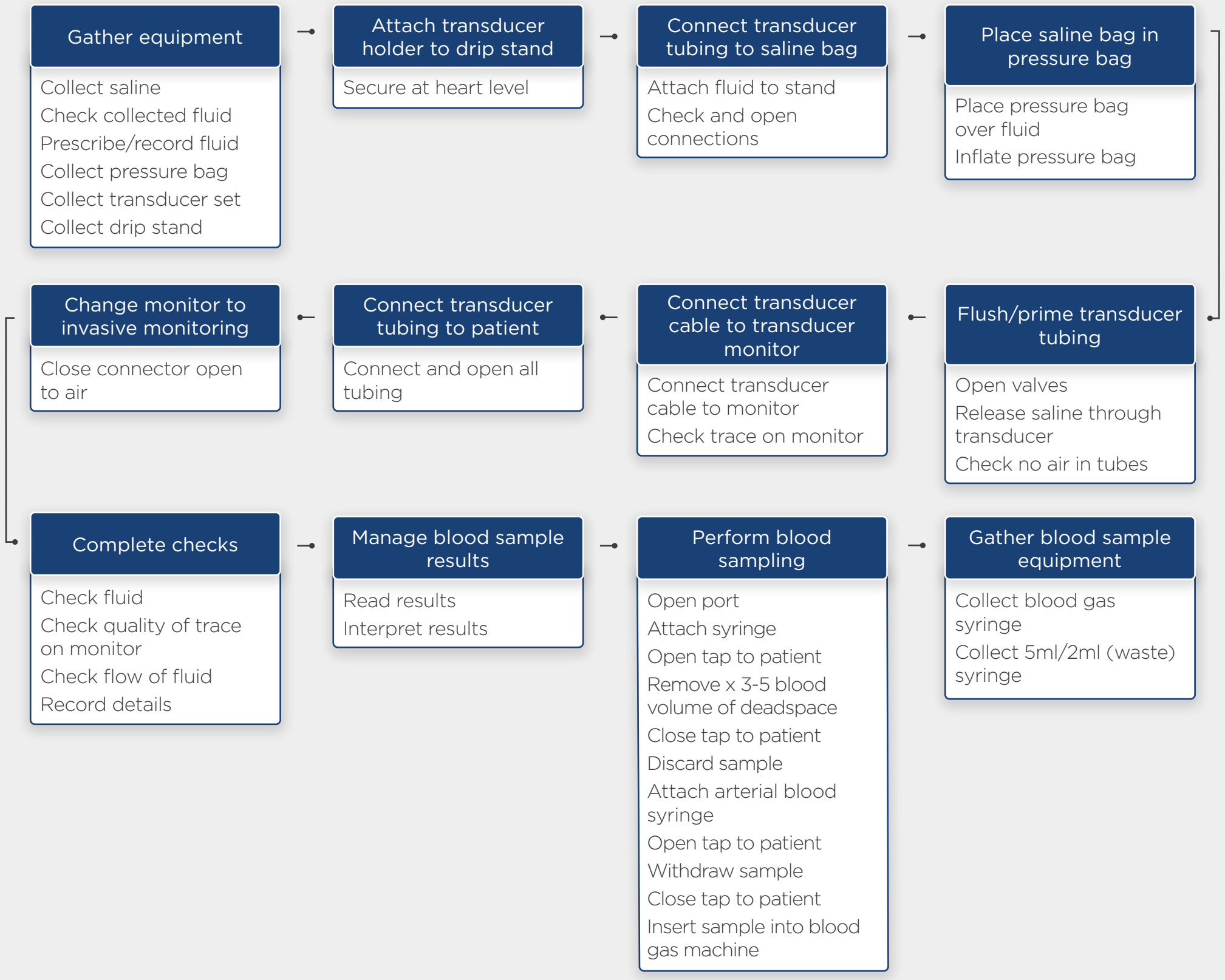
5.2.1 The investigation explored the known risks associated with the tasks required to set up an arterial line and take a blood sample. The investigation also sought to analyse the robustness of existing safety controls to manage these known risks.

5.2.2 A high-level task analysis was completed based on expert descriptions and observations of the setting up and taking of a blood sample from an arterial line (see figure 13). This high-level and simplified description of tasks was used to further analyse why the task may influence patient safety. The method used for this further analysis was based on the Systemic Human

Error Reduction and Prediction Approach (SHERPA) (Embrey, 2014). This approach considers how the contextual factors identified from the reference event, literature (**see 1.4.3**) and the survey completed by two professional bodies may influence human performance. SHERPA facilitates consideration of how systemic factors influence the reliability of each task. An example of the detail obtained from this method can be found in **appendix 4**.

5.2.3 The investigation also heard from stakeholders about the challenges associated with the implementation of safety controls relevant to arterial lines. The following sections summarise the evidence on the risks already known.

Figure 13 High level task analysis for setting up an arterial line system and taking a blood sample



Setting up the arterial line system

5.2.4 It has been well recognised that medication packaging can have an impact on the selection and subsequent use of the wrong medication (National Patient Safety Agency, 2008b). The National Patient Safety Agency (NPSA) report acknowledges that injectable medication, including medication delivered in infusion bags, is particularly susceptible to error. The NPSA report made several recommendations for the presentation of written information on bags of fluid. The investigation reviewed the current design of fluid labelling and concluded these do not reflect the NPSA recommendations (National Patient Safety Agency, 2008b), which include:

- placement of key information, for example the name of the medication, at the bottom of the bag close to the attachment of tubing
- varying elements of the design to enable differentiation between similar products
- judicious use of colour for high-risk infusions
- where colour can't be used, varying the presentation of text and using graphic components, for example the medication name within a shape
- medication storage boxes should be clearly labelled on three sides and judicious use of colour for highlighting information.

5.2.5 A more recent review by the Department of Health and Social Care into reducing medication-related harm still highlights the need to work with industry and the MHRA to 'develop solutions' to reduce the risk associated with 'look-alike sound-alike drugs' (Department of Health and Social Care, 2018). Furthermore, the coroner's report into the death of Susan Warby concluded that future deaths 'could occur unless action is taken' on the lack of distinctive labelling of fluids intended for use with arterial lines (Courts and Tribunals Judiciary, 2020). A response by the MHRA to the coroner's report explains why colour cannot be used to support correct identification in fluid bags. However, the response does not address any other potential design solution and indicates risk mitigation must therefore 'be employed locally within clinical areas' (Medicines and Healthcare products Regulatory Agency, 2020b). Guidelines and a recent study both present alternative designs, which do not rely on colour, to increase the visibility of labelling with the intention of reducing selection errors (Lusk et al, 2022; National Patient Safety Agency, 2008b).

5.2.6 The storage of bags of flush fluids was identified as contributing to the outcome in the reference event (**see 4.1.16 to 4.1.20**). The risk that storage plays in the ease of selection of intravenous fluids from working environments and storerooms had been previously recognised by others (Association of Anaesthetists of Great Britain and Ireland, 2014; Gupta and Cook, 2013; National Patient Safety Agency, 2008a). The investigation heard that often little attention is given to the adequacy of storage for large volumes or to the inherent risks in infusion products in critical care units. 'Health building notes' provide best practice guidance on the design of healthcare spaces. These were considered for the storage of infusion products in critical care areas, but provide limited information on how healthcare storage environments can be designed to support safe selection of these products (NHS England and NHS Improvement, 2021b; Department of Health, 2013). Guidelines for the provision of intensive care services highlight that issues remain relating to adequate storage space, despite new critical care units being built (The Faculty of Intensive Care Medicine and Intensive Care Society, 2019).

5.2.7 The availability of pressure infusion bags that obscure the labelling on the flush fluid bag, as seen in the reference event, reduces the opportunity to identify an incorrect flush fluid. The use of non-transparent pressure infusion bags has been previously raised as a safety issue (Association of Anaesthetists of Great Britain and Ireland, 2014; Gupta and Cook, 2013; National Patient Safety Agency, 2008a). However, a recent small simulation study suggested that even with a transparent pressure infusion bag the label may still not draw the clinician's attention and lead to the identification of an incorrect bag (Patel et al, 2020).

5.2.8 Staffing and caseload have been suggested as influencing adherence to local procedures that recommend checks (Gupta and Cook, 2013). The investigation found from the reference event and subsequent SHERPA analysis that the workload, staff availability and levels of fatigue within the team influenced the likelihood of safety checks being completed. These findings reflect the current concern within healthcare, where checking forms the main safety control relied upon to manage known risks (Koyama et al, 2020). The robustness of checking to ensure the safety of arterial flush fluids is a well-established problem (Association of Anaesthetists of Great Britain and Ireland, 2014; Gupta and Cook, 2013; National Patient Safety Agency, 2008a).

HSIB makes the following safety observation

Safety observation O/2022/180:
It may be beneficial to recognise that workload and fatigue will influence the reliability of safety controls dependent on staff time and attention.

Prescribing and recording

5.2.9 In 2008, the NPSA highlighted the need for assurances of the prescription and checking of infusion fluids (National Patient Safety Agency, 2008a). The investigation of the reference event and evidence from pharmacy and clinical professions suggested that when patients are admitted to critical care units, prescriptions may be pre-populated in electronic prescribing systems. The investigation heard from stakeholders that Trust audit data suggests these prescriptions are not consistently signed when a flush fluid is administered.

5.2.10 To prescribe medication requires a qualified member of staff to document the type, strength, route of delivery and frequency of a medication. Currently the NHS has both paper and electronic systems and signing of a prescription on administration of a medication is a legal requirement. The SHERPA analysis highlighted factors influencing the reliability of the checks or signing of the prescription. These included a perception of the low risk of the flush fluid to the patient and a conflict in tasks due to time pressures associated with administering treatment to a critically ill patient.

5.2.11 Saline is used as an 'off-label' medication for use as a flush fluid. This means that it is used in a way that differs from the use for which it was authorised (Medicines Healthcare products Regulatory Agency, 2014b). This potentially increases the risk since it means that the MHRA has not examined the risks or benefits of using the medication in that way. Off-label prescribing remains acceptable if there is no suitable alternative and use is in accordance with the body of respected medical opinion. Manufacturers cannot advertise or recommend that medication is used in any way other than that specified in its licence. The MHRA monitors the safety of medication including off-label use via the Yellow Card reporting system.

5.2.12 The current off-label use of saline for an arterial flush fluid suggests that manufacturers do not have responsibility for the risk incurred for this use. This transfers the risk to the healthcare system; however, when this becomes an accepted practice healthcare providers may not know of the risk and subsequently may not mitigate for it.

Taking a blood sample

5.2.13 The design of transducer systems – that is, whether they are open or closed – influences the likelihood of blood sample contamination from the flush fluid (Association of Anaesthetists of Great Britain and Ireland, 2014; Gupta and Cook, 2013). A recent small-scale simulation study indicated that despite training and procedures to inform on the recommended sampling strategy contamination of a blood sample occurred where a flush fluid containing glucose was in place. This was the case for both open and closed transducer systems; however, the contamination was significantly reduced with the closed system (Patel et al, 2020). The conclusion from the existing evidence is that despite following the recommendations on how to take a sample, contamination of a blood sample will still occur, although there is less of a risk with a closed system (Patel et al, 2020; Gupta and Cook, 2013; National Patient Safety Agency, 2008a). These findings contradict the evidence heard by the coroner in issuing the prevention of future deaths notice for Susan Warby's case. The evidence heard suggested that 'a good technique used by staff would prevent false readings being obtained' (Courts and Tribunals Judiciary, 2020).

Interpreting blood test results

5.2.14 The investigation heard that in the context of critically ill patients, blood glucose levels outside of the expected range and the use of insulin occur frequently and can become normalised by staff. The process for recording blood glucose levels and insulin may vary between paper and electronic systems. Both systems can make it challenging for staff to effectively recognise abnormal patterns, sufficient to direct attention to the flush fluid bag as a potential source of the altered blood glucose levels (Association of Anaesthetists of Great Britain and Ireland, 2014; Gupta and Cook, 2013).

5.2.15 The justification heard by the investigation for interpreting blood glucose levels from an arterial line were convenience and accepted practice. This does not allow for an independent blood sample (separate from the flush fluid) to routinely be used to compare blood glucose levels.

5.3 Stakeholder engagement

The investigation has established that taking a blood sample via an arterial line has persistent safety issues, which may not be reflected accurately in the formal reporting systems. Hence, it is impossible to capture a true picture of the prevalence and level of associated harm. The investigation found concerns within the healthcare system that recent events, namely the COVID-19 pandemic, have heightened this risk due to variability in staff resources as organisations respond to increasing demands.

The investigation sought to understand the effectiveness of, and challenges to, the implementation of previously recommended safety controls. Key stakeholders were engaged and remote interviews completed with each. This provided further evidence of the safety issues summarised in **section 5.2**. Three workshops were subsequently held to explore this evidence and consider suitable recommendations to address the persistent safety issues with these stakeholders.

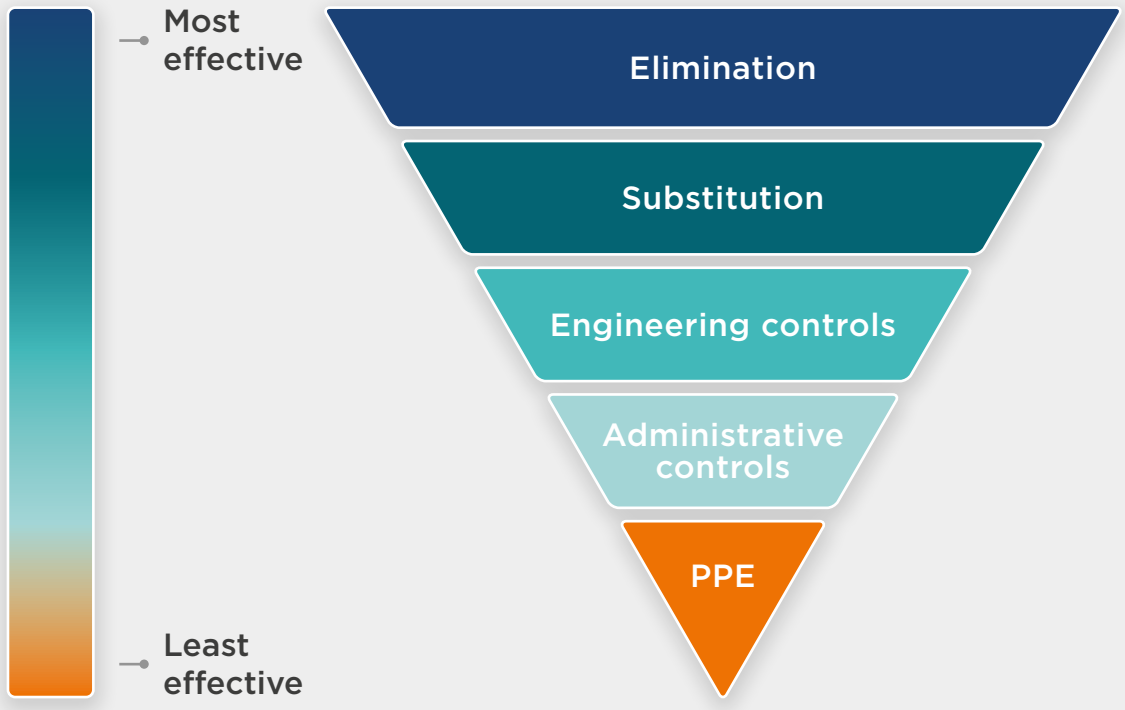
5.3.1 The investigation identified 22 stakeholder organisations (**see appendix 2**). These included the professional bodies representing healthcare staff who use arterial lines, healthcare regulators and safety bodies and representatives from the commercial sectors of pharmaceutical and medical devices. The workshops were held between December 2021 and March 2022. The first workshop, held in December, was attended by 23 participants representing the pharmaceutical community, and the second, held in January, was attended by 22 representatives of the clinical community. The third workshop, held in March, included representatives from the first two workshops and stakeholders from national and regulatory organisations.

5.3.2 The aim of the workshops was to gather further insight into current guidance, procedures and existing safety controls and challenges for the implementation of stronger safety controls.

5.3.3 The first two workshops facilitated discussions on the safety issues relevant to the key tasks of setting up and taking a blood sample from an arterial line system (**see figure 13 in section 5.2**). Each discussion considered the potential risks associated with each of the tasks. Information was recorded on how these risks are currently managed or where there are opportunities to identify and rectify the wrong flush fluid.

5.3.4 The discussions progressed to identifying potential stronger controls available for managing the risks. This was done with reference to the hierarchy of controls model (The National Institute for Occupational Safety and Health, n.d.) (**see figure 14**).

Figure 14 The hierarchy of controls relevant



Elimination: Redesign the activity such that the risk is removed or eliminated.

Substitution: Replace the activity with an activity that reduces the risk. Care is required to avoid introducing new hazards from the substitution.

Engineering controls: Design measures that help control or mitigate risks, such as barriers, guards and so on. Priority should be given to measures that provide collective protection rather than those that just protect individuals or a small group of people.

Administrative controls: Identifying and implementing the procedures to improve safety, such as undertaking risk assessments, preparing and communicating mitigating procedures, and increasing signage.

PPE: Personal protective equipment: local kit to mitigate the risks to those exposed to the hazard. People must be familiar with the function and limitation of each item of PPE for this to be an effective measure. Ideally, PPE is only considered after all previous measures higher in the hierarchy are identified as not being fully effective in controlling the risks.

5.3.5 When developing safety controls it can be beneficial to aim at the highest level possible of the hierarchy of controls model, as mitigations decrease in effectiveness the further down they are in the hierarchy. Therefore, the workshop participants were encouraged to start with a focus on how these risks could be eliminated, substituted or designed out, rather than solely relying on administrative controls, for example checks and training.

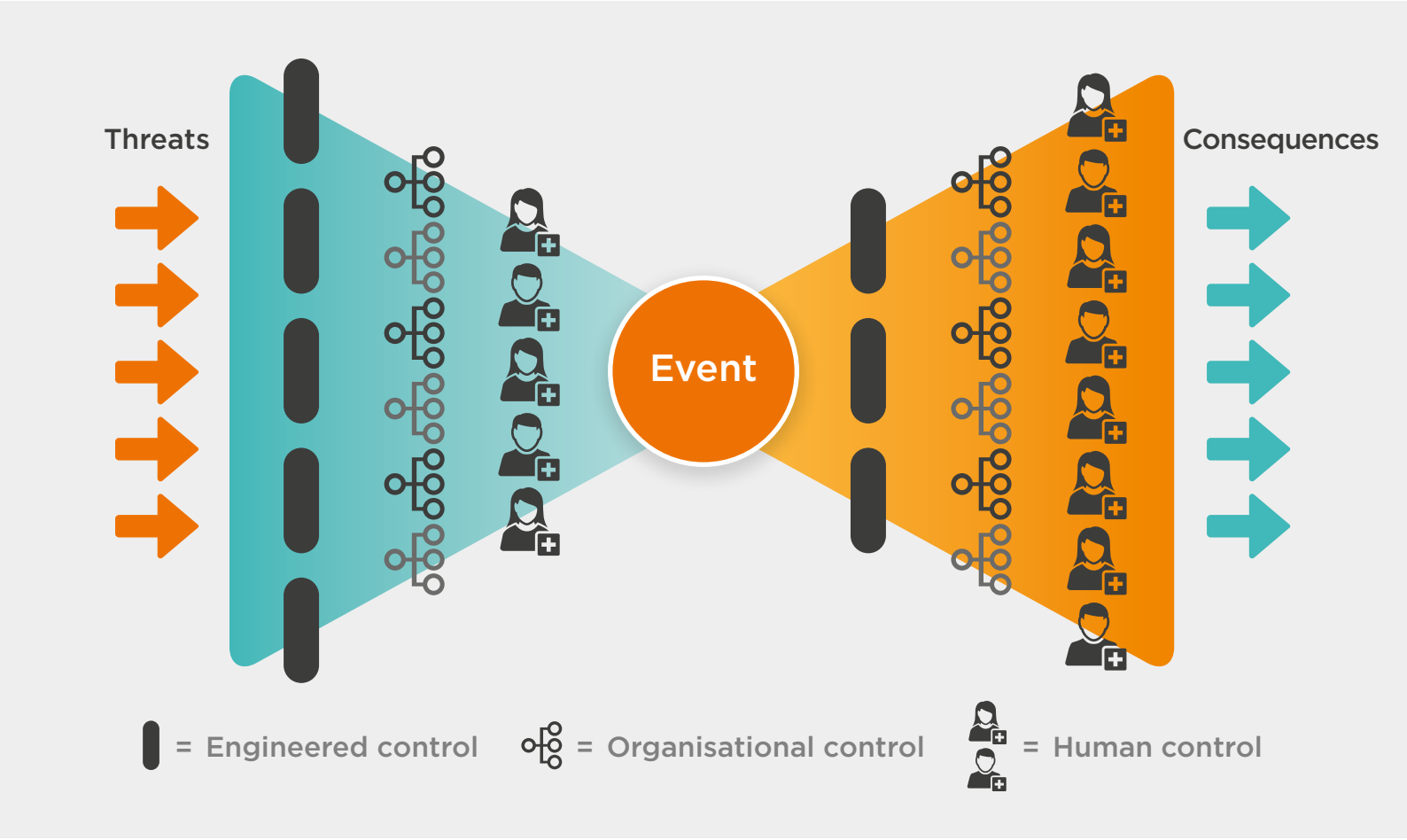
5.3.6 The evidence from the first two workshops and the investigation of the reference event were integrated and a visualisation developed to enable a shared understanding for the final workshop. This approach facilitated a multidisciplinary engagement with those who are able to influence the implementation and the co-design of recommendations.

Stakeholder workshop findings

5.3.7 The visualisation produced was based on a Bowtie approach (**see figure 15**). Bowtie analysis allows the visualisation of threats to safety (McLeod and Bowie, 2018; Chartered Institute for Ergonomics and Human Factors, 2016). Bowtie analysis considers the cultural and technical (sociotechnical) context within which a hazard sits at various levels in a system, such as a hospital, a hospital ward or a side-room. By introducing the concept of weakened but not eliminated defences, it allows an understanding of how safety controls can fail. An advantage of bowtie analysis is that it provides a means to communicate by representing risk diagrammatically to a diverse audience. The intention is that organisations can prioritise activity correctly (De Ruijter and Guldenmund, 2016).

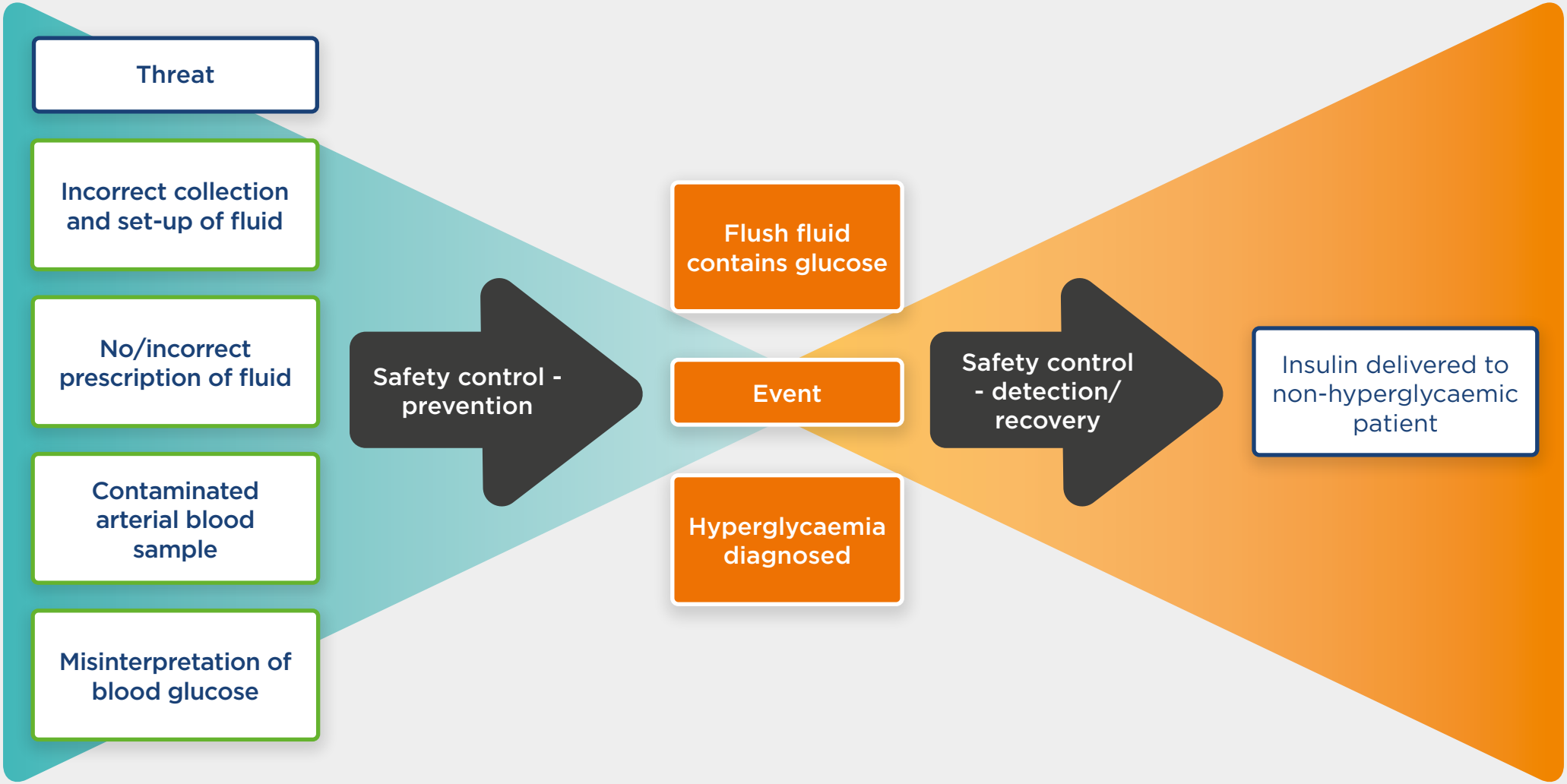
5.3.8 Previous HSIB reports provide a detailed description of bowtie analysis (**Healthcare Safety Investigation Branch, 2021a**, **Healthcare Safety Investigation Branch, 2021b**).

Figure 15 Bowtie analysis visualisation



5.3.9 This approach will be used to describe the findings from the workshops. Figure 16 illustrates the two main events in the centre of the image, which both have the potential to cause patient harm: glucose within the flush fluid and the subsequent inaccurate diagnosis of hyperglycaemia. These may lead to the outcome (right-hand side of figure 16) of the unnecessary delivery of insulin. Both events were systematically considered during the workshop, to understand the effectiveness of safety controls intended to prevent these events and those safety controls intended to identify and enable recovery to avoid harm if the events occurred.

Figure 16 Visualisation of threats to patient safety associated with blood sampling via the arterial line system



5.3.10 The investigation's evidence highlighted four clear threats (left-hand side of figure 16) which may lead to these events. The remainder of this section of the report will present the investigation findings for these four threats:

1 incorrect collection and set-up of the flush fluid

2 no or incorrect prescription of flush fluid

3 contamination of an arterial line blood sample

4 misinterpretation of the blood glucose results.

Table 2 summarises the findings relative to the strength of the main safety controls relied upon to manage all four threats.

Table 2 Summary of key issues relating to the four threats

Safety control	Description of safety issue	Factors influencing safety control
Check of flush fluid	Missed checks Insufficient attention to checks Large number of checks	Perception of risk relevant to flush fluid Workload Conflicting priorities of tasks Checking fatigue Staff fatigue
Prescription	Pre-populated prescription Lack of closed-loop administration system (feedback to confirm that details are accurately matched)	Normalisation of practice Variability in policies Workload Conflicting priorities of tasks
Sampling technique	Variability in technique Inadequate removal of blood before taking the blood sample Failure to remember the advised sampling technique	Normalisation of practice Misjudgement Training Workload Time pressure Perception of risk
Interpretation of blood glucose results	Design of interface to inform and alert to results Normalisation of results outside of expected range	Procurement Technical design and expertise in system usability Normalisation of practice

5.3.11 The following sections will consider significant findings specific to each of these threats. A bowtie image for each threat uses colour to indicate the effectiveness of current safety controls as reflected by the hierarchy of controls model (the darker the tone, the higher in the hierarchy – see figure 14). The workshops also considered how to strengthen existing controls by considering the following questions:

- Do we need to do this, can we eliminate it?
- Can we substitute and achieve the same outcome with less risk?
- Can we design an alternative (process/equipment)?

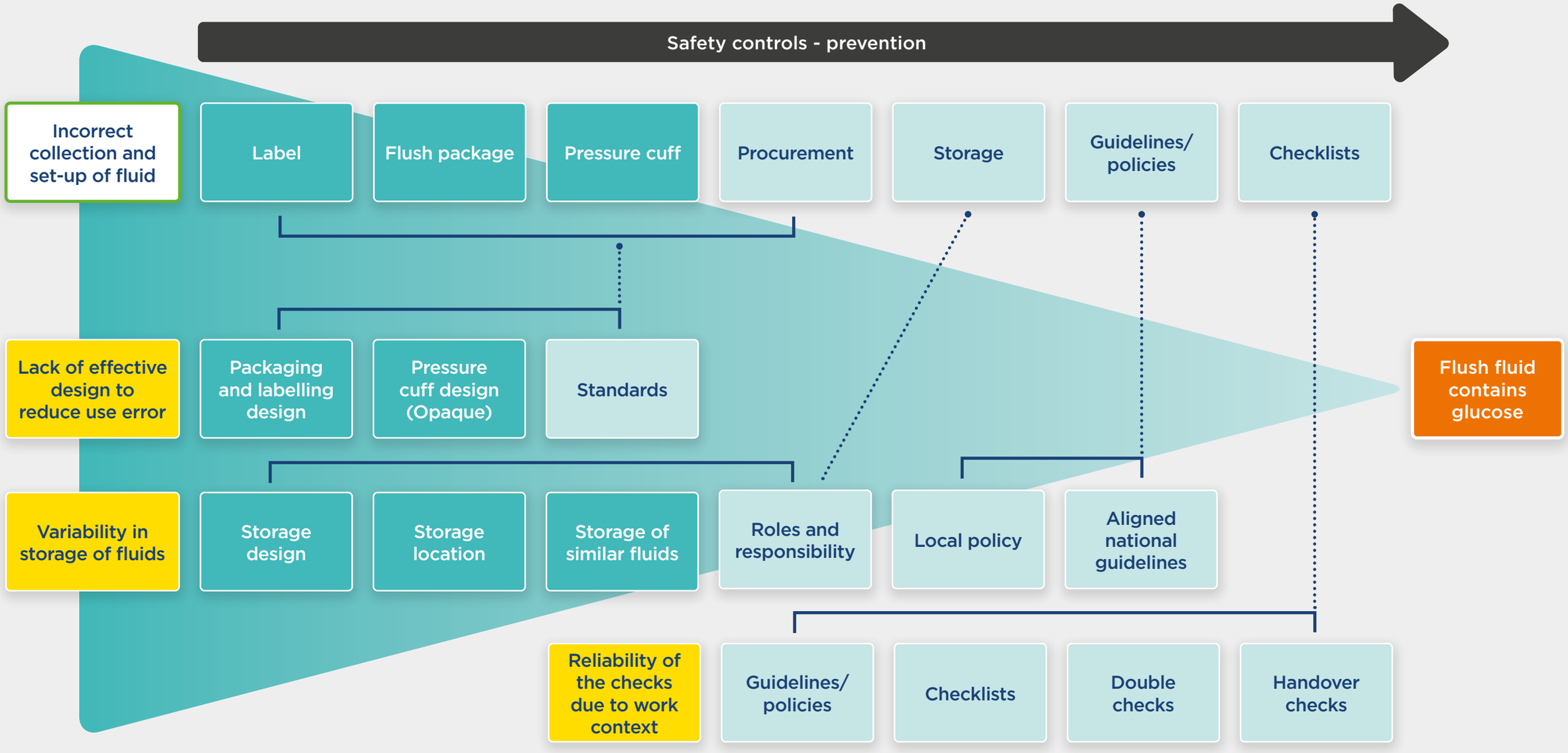
If these aren't possible ...

- Can we make existing controls stronger?

Incorrect collection and set-up of the flush fluid

5.3.12 The evidence suggested several systemic factors may influence the reliability of the tasks required by staff to select and set up a flush fluid. The accuracy or variability in the way these tasks were completed was influenced by the storage, design of labels and procurement of pressure infusion bags. Figure 17 illustrates the existing safety controls relied upon to manage these risks.

Figure 17 Safety controls to manage the risk of the collection of the wrong flush fluid



Design of flush fluid label and pressure infusion bags

5.3.13 The practice of storing bags of fluids within their original boxes and the design of the manufacturer's label on the fluid bags do not help staff to easily differentiate a bag of fluid with and without glucose. Current guidance encourages trusts to consider storage as an approach to enhance safety in the selection of similar looking and sounding medicines (Royal Pharmaceutical Society, 2018). The investigation heard from stakeholders that in reality, enhancing safety through storage is not easy to achieve: "Storage is a labelling, packaging, space and staffing issue."

5.3.14 The stakeholder workshops reiterated the investigation's findings from the reference event and historical reports (**see 5.2.4 to 5.2.7**). There was a consensus by stakeholders that labelling presents a risk and is a key contributory factor to selection errors.

5.3.15 The MHRA provides best practice guidance on labelling and packaging (Medicines and Healthcare products Regulatory Agency, 2020a) but does not make specific reference to infusion bags and the recognised challenges associated with them (Medicines and healthcare products Regulatory Agency, 2014a; National Patient Safety Agency, 2008b).

5.3.16 Stakeholders also considered the use of non-transparent pressure infusion bags as an obvious risk in the system. There was a strong consensus that where work might be done to improve the design of the flush fluid label the use of a pressure infusion bag that obscured the label did not make sense. Two stakeholders described how they had been involved in removing non-transparent pressure infusion bags at their trust or at a regional level.

5.3.17 The investigation heard from representatives of NHS Supply Chain, the organisation that sources and supplies healthcare products for NHS care providers. They reported that the current technical specification for procurement of pressure infusion bags by trusts requests the 'ability to see substance contents and fluid levels in fluid bags and containers'. Stakeholders described how even where best practice had been adopted in the use of transparent pressure bags, they had recently experienced problems with consistently obtaining clear pressure bags. Variability in procurement practices across the NHS were considered as highly influential to the procurement of devices and clearly did not reflect NHS Supply Chain's specification.

HSIB makes the following safety observation

Safety observation O/2022/181:
It may be beneficial, to undertake product essential specification development with end users as part of any NHS procurement framework renewal.

5.3.18 The workshop stakeholders also concluded that reliance upon checks to manage the risk of a selection error was inadequate. A stronger design solution was considered necessary. There was an agreement that the context of very unwell patients, staff workload, workforce and time pressure all weakened the reliance on checks. The use of pressure infusion bags that obscured flush fluid labels and the lack of distinctive features to distinguish between a clear fluid with or without glucose all contributed to the likelihood that the wrong fluid may be selected. Previous safety recommendations and the evidence from the reference event and the coroner's judgement in the Susan Warby case have been considered. HSIB makes the following safety recommendations with the intention that they will provide design guidance for manufacturers to manage the risk associated with fluid selection, and ensure fluid labels can be consistently read from all directions at all times when the pressure infusion bag is inflated.

HSIB makes the following safety recommendations

Safety recommendation R/2022/200:
HSIB recommends that the Medicines and Healthcare products Regulatory Agency [Head of Metabolic Disorders and Renal Systems] engages with other national regulators and relevant stakeholders to develop design guidance on labelling and packaging specific to fluids to reduce selection errors.

Safety recommendation R/2022/201:
HSIB recommends that the Medicines and Healthcare products Regulatory Agency [Head of Metabolic Disorders and Renal Systems] reviews and acts on the available evidence to regulate for the use of pressure infusion bags that allow fluid labels to be read when inflated.

Storage of flush fluids

5.3.19 Stakeholders reiterated well-recognised issues relating to the availability of sufficient and high-quality space for storage within NHS facilities. Stakeholders considered that a low priority is placed on storage, the responsibility for storage and the impact on safety.

5.3.20 The investigation sought an international perspective of this problem and contacted the Institute for Safe Medication Practices and International Medication Safety Network. This was not a problem they currently recognised or were focused on. The investigation also spoke with an anaesthetist based in the United States. They indicated that in critical care environments, in their experience, glucose fluid was stored remotely and a technical closed-loop medicines administration system and barcode scanning were used to ensure the correct fluid was retrieved. Similar practices in storing glucose-based fluids away from saline were suggested by stakeholders familiar with UK operating theatre environments. Stakeholders recognised this may delay retrieval time.

5.3.21 Stakeholders also shared how some trusts chose to store all of the separate components required for an arterial line as a complete set. This implies removing the flush fluid from the locked drug cupboard and storing it in an alternative way, which may vary from policies that require all medications to be stored in a designated locked facility.

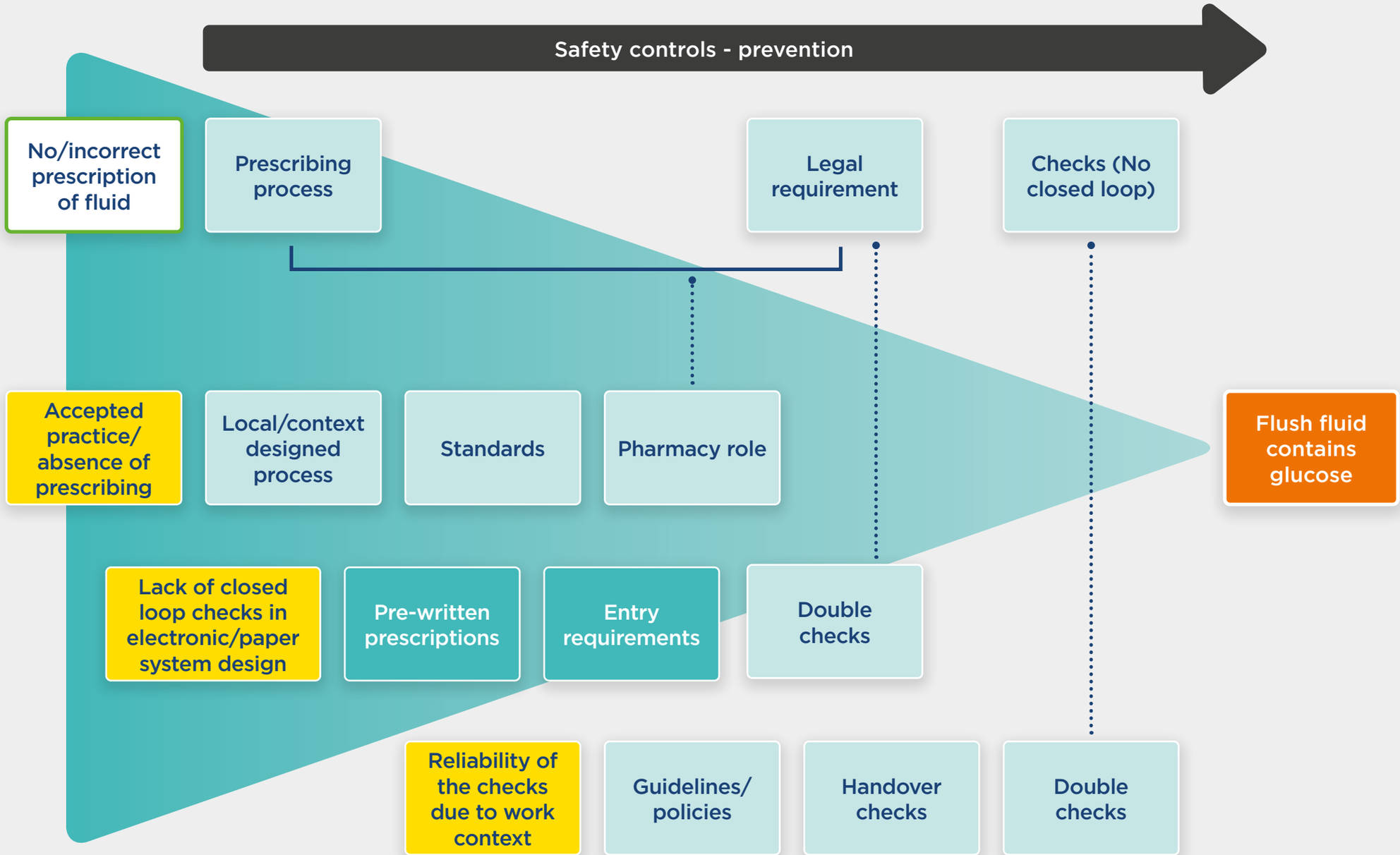
HSIB makes the following safety observation

Safety observation O/2022/182:
It may be beneficial for future reviews of the design of storage space within critical care units to consider the engagement of expertise in physical workspace design.

Prescription of flush fluid

5.3.22 Stakeholders acknowledged that although a prescription for medication is a legal requirement, it appears to present as a weak safety control in the context of the use of saline as a flush fluid in an arterial line system. The evidence indicated that the context of work and normalised practices, pre-population of the prescription, and the lack of reliability of subsequent checks were all factors in reducing the effectiveness of the prescription as a safety control (**see figure 18**).

Figure 18 Safety controls to manage the risk associated with the prescribing of medication



5.3.23 The perception of saline as a low-risk product and the frequency with which it is used are recognised as reasons why prescribing fails to function as an effective control to prevent the incorrect flush being used. Stakeholders told the investigation that "nurses selected sodium chloride (saline) for multiple different things, multiple times a day and it is perceived as 'non-risky' which will affect how much attention is given".

5.3.24 Pharmacists play a critical role in checking the accuracy and completeness of prescriptions. In the critical care environment, the recommendations suggest a minimum of 5 days of pharmaceutical support a week. However, NHS England and NHS Improvement has advised units to increase this to 7 days a week by 2020 (NHS England, 2016), although it has been suggested that it may not be feasible to implement this for all units (The Faculty of Intensive Care Medicine and Intensive Care Society, 2019). The double checks required and signed on the prescription by nursing and medical staff were recognised as inconsistently completed. Stakeholders echoed the academic literature recognising workload pressures, perception of the risk and reliability of a double check as reasons for discrepancies (Koyama et al, 2020). Variability in the need for a prescription in different clinical contexts where arterial lines are used was also cited. Medication practices in operating theatres differed from those used in critical care units and with recent pressures caused by the COVID-19 pandemic more operating theatre staff have been required to support critical care units. Stakeholders suggested this may have increased the variability in practices.

5.3.25 Stakeholders also expressed concern about the unintended consequence created by the use of pre-populated prescriptions of 'bundles' of medications typically required for critical care patients. These bundles include flush fluid and insulin. It was suggested to the investigation that their use may lower the attention staff give to these medications and reduce the level of conscious decision made to administering these medications. The unintended consequence of using pre-populated prescriptions, which are intended to aid efficiency and reduce workload, is similar to a longstanding problem recognised in automation within technical systems (Bainbridge, 1983). Stakeholders suggested that technology to support closed-loop medicines administration and checking (where technology confirms the correct medication) was not widely in use.

5.3.26 In summary, although a prescription is still necessary, the variability in practice across clinical environments and the lack of a reliable closed-loop medicines administration system reduce the effectiveness of this safety control. NHS England and NHS Improvement stakeholders stated that the use of barcode medication checking systems was currently under review to consider their use within the NHS.

HSIB makes the following safety observations

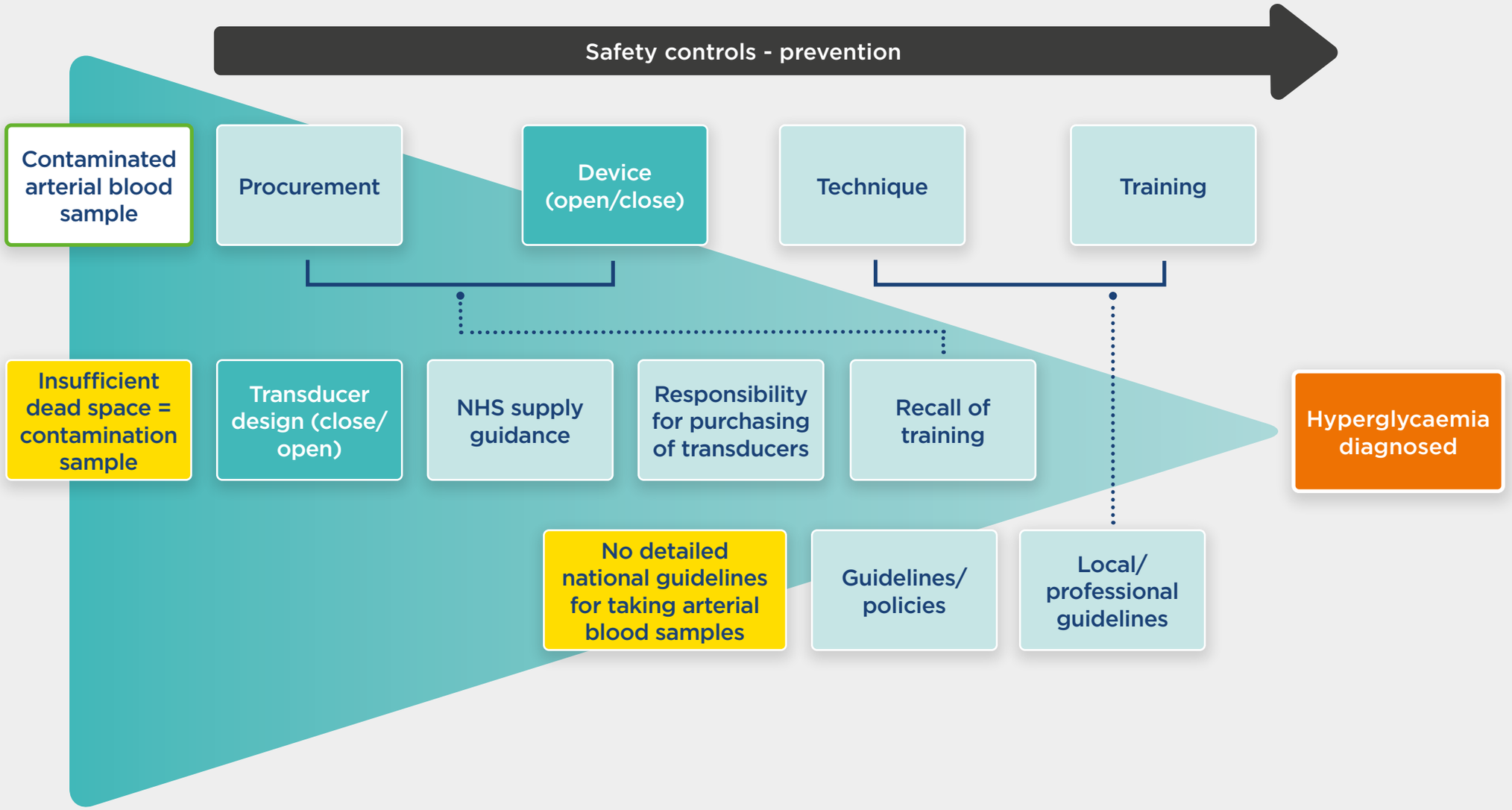
Safety observation O/2022/183:
It may be beneficial to increase the speed of implementation of the use of technology to support closed-loop medicines administration systems.

Safety observation O/2022/184:
It may be beneficial to review the unintended consequences associated with the use of pre-populated prescriptions for arterial flush fluid and also insulin.

Contamination of arterial blood samples

5.3.27 The transducer device available to trusts for arterial lines require staff to mitigate for the transducer's inability to prevent contamination from the flush fluid. This is only an issue if a flush fluid contains anything other than saline. Checks and training in the procedure of taking blood are all relied upon to enhance safety and manage the risk associated to the transducer's current design (**see figure 19**). There are two types of transducer available to healthcare: open and closed systems (**see figure 2** in section 1). It is recognised that some closed systems reduce but do not eliminate the risk of contamination of a blood sample by flush fluid. Trusts train staff on a technique to reduce the likelihood of contamination from the flush fluid. This relies on withdrawing a volume of blood three to five times the 'dead space' between the port and the patient (**see 1.3.5**). This dead space is not a fixed volume as transducer systems vary and there are no markings on the tubes to indicate the volume required. The MHRA acknowledged this risk in 2014 (Medicines and Healthcare products Regulatory Agency, 2014a), but there does not appear to have been any further modification to labelling, device instructions or design to address the risk.

Figure 19 Safety controls to manage the risk associated with the contamination of arterial line blood samples



5.3.28 Trusts continue to procure open systems despite the evidence that closed systems may reduce the risk. Stakeholders suggested that continual vigilance and review of devices with the capability to minimise and preferably eliminate contamination from the flush fluid may help to remove the safety risks associated with blood sampling via an arterial line.

5.3.29 The current Yellow Card reporting system (**see 5.1.1**) does not appear to be effective in raising recognised concerns. Furthermore, the post-market surveillance legally required by manufacturers has not provided evidence of the device related issues found by this investigation. These two areas impede regulatory bodies from obtaining the information necessary to inform the safety of devices routinely procured by trusts. Therefore, HSIB makes the following safety recommendations to ensure appropriate action is taken to manage the known risks related to the design of the medical devices.

HSIB makes the following safety recommendations

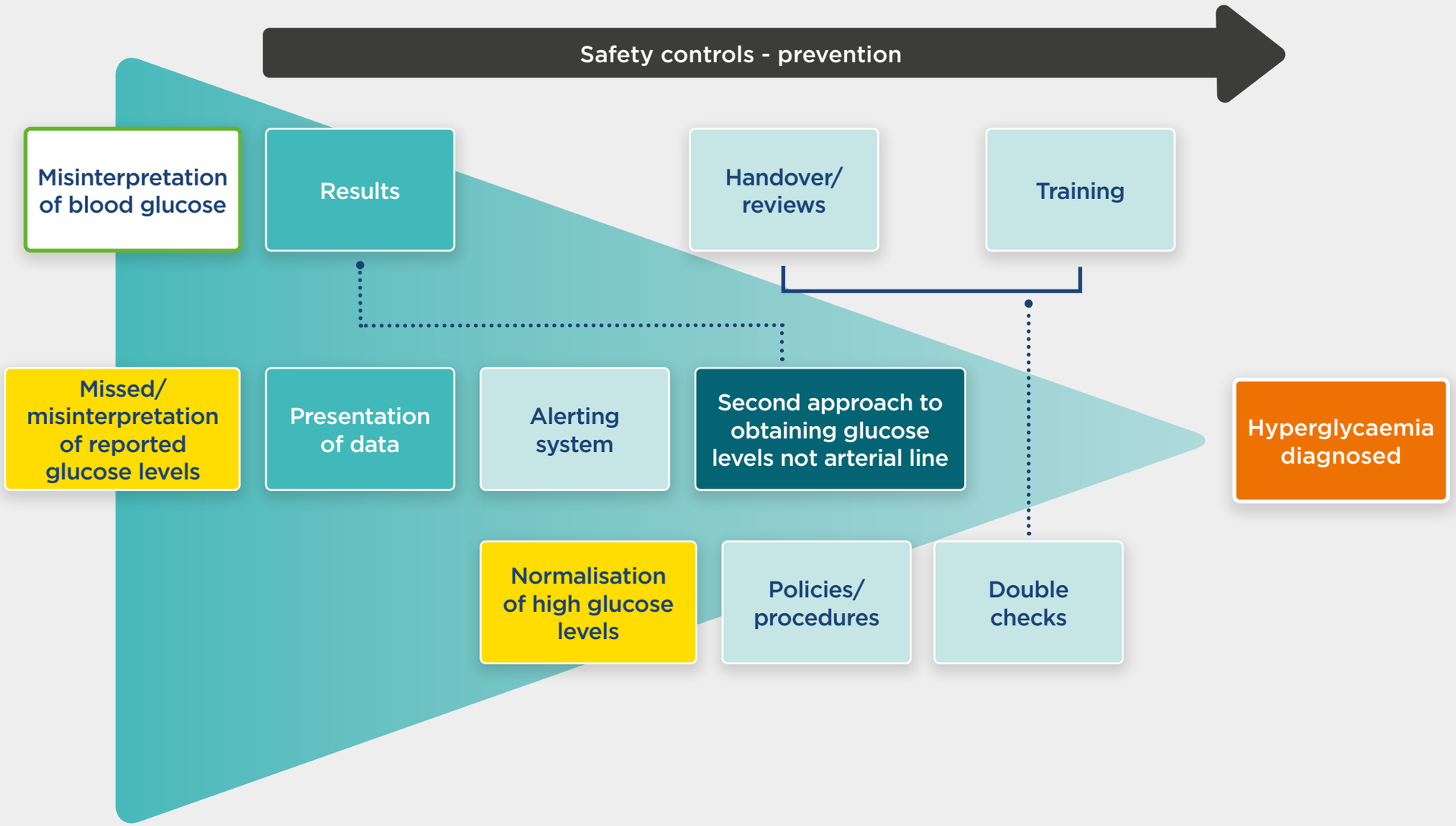
Safety recommendation R/2022/202:
HSIB recommends that the Medicines and Healthcare products Regulatory Agency [Head of Metabolic Disorders and Renal Systems] communicates to all relevant stakeholders and acts on the available evidence concerning the management of the risks associated with arterial transducer line sets.

Safety recommendation R/2022/203:
HSIB recommends that the Department of Health and Social Care [Director of Medical Technology], once post-market surveillance data is available, involves relevant stakeholders including the Association of Anaesthetists' review and determine appropriate actions that could be taken to further mitigate the risk of blood sample contamination by the flush fluid when using arterial transducer line systems.

Interpretation of blood glucose results from arterial line samples

5.3.30 The investigation heard that the normalisation of patients in critical care having high levels of blood glucose may reduce clinicians' attention to blood glucose levels outside of the expected range. This normalisation reduces the likelihood that further checks would routinely direct staff to suspect the use of an incorrect flush fluid. The risk of the incorrect interpretation of the cause of high blood glucose levels is compounded by the way trends in blood glucose levels are presented on patient record systems. The existing safety controls relied upon to manage the risk of misinterpretation are illustrated in figure 20.

Figure 20 Safety controls to manage the risk associated with misinterpretation of blood glucose levels



5.3.31 Stakeholders who attended the investigation's workshops discussed the elimination of the risk of misinterpretation through alternative approaches to monitoring blood glucose levels. Systems currently available to continuously measure blood glucose were considered positively. However, stakeholders suggested that the lack of reporting of arterial line system incidents meant it was not possible to justify the scale and costs associated with the implementation of such systems. The investigation concluded that this should be regularly reviewed and considered as a safety control in the future.

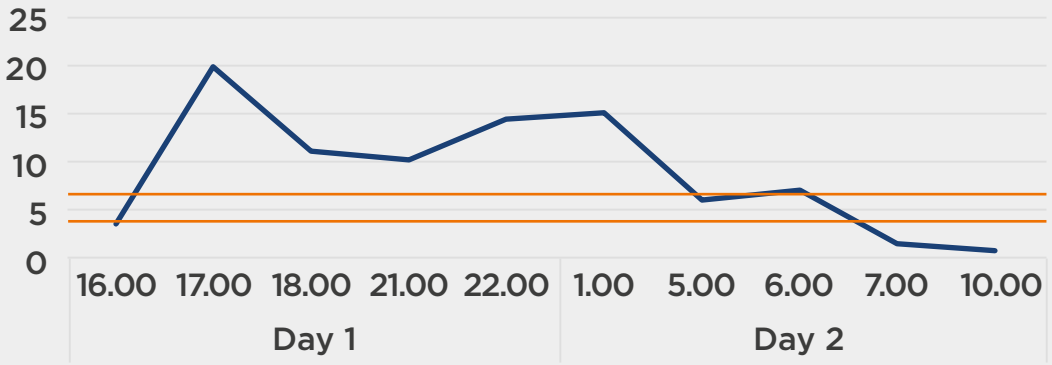
5.3.32 Stakeholders recognised that, until changes to the design of transducers eliminated the risk of contamination, alternative safety controls were required to increase the likelihood of identifying an inaccurate blood glucose level. Such controls might involve the taking of a second blood sample from an alternative site; a capillary blood glucose test (finger prick test) is most frequently used for this purpose. Completing a second test at the time of every arterial blood sample was considered impractical in the context of critical care. This is due to the physiological condition of the patient's circulation, and the time pressure and likelihood that it may not be reliably completed. The introduction of 'trigger point' capillary testing was suggested as a pragmatic approach, for example testing prior to administering insulin, on putting up or changing a flush fluid and even at the start of a shift. This may not prevent the contamination from the flush fluid but would increase the likelihood of its identification and increase safety controls associated with the delivery of insulin treatment.

5.3.33 Paper and electronic systems currently record glucose levels using numerical values rather than a trend line. Figure 21 shows the different ways of presenting the data. It is recognised that use of a trend line supports early identification of change, which can be enhanced with lines to indicate where a change may fall outside of a predefined limit (Burns and Hajdukiewicz, 2004).

Figure 21 Comparison in the visibility of change in blood glucose levels between the use of numerical values and trend lines

Day 1									
	15.00	16.00	17.00	18.00	19.00	20.00	21.00	22.00	23.00
Blood glucose (mmol/litre)		3.5	19.9	11.1			10.2	14.4	

Day 2											
	00.00	01.00	02.00	03.00	04.00	05.00	06.00	07.00	08.00	09.00	10.00
Blood glucose (mmol/litre)		15.1				6.0	7.0	1.4			0.7



Target range based on Trust protocol November 2020

5.3.34 Stakeholders considered existing guidance or practice may not reliably increase clinician's vigilance to the identification and questioning of extreme changes in blood glucose levels, such as an erratic trend or a single outlier. This was seen in the investigation of the reference event. The presentation of information or the alerts generated by IT systems were not enough to increase clinicians' attention.

HSIB makes the following safety observations

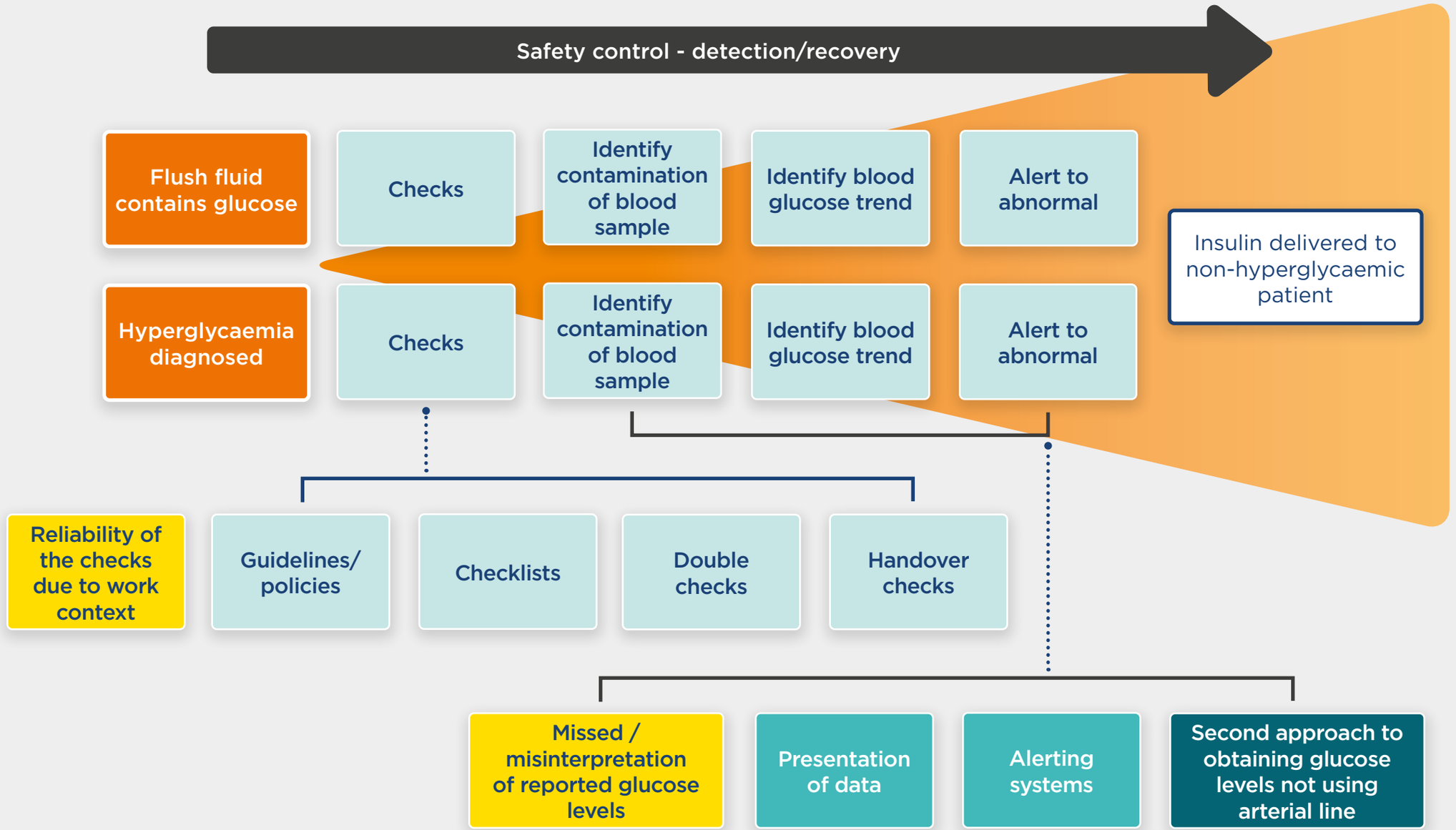
Safety observation O/2022/185:
It may be beneficial if regulatory bodies remain alert to and encourage the adoption of alternative approaches to continuous glucose monitoring.

Safety observation O/2022/186:
It may be beneficial to consider how the design processes and guidance for blood glucose recording can support identification and early warning of a potential blood sample contamination by flush fluid.

Management and detection of the risk

5.3.35 The investigation has considered how to avoid using the wrong flush fluid or contamination of blood samples from the flush fluid. The bowtie image (to the right of the events) also presents the potential for detection once the incorrect flush fluid has been used (see figure 22). The safety controls for detection mirror those for prevention and therefore will equally vary in their reliability.

Figure 22 Safety controls to manage the risk once the incorrect flush fluid has been used



5.3.36 The investigation has heard that currently there is no device or process that can eliminate the risk of arterial line blood contamination if the wrong flush fluid is used. The investigation has highlighted a number of systemic factors likely to influence the reliability of the use of the correct flush fluid. Until these systemic factors can be addressed there is a need for healthcare systems to raise awareness of this risk and understand how procurement decisions, storage facilities and staff practices can be optimised to strengthen safety around this issue.

5.3.37 The existing safety controls rely heavily upon repetitive checks and staff attention to avoid the traps that remain in selecting similar looking products and sampling blood to avoid contamination from the flush fluid. Stakeholders were emphatic that staff workload, work pressures and conflicts in staff tasks heavily contributed to the reliability and the effectiveness of the existing safety controls. These opinions were supported by the reference event findings which appeared to impact the. effectiveness and ability for staff to complete all necessary checks.

5.3.38 A number of practical approaches to managing the residual risk were considered during this investigation and believed valuable by stakeholders. Until post-market surveillance can inform manufacturers and the design of arterial line systems, there will be a need to develop further guidance to support clinical staff to follow practices to manage this systemic risk. Trusts will also need to consider the findings of this investigation in their procurement decision making and guidance on/priority given to storage for arterial line products.

5.3.39 The investigation considers that the existing controls are low in the hierarchy of controls and that there is a continual need to mitigate for these risks. The investigation acknowledges that the risks will remain until medication and device design issues can be addressed by regulators and manufacturers. The investigation also heard in the future use of arterial lines may extend to enhanced care settings (a ward setting where an upskilled workforce with ready access to the critical care team). Professional bodies and regulators should consider the evidence from this report to develop national guidance to implement and evaluate the following controls:

- review of the development and use of ‘arterial line kits’ developed by trusts to meet local protocols and separate storage from glucose products

- storage to use principles of design to reduce known errors for example, layout, labelling, separation of common look-alike sound-alike medications

- procurement and use of only transparent pressure infusion bags for use with arterial lines
- procurement of closed system transducer sets
- detailed description of best practice in the sampling technique for an arterial line
- trigger point testing via a second route, for example before insulin is started – this may include during high or erratic blood glucose recording, changes of shifts, change of fluid bag (allowing for some time to elapse before testing)
- closed-loop medication administration and checking, for example barcoding medication administration systems
- acknowledge and review risks associated with pre-populated prescribing associated with prescribing in critical care environments.

5.3.40 The investigation was told that implementing and evaluating these measures would require support from a range of national stakeholders but would need to be co-ordinated by a central body to ensure they were effective. HSIB therefore makes the following safety recommendation with the intention that the Association of Anaesthetists will design national guidance with representation from all relevant healthcare professionals within the following clinical areas: critical care, operating theatres and emergency departments.

HSIB makes the following safety recommendation

Safety recommendation R/2022/204:
HSIB recommends that the Association of Anaesthetists [President] works with relevant professional organisations to revise existing national guidance to manage the risks of contamination by the flush fluid when using an arterial line to take a blood sample.

HSIB notes the following safety action

Safety action A/2022/053:
The Association of Anaesthetists has started to identify relevant stakeholders for the development of guidance on blood sampling when using arterial transducer line systems.

5.3.41 The intention of the following safety recommendation is to provide assurance that NHS providers have implemented the future national guidance.

HSIB makes the following safety recommendation

Safety recommendation R/2022/205:
HSIB recommends that the Care Quality Commission [Chief Executive] reviews the recommendations from the Association of Anaesthetists on how to manage the risks of contamination by the flush fluid when using an arterial transducer line and determines any appropriate actions for the oversight of governance and assurance arrangements within NHS providers following.

6 Summary of findings, safety recommendations, safety observations and safety action

6.1 Findings

- The physical layout and design of the clinical and storage areas will influence how reliably staff are able to select and collect similar-looking equipment and medication.

- The labelling of bags of fluids, similar looking medications and manufacturers' packaging reduce the reliability of selecting the correct flush fluid in the context of a critical care unit with time pressures and high workloads.

- The procurement and design of arterial transducer line equipment, the pressure infusion bags and transducer, do not assist in the identification of the incorrect flush fluid or prevent contamination from the flush fluid of a blood sample taken from the arterial line. Alternative equipment, for example transparent pressure infusion bags and closed arterial transducer lines, are currently available to the NHS. These may reduce the risk but are not routinely in use.

- Challenges in the provision of a consistent suitable workforce and high workloads have a detrimental effect on the safety controls currently relied upon to avoid or identify the risk of using the wrong flush fluid. Safety checks and training lack resilience to organisational pressures regularly experienced within critical care units.

- There can be a delay in identifying the contamination with glucose of an arterial line blood sample due to a normalisation and acceptance that critically ill patients may have altered blood glucose levels and require insulin treatment, and a perceived low risk associated with the use of a flush fluid.

- The design of systems to record and monitor information relevant to the arterial transducer line system and blood glucose levels do not easily alert staff to the potential use of the wrong flush fluid.

- Recommendations issued over the last 14 years by national safety bodies and professional healthcare organisations to address the safety of blood sampling associated with arterial lines have not been effectively implemented.

6.2 Safety recommendations and safety observations

The intention of this safety recommendation is to provide design guidance for manufacturers to manage the risk associated with fluid selection. All aspects of label design should be considered this recommendation is broader than the judicious use of colour as the approach to increasing label safety.

Safety recommendation R/2022/200:
HSIB recommends that the Medicines and Healthcare products Regulatory Agency [Head of Metabolic Disorders and Renal Systems] engages with other national regulators and relevant stakeholders to develop design guidance on labelling and packaging specific to fluids to reduce selection errors.

The intention of this safety recommendation is to ensure fluid labels can be consistently read from all directions at all times when the pressure infusion bag is inflated.

Safety recommendation R/2022/201:
HSIB recommends that the Medicines and Healthcare products Regulatory Agency [Head of Metabolic Disorders and Renal Systems] reviews and acts on the available evidence to regulate for the use of pressure infusion bags that allow fluid labels to be read when inflated.

The intention of this safety recommendation is to increase awareness of and action on known risks related to the design of the medical devices.

Safety recommendation R/2022/202:
HSIB recommends that the Medicines and Healthcare products Regulatory Agency [Head of Metabolic Disorders and Renal Systems] communicates to all relevant stakeholders and acts on the available evidence concerning the management of the risks associated with arterial transducer line sets.

The intention of this safety recommendation is to assure appropriate action is taken to manage the known risks related to the design of the medical devices.

Safety recommendation R/2022/203:
HSIB recommends that the Department of Health and Social Care [Director of Medical Technology], once post-market surveillance data is available, involves relevant stakeholders including the Association of Anaesthetists' review and determine appropriate actions that could be taken to further mitigate the risk of blood sample contamination by the flush fluid when using arterial transducer line systems.

The intention of this safety recommendation is for the Association of Anaesthetists to revise existing national guidance in collaboration with all relevant healthcare professionals including the following clinical areas: critical care, theatres and emergency departments.

Safety recommendation R/2022/204:
HSIB recommends that the Association of Anaesthetists [President] works with relevant professional organisations to revise existing national guidance to manage the risks of contamination by the flush fluid when using an arterial line to take a blood sample.

The intention of this safety recommendation is to provide assurance that NHS providers have implemented the future national guidance.

Safety recommendation R/2022/205:
HSIB recommends that the Care Quality Commission [Chief Executive] reviews the recommendations from the Association of Anaesthetists on how to manage the risks of contamination by the flush fluid when using an arterial transducer line and determines any appropriate actions for the oversight of governance and assurance arrangements within NHS providers following.

HSIB makes the following safety observations

Safety observation O/2022/179:
It may be beneficial to recognise that safety risks are not reliably reported and therefore that the likelihood and level of harm may not be accurately reflected through existing reporting systems.

Safety observation O/2022/180:
It may be beneficial to recognise that workload and fatigue will influence the reliability of safety controls dependent on staff time and attention.

Safety observation O/2022/181:
It may be beneficial, to undertake product essential specification development with end users as part of any NHS procurement framework renewal.

Safety observation O/2022/182:
It may be beneficial for future reviews of the design of storage space within critical care units to consider the engagement of expertise in physical workspace design.

Safety observation O/2022/183:
It may be beneficial to increase the speed of implementation of the use of technology to support closed-loop medicines administration systems.

Safety observation O/2022/184:
It may be beneficial to review the unintended consequences associated with the use of pre-populated prescriptions for arterial flush fluid and also insulin.

Safety observation O/2022/185:
It may be beneficial if regulatory bodies remain alert to and encourage the adoption of alternative approaches to continuous glucose monitoring.

Safety observation O/2022/186:
It may be beneficial to consider how the design processes and guidance for blood glucose recording can support identification and early warning of a potential blood sample contamination by flush fluid.

HSIB notes the following safety action

Safety action A/2022/053:
The Association of Anaesthetists has started to identify relevant stakeholders for the development of guidance on blood sampling when using arterial transducer line systems.

7 References

Association of Anaesthetists of Great Britain and Ireland. (2014) Arterial line blood sampling: preventing hypoglycaemic brain injury. Anaesthesia, 69 (4), 380-385 [Online]. DOI: 10.1111/anae.12536.

Badawi, O., Waite, M., Fuhrman, S. and Zuckerman, I. (2012) Association between intensive care unit-acquired dysglycaemia and in-hospital mortality. Critical Care Medicine, 40 (12), 3180-3188 [Online]. DOI: 10.1097/CCM.0b013e3182656ae5 Bainbridge, L. (1983) Ironies of automation. Automatica, 19 (6), 775-779 [Online]. DOI: 10.1016/0005-1098(83)90046-8.

Burns, C. and Hajdukiewicz, J. (2004) Ecological Interface Design. Boca Raton, Florida: CRC Press.

Carayon, P., Schoofs Hundt, A., Karsh, B. T., Gurses, A. P., Alvarado, C. J., Smith, M. and Flatley Brennan, P. (2006) Work system design for patient safety: the SEIPS model. Quality and Safety in Health Care, 15 (1), i50-i58 [Online]. DOI: 10.1136/qshc.2005.015842.

Chartered Institute for Ergonomics and Human Factors. (2016) Human factors in barrier management [Online]. Available at **https://ergonomics.org.uk/resource/human-factors-in-barrier-management.html** (Accessed 14 April 2022).

Courts and Tribunals Judiciary. (2020) Regulation 28: Report to prevent future deaths (1) [Online]. Available at **https://www.judiciary.uk/wp-content/uploads/2020/11/Susan-Warby-2020-0188_Redacted.pdf** (Accessed 14 April 2022).

Dawson, D. (1997) Fatigue, alcohol and performance impairment. Nature, 388 (235) [Online]. DOI: 10.1038/40775.

Dawson, D. and McCulloch, K. (2005) Managing fatigue: it's about sleep. Sleep Medicine Reviews, 9 (5), 365-380 [Online]. DOI: 10.1016/j.smrv.2005.03.002.

Department of Health. (2013) Health building note 04-02. Critical care units [Online]. Available at **https://www.england.nhs.uk/wp-content/uploads/2021/05/HBN_04-02_Final.pdf** (Accessed 14 April 2022).

Department of Health and Social Care. (2018) The report of the short life working group on reducing medication-related harm [Online]. Available at **https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/683430/short-life-working-group-report-on-medication-errors.pdf** (Accessed 14 April 2022).

De Ruijter, A. and Guldenmund, F. (2016) The bowtie method: A review. Safety Science, 88, 211-218 [Online]. DOI: 10.1016/j.ssci.2016.03.001.

Diabetes.co.uk. (2022) Blood sugar level ranges [Online]. Available at **https://www.diabetes.co.uk/diabetes_care/blood-sugar-level-ranges.html#:~:text=For%20the%20majority%20of%20healthy,dL)%202%20hours%20after%20eating** (Accessed 20 June 2022).

Embrey, D. (2014) Application of SHERPA to predict and prevent use error in medical devices. Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care, 3 (1), 246-253 [Online]. DOI: 10.1177/2327857914031040.

The Faculty of Intensive Care Medicine and Intensive Care Society. (2019) Guidelines for the provision of intensive care services [Online]. Available at **https://www.ficm.ac.uk/sites/ficm/files/documents/2021-10/gpics-v2.pdf** (Accessed 14 April 2022).

Gupta, K. J. and Cook, T. M. (2013) Accidental hypoglycaemia caused by an arterial flush drug error: a case report and contributory causes analysis. Anaesthesia, 68 (11), 1179-1187 [Online]. DOI: 10.1111/anae.12388.

Health and Safety Executive. (n.d.) Noise. Advice for employers [Online]. Available at **https://www.hse.gov.uk/noise/advice.htm** (Accessed 14 April 2022).

Health and Safety Executive. (2020) Noise exposure ready-reckoner (daily exposure) [Online]. Available at **https://www.hse.gov.uk/noise/dailyexposure.pdf** (Accessed 14 April 2022).

Healthcare Safety Investigation Branch. (2018) Design and safe use of portable oxygen systems [Online]. Available at **https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/HSIB_Design_and_Safe_Use_of_Portable_Oxygen_Systems_I2017013_Full_report.pdf** (Accessed 14 April 2022).

Healthcare Safety Investigation Branch. (2019) Placement of nasogastric tubes [Online]. Available at **https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/HSIB_Placement_of_nasogastric_tubes_Report_V07.pdf** (Accessed 14 April 2022).

Healthcare Safety Investigation Branch. (2021a) Wrong site surgery – wrong tooth extraction [Online]. Available at **https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/HSIB_Wrong_Site_Surgery_-_Wrong_Tooth_Extraction_Report_V07.pdf** (Accessed 14 April 2022).

Healthcare Safety Investigation Branch. (2021b) Wrong site surgery – wrong patient: invasive procedures in outpatient settings [Online]. Available at **https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/HSIB_Wrong_site_surgery_-_wrong_patient_Report_V08.pdf** (Accessed 14 April 2022).

International Civil Aviation Organisation. (n.d.) Fatigue management [Online]. Available at **https://www.icao.int/safety/fatiguemanagement/Pages/default.aspx** (Accessed 14 April 2022).

Institution of Occupational Safety and Health. (n.d.) Noise [Online]. Available at **https://iosh.com/health-and-safety-professionals/improve-your-knowledge/occupational-health-toolkit/noise/** (Accessed 14 April 2022).

International Organization for Standardization. (2021) IEC 62366-1:2015: Medical devices – Part 1: Application of usability engineering to medical devices [Online]. Available at **https://www.iso.org/standard/63179.html** (Accessed 19 April 2022).

Kahneman, D. and Klein, G. (2009) Conditions for intuitive expertise: a failure to disagree. American Psychologist, 64 (6), 515-26 [Online]. DOI: 10.1037/a0016755

Karsh, B-T., Holden, R. J., Alper, S. J. and Or, C. K. L. (2006) A human factor engineering paradigm for patient safety – designing to support the performance of the healthcare professional. Quality and Safety in Health Care, 15, i59-i65 [Online]. DOI: 10.1136/qshc.2005.015974.

Kerr, D. E., Wenham, T. and Munir, A. (2017) Endocrine problems in the critically ill 1: diabetes and glycaemic control. BJA Education, 17 (11), 370-376 [Online]. DOI: 10.1093/bjaed/mkx024.

Kirwan, B. and Ainsworth, L. K. (1993) A Guide to Task Analysis. London: CRC Press.

Koyama, A. K., Maddox, C.-S. S., Li, L., Bucknall, T. and Westbrook, J. I. (2020) Effectiveness of double-checking to reduce medication administration errors: a systematic review. BMJ Quality and Safety, 29 (7), 595-603 [Online]. DOI: 10.1136/bmjqs-2019-009552.

Lusk, C., Catchpole, K., Neyens, D. M., Goel, S., Graham, R., Elrod, N., Paintlia, A., Alfred, M., Joseph, A., Jaruzel, C., Tobin, C., Heinke, T. and Abernathy, J. H. (2022) Improving safety in the operating room: medication icon labels increase visibility and discrimination. Applied Ergonomics, 104, 103831 [Online]. Available at **https://www.sciencedirect.com/science/article/abs/pii/S0003687022001545?dgcid=coauthor** (Accessed 21 June 2022).

Marik, P. E. and Egi, M. (2014) Treatment thresholds for hyperglycemia in critically ill patients with and without diabetes. Intensive Care Medicine, 40 (7), 1049-1051 [Online]. DOI: 10.1007/s00134-014-3344-2.

McLeod, R. and Bowie, P. (2018) Bowtie analysis as a prospective risk assessment technique in primary healthcare. Policy and Practice in Health and Safety, 16 (2), 177-193 [Online]. DOI: 10.1080/14773996.2018.1466460.

Medicines and Healthcare products Regulatory Agency. (2014a) Glucose solutions: false blood glucose readings when used to flush arterial lines [Online]. Available at **https://www.gov.uk/drug-safety-update/glucose-solutions-false-blood-glucose-readings-when-used-to-flush-arterial-lines** (Accessed 28 June 2021).

Medicines and Healthcare products Regulatory Agency. (2014b) Off-label or unlicensed use of medicines: prescribers' responsibilities [Online]. Available at **https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities** (Accessed 19 April 2022).

Medicines and Healthcare products Regulatory Agency. (2020a) Best practice in the labelling and packaging of medicines [Online]. Available at **https://www.gov.uk/government/publications/best-practice-in-the-labelling-and-packaging-of-medicines** (Accessed 19 April 2022).

Medicines and Healthcare Products Regulatory Agency. (2020b) Regulation 28 report concerning Susan Warby [Online]. Available at **https://www.judiciary.uk/wp-content/uploads/2020/11/2020-0188-Response-from-MHRA-Redacted.pdf** (Accessed 14 April 2022).

Mesotten, D., Preiser, J.-C. and Kosiborod, M. (2015) Glucose management in critically ill adults and children. Lancet Diabetes Endocrinology, 3 (9), 723-33 [Online]. DOI: 10.1016/S2213-8587(15)00223-5.

National Institute for Health and Care Excellence. (n.d.) Hypoglycaemia [Online]. Available at **https://bnf.nice.org.uk/treatment-summary/hypoglycaemia.html** (Accessed 15 June 2021).

The National Institute for Occupational Safety and Health. (2015) Hierarchy of controls [Online]. Available at **https://www.cdc.gov/niosh/topics/hierarchy/default.html** (Accessed 19 April 2022).

National Patient Safety Agency. (2008a) Rapid response report PSA/2008/RRR006. Problems with infusions and sampling from arterial lines [Online]. Available at **https://webarchive.nationalarchives.gov.uk/ukgwa/20171030124411mp_/http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60292&type=full&servicetype=Attachment** (Accessed 14 April 2022).

National Patient Safety Agency. (2008b) Design for patient safety: a guide to labelling and packaging of injectable medicines [Online]. Available at **https://www.rca.ac.uk/research-innovation/research-centres/helen-hamlyn-centre/research-projects/2007-projects/safer-design/** (Accessed 6 March 2022).

NHS England. (2016) Transformation of seven day clinical pharmacy services in acute hospitals [Online]. Available at **https://www.england.nhs.uk/wp-content/uploads/2016/09/7ds-clinical-pharmacy-acute-hosp.pdf** (Accessed 30 March 2022).

NHS England. (2019) Schedule 2 – the services [Online]. Available at **220502S-adult-critical-care-service-specification.pdf** (england.nhs.uk) (Accessed 19 April 2022).

NHS England and NHS Improvement. (n.d.) Enduring standards that remain valid from previous patient safety alerts [Online]. Available at **https://www.england.nhs.uk/patient-safety/patient-safety-alerts/enduring-standards/standards-that-remain-valid/** (Accessed 11 April 2022).

NHS England and NHS Improvement. (2021a) NRLS official statistics publications: data quality statement [Online]. Available at **https://www.england.nhs.uk/wp-content/uploads/2021/09/NRLS-Data-Quality-Statement-Sept-21-FINAL.pdf** (Accessed 19 April 2022).

NHS England and NHS Improvement. (2021b) Health building note 14-02 – medicines storage in clinical areas [Online]. Available at **https://www.england.nhs.uk/wp-content/uploads/2021/05/HBN-14-02-Medicines-storage-in-clinical-areas.pdf** (Accessed 14 April 2022).

Patel, V., Skorupska, N., Hodges, E. J., Blunt, M. C., Young, P. J. and Mariyaselvam, M. Z. (2020) The glucose error in arterial sampling: assessing staff awareness and the effect of sampling technique. Journal of the Intensive Care Society, 22 (4), 319-327 [Online]. DOI: 10.1177/1751143720968494.

Plowright, C. and Sumnall, R. (2022) Essential critical care skills 3: arterial line care. Nursing Times, 118 (1), 24-26 [Online]. Available at **https://www.nursingtimes.net/clinical-archive/critical-care/essential-critical-care-skills-3-arterial-line-care-13-12-2021/** (Accessed 28 April 2022).

Royal College of Nursing. (2021) Nursing workforce standards: supporting a safe and effective nursing workforce [Online]. Available at **https://www.rcn.org.uk/professional-development/publications/rcn-workforce-standards-uk-pub-009681** (Accessed 14 April 2022).

Royal Pharmaceutical Society. (2018) Professional guidance on the safe and secure handling of medicines [Online]. Available at **https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines** (Accessed 19 April 2022).

Stapleton, R. D. and Heyland, D. K. (2022) Glycemic control in critically ill adult and pediatric patients [Online]. Available at **https://www.medilib.ir/uptodate/show/1600** (Accessed 28 April 2022).

Tase, A., Ni, M. Z., Buckle, P. and Hanna, G. B. (2022) Current status of medical device malfunction reporting: using end user experience to identify current problems. BMJ Open Quality, 11 (2), e001849 [Online]. DOI: 10.1136/bmjoq-2022-001849.

The Working Time Regulations 1998 [Online]. Available at **https://www.legislation.gov.uk/uksi/1998/1833/contents/made** (Accessed 24 March 2022).

Appendix 1 Key information on data extraction and analysis from the National Reporting and Learning System (NRLS)

The NRLS was searched using the following criteria.

Theme/area	Description/comment
Source of data	National Learning and Reporting System (NRLS)
Library/dataset	All standard map
Date of extraction	25 October 2021
Date used for qualifying extraction	Date reported: 1 September 2016 to 31 August 2021
Categorical filters	Free text field
Country	England
Search term	%_arterial_%

The results were then further filtered to exclude incidents where the age in the 'patient age range' field was 17 years or less. Incidents where the patient's age was not provided were filtered to exclude those where the clinical area in the 'In03 Location' described the location of a children's healthcare provider. The remaining incidents with no patient age were included in the analysis, so may have included incidents where the patient was aged 17 years or less.

The data was filtered to provide the two time periods for analysis:

Period 1 – On and between 1 September 2016 to and including 31 August 2020.

Period 2 – On and between 1 September 2020 to and including 31 August 2021.

The filtered data from period 1 above was reviewed and incidents relating to the wrong infusion flush solution were manually extracted.

The filtered data from period 2, specific to the time when the reference event occurred, was read line by line and incidents relating to the wrong infusion flush solution were manually extracted. Incidents were only included where the report identified a mismatch between the flush solution selected and the flush solution that the local guidelines specified.

For assurance, an electronic search of all field was completed using the terms 'wrong fluid', 'transduce', 'transduced', 'transducer', 'flush bag' and 'arterial flush'. This did not identify any new incidents.

Summary of wrong arterial flush infusion incidents reported to the NRLS on and between 1 September 2020 to 31 August 2021

Reported degree of harm	Number of incident reports		
	By harm level	Associated with hyperglycaemia	Requiring initiation of dose increase of insulin
Moderate harm	2	2	2
Low harm	12	6	3
No harm	130	10	3
All harms	141	18	8

Summary of wrong arterial flush infusion incidents reported to the NRLS from 2005 until 2015

Reported degree of harm	Number of incident reports		
	Before 2008	After 2008	Total
Associated with hyperglycaemia	2	4	6
Severe harm	0	2	2
All harms	40	259	299

This contrasts with a previously reported analysis of NRLS data from 2005 until 2015 described by Patel et al (2020). This reported an increase in the average number of incidents reported per year between 2005 and 2021. There were more episodes of hypoglycaemia reported in the detailed analysis than were reported between 2005 and 2015 (18 compared with 6 respectively).

Appendix 2 Stakeholders – workshop attendees

Representatives from the following organisations took part in the investigation's workshops.

Clinical	Pharmaceutical	Commercial	National
Association of Anaesthetists	UK Clinical Pharmacy Association	Association of the British Pharmaceutical Industry	NHS Supply Chain
Royal College of Anaesthetists	Royal Pharmaceutical Society	Association of British HealthTech Industries	Health Education England
The Safe Anaesthesia Liaison Group			Medicines and Healthcare products Regulatory Agency
Centre for Perioperative Care			Care Quality Commission
The Faculty of Intensive Care Medicine			Chartered Institute of Ergonomics and Human Factors
Intensive Care Society			Medicines Safety Improvement Programme, NHS England and NHS Improvement
College of Operating Department Practitioners			Specialist Pharmacy Services (SPS) NHS England and NHS Improvement
Association for Perioperative Practitioners			Medical Technologies Directorate, Department of Health and Social Care
British Association of Critical Care Nurses			
Royal College of Emergency Medicine			

Appendix 3 Examples of staff shift patterns and hours of work

D = day, DO = day off, LD = long day, N = night, A/L = annual leave, SD = study day Red = incorrect flush fluid indentified

Example 1

	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
NHS			DO	DO	DO	DO	DO	DO	DO	DO	DO	DO	DO	DO	DO	DO	DO	DO	DO	DO	DO	DO	DO	DO	D	D	DO	D
NHS Professionals																												

Example 2

	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
NHS	DO	DO	D	DO	LD	LD	DO	D	D	DO	DO	D	L	N	N	N	N	DO	DO	DO	LD	LD	DO	A/L LD		D	DO	D
NHS Professionals											D														D			

Example 3

	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
NHS	N	N	N	DO	DO	DO	DO	DO	DO	N	N	N	N	DO	DO	DO	DO	D	D	D	DO	N	N	N	N	DO	DO	DO
NHS Professionals		DO		N	N	N	N							N	N							LD		DO				

Example 4

	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
NHS		Induction			LD	LD		SD	S/L	SD	A/L	N	N	A/L	N	N	N	DO			N	N	DO	DO	N	N	N	DO
NHS Professionals																												

Appendix 4 A sample of information from the Systemic Human Error Reduction and Prediction Approach (SHERPA) (Embrey, 2014)

Representatives from the following organisations took part in the investigation's workshops.

	Task type	Failure type	Failure description	Consequence	Existing safety controls	Performance influencing factors
Gather equipment						
Collect 0.9% sodium chloride (500ml) from storage location (IV trolley, fluid storeroom, bedside?)	Selection	Incorrect selection	• Incorrect content • Incorrect volume • Incorrect strength (%)	Glucose selected instead of 0.9% sodium chloride	Subsequent double check	Time-critical task Design of label Storage layout Organisation – policy Fatigue Workload Motivation – priorities
Check collected correct fluid – double/single checking policy	Checking	Check	• Inadequate attention to check • No check	Control for selection of double check ineffective	Double check and signature in record system	Motivation – priorities Perceived risk Time pressure Fatigue Workload
Sign in record	Recording	Action omitted	• Omitted second signature? • May not be prescribed in records to add signature to	Lack of accountability for second check	None at time of incident – no forcing function in IT system for signature	Motivation – priorities Perceived risk Time pressure Fatigue Workload
Complete checks						
Type of fluid	Check	Check omitted	• No check • Inadequate check	Missed incorrect fluid	Next shift handover check	Memory Time pressure Culture Workload
Perform blood sampling						
Withdraw estimated volume equivalent to x3 to x5 of dead space	Action	Amount too little	• Inadequate amount of blood withdrawn to reduce the risk associated with the contamination of blood sample to be tested	Inaccurate analysis of blood gas sample, which implies hyperglycaemia in the event of a glucose based flush fluid incorrectly used Incorrect clinical conclusion and subsequent treatment with insulin and potential for neurological harm or death	Waste sample – x3 to x5 dead space Medical review to consider risk of flush fluid prior to treatment with insulin Closed systems, which control volume of waste sample and return blood back to patient's system, may reduce risk of sample contamination	Motivation – priorities Perceived risk of flush Time pressure Fatigue Workload Reliability of staff to correctly recall and estimate the volume of dead space required

WWW.HSIB.ORG.UK
@hsib_org

HSIB
HEALTHCARE SAFETY INVESTIGATION BRANCH

Further information

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

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

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

Contact us

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

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

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