



Investigation report

Residual drugs in intravenous cannulae and extension lines

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Medical devices, Checking

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Contents

[Show subheadings](#)

[A note of acknowledgement](#)

[Executive Summary](#)

[1 Background and context](#)

[2 The reference event](#)

[3 Involvement of HSIB](#)

[4 Analysis and findings from the reference event](#)

[5 Analysis and findings from the wider investigation](#)

[6 Summary of HSIB findings, safety recommendations and safety observations](#)

[7 Endnotes](#)

[8 References](#)

[9 Appendix](#)

A note of acknowledgement

We are grateful to Spencer, whose experience is documented in this report. The report's safety recommendations, which have been developed by examining the care Spencer received and the issues which arose, support Spencer's wish to prevent other patients having the same experience.

We are also grateful to the various NHS organisations and their staff who contributed to the investigation at various stages. We would also like to thank stakeholders from medical royal colleges, professional bodies, allied health professional colleges, and industry. Their expertise and insight allowed greater depth of understanding of the issues explored, and supported the development of the safety recommendations and safety observations that will ultimately help to improve safe and effective care in future.

Executive Summary

Background

This investigation examines the patient safety issues that occur when residual drug that has been left behind in intravenous (IV) cannulae and extension lines is inadvertently administered to a patient. As an example, the investigation focuses on a specific incident where residual drugs remained in a patient's IV cannula and extension line following the administration of anaesthesia. This incident is referred to as 'the reference event'.

Neuromuscular blocking agents (NMBAs) (also known as muscle relaxants) are a class of drug used when anaesthetising patients during an operation. When administered, the neuromuscular blocker produces paralysis of all skeletal muscle including those controlling the vocal cords. This allows an endotracheal tube (breathing tube) to be placed in the trachea (windpipe), as well as relaxing the patient's muscles during surgery to aid surgical access.

NMBAs also paralyse the muscles required to breathe until the effects of the paralysing agent have ceased; during this period, the patient requires external support to breathe. NMBAs need to be given with an anaesthetic to prevent the patient being awake and unable to move and breathe.

To administer muscle relaxants and anaesthetic drugs, a thin plastic tube called a cannula is inserted into a patient's vein. Extension lines may be attached to the cannula to increase the points of access to allow multiple drugs to be given at the same time. After administration, the drugs should be flushed through the cannula and extension line. This is to prevent any residual drugs inadvertently entering the patient's bloodstream later on.

A patient safety alert issued by NHS Improvement in November 2017 stated that in the three years from April 2014, 58 incidents of residual anaesthetic or sedative drugs in cannulae and extension lines, involving either adults or children, were reported to the National Reporting and Learning System (a central database of patient safety incident reports). Eighteen were reported as causing respiratory arrest (that is, the patient stopped breathing) and the remaining incidents described effects including temporary paralysis, muscle spasms, and difficulty breathing.

The issue of residual drugs in cannulae and extension lines has existed for many years. Actions have been taken to mitigate the likelihood of such events occurring, such as the publication of papers within the anaesthetic community and the issuing of patient safety information. The NHS patient safety alert issued in 2017 required all organisations to add prompts to existing procedure documentation. This included an extra question in the 'Sign Out' of trusts' locally adapted World Health Organization (WHO) surgical safety checklists, asking the anaesthetist if all cannulae and intravenous lines have been flushed or removed.

The reference event

Spencer, a man aged 42 years with a complex health history, was admitted to hospital with a kidney infection. On the second day in hospital, it was decided that he needed an operation, that same day, to drain his infected kidney. The procedure, known as a nephrostomy, was undertaken in the interventional radiology (IR) department as it uses X-ray imaging to guide the doctors. It is a keyhole procedure, so is less invasive than carrying out an equivalent operation in the main operating theatres.

The procedure required Spencer to be under general anaesthetic. A request was made to the operating theatre co-ordinator to arrange for an anaesthetist and operating department practitioner (ODP) to attend the IR suite at the agreed start time. For 'same-day' cases, the anaesthetic team was formed dynamically, using staff who were on call or were available.

The procedure was scheduled for early afternoon. Blood needed to be taken from Spencer prior to the operation, but the team on the ward had trouble finding a vein to take blood from. This meant the procedure was delayed by around 90 minutes. Spencer arrived at the IR suite with a non-ported IV cannula (a cannula without an opening for a syringe) already in place. Due to the anticipated difficulty with inserting a further ported cannula (the type used more typically for an

anaesthetic), the anaesthetist opted to administer the anaesthetic drugs via the existing cannula. After Spencer was asleep, a further cannula was inserted and the remainder of the anaesthetic was managed via this additional cannula.

The procedure was completed and the team used a locally adapted version of the WHO surgical safety checklist to confirm required actions at the end of the procedure. The cannulae and extension lines were reported to be flushed and Spencer was woken from the anaesthetic. At that point, it was usual practice for a patient's recovery to be overseen by a post-anaesthetic recovery practitioner, but one was not available. The IR department was about to close, and this meant arrangements had to be made to move Spencer to an alternative post-anaesthetic recovery unit (PACU). The ODP attempted to have Spencer accepted into the day-case operating theatre and main operating theatre PACUs; however, both initial attempts were unsuccessful due to these units being full. The anaesthetist decided that the safest course of action was to return to the main theatre PACU as the IR was being shut and it was not appropriate to continue in that environment. Spencer was in the operating theatre PACU for a short period of time before being taken back to the surgical assessment ward. The usual process for admitting and discharging patients from the PACU was not undertaken.

Shortly after arriving on the ward, Spencer complained of feeling unwell and was diagnosed as having an infection. The urology registrar (a doctor who specialises in diseases of the kidneys, bladder and prostate) prescribed IV antibiotics to treat the infection and IV paracetamol to treat the pain and fever.

A member of the nursing team gave the antibiotics and set up the IV paracetamol infusion (drip) according to the prescription. However, it was later identified that Spencer's IV paracetamol had 'stopped working'. The agency nurse who was caring for Spencer was not trained to administer IV drugs and sought an IV-trained nurse to assist.

The IV-trained nurse flushed both cannulae with sodium chloride to restore the administration of the paracetamol. Soon after the flushing was done, Spencer started to complain of feeling strange, stating he could not breathe, before going limp. Fortunately, Spencer's respiratory arrest was witnessed by a doctor who immediately commenced manual ventilation via a bag-valve mask. Spencer began to breathe on his own a few minutes later and suffered no physical harm. However, he has reported significant psychological impact and is suffering from both nightmares and flashbacks.

The investigation found that the most likely cause of Spencer's respiratory arrest was that a residual volume of the NMBA, suxamethonium, had remained in Spencer's non-ported cannula and extension line following the administration of his anaesthetic. It had then been flushed through a few hours later by the nurse on the surgical ward, causing Spencer to go into respiratory arrest.

National investigation

The HSIB investigation explored the perioperative pathway (the care provided before, during and after an operation) in relation to residual drugs in intravenous cannulae and extension lines. This included:

- observing how surgical safety checklists are used in operating theatre and non-theatre settings to ensure that cannula flushing is undertaken
- exploring the design, procurement and change management of intravenous consumables, such as cannulae and extension lines
- examining medicines safety, management, and governance arrangements, including prescribing arrangements, record keeping, medicines dosage and presentations, and reporting of incidents.

Summary of findings

The findings are grouped into three key themes:

- measures that could be put in place (mitigations) which could reduce the risk of residual drugs in cannulae and extension lines
- planning for and delivery of emergency procedures in the nontheatre setting
- reporting of incidents.

Key findings associated with mitigations which could reduce the risk of residual drugs in cannulae and extension lines

The investigation found:

- One of the key risk factors associated with residual drugs in cannulae and extension lines is the risks associated with the drug itself – particularly drugs that can have a clinically significant effect in low volumes.
- Flushing is a key mitigation for preventing the risk of residual drugs in cannulae and extension lines; however, it is a less effective solution for preventing these events than removing, substituting or engineering out the risk.
- There are issues associated with the design of IV equipment which increase the risk of residual drugs in cannulae and extension lines. There may be opportunities to improve the design of equipment to ‘design out’ the potential for errors. The unintended consequences of redesign would need to be considered.
- Where certain drugs are used, such as NMBAs and some strong opioids (relaxant or pain-relieving drugs), flushing becomes a safety-critical task. However, the task of flushing is

functionally the same and there are limited additional steps or process alterations that mark the flushing of a consequential drug versus flushing to maintain the flow of fluid through a cannula.

- Surgical safety checklists are used to mitigate the risk of residual drugs in cannulae and extension lines following anaesthesia. Items on the surgical safety checklist act as prompts for expected actions or tasks, and do not include second/ independent checks or other hazard control activities proportionate to the risks being addressed by the process.
- Greater attention and focus is given to the initial 'Sign In' and 'Time Out' phases of the surgical safety checklist compared to the 'Sign Out' phase. The Sign Out process appears to compete with other tasks and processes and is often rote-learned and anticipated. This presents the risk that the purpose of the checklist is lost and safety-critical checks overlooked.
- There is variation between IV devices and associated equipment. Many of these devices appear outwardly similar but, according to manufacturers' information, have variable specifications relating to the potential for regurgitation (fluid going in the opposite direction than intended).
- Consumable intravenous equipment may be subject to change for a range of reasons which may include availability, cost, newer/better variants, and quality. Training and awareness of these changes is rarely provided, but there is a risk that staff are not made aware of changes to specification and/or device performance.
- Several years ago, healthcare trusts acted upon guidelines issued in 2014 for the prevention of healthcare-associated infections in NHS hospitals in England to minimise the number of ports on cannulae. The change management process at the time to the use of non-ported cannulae was sub-optimal and did not consider a wide range of stakeholders, including the end users.
- In adult care, the administration of flushes is rarely listed or recorded on perioperative documentation.
- Patients with multiple IV access sites are believed to be at greater risk of incidents involving residual drugs in cannulae and extension lines. Recording of IV sites in documentation is not consistent.
- Paediatric anaesthetic practice differs from adult practice as flushes are prescribed and reconciled due to the specific additional considerations when administering anaesthetics to small children.

Key findings associated with planning for and delivery of emergency procedures in the non-theatre setting

The investigation found:

- There is limited guidance around the planning process for undertaking anaesthesia in the non-theatre setting. This may impact on the follow-up actions should an adverse event occur.
- Guidance from the Royal College of Anaesthetists promotes the use of co-ordinators in the booking of emergency cases, but there is a lack of specific guidance on oversight of patients throughout the perioperative pathway, particularly for cases in the non-theatre setting.
- Anaesthetists report that the team dynamics in non-theatre settings are different from those they experience when working as part of a surgical team in the operating department.
- Medicines given during perioperative care may not be transcribed into the patient's main drug chart/record.

Key findings associated with the reporting of incidents

- The reporting of incidents of 'awareness under general anaesthetic' is well established but the circumstances of the reference event may not fulfil the published definition. This may result in underreporting of such incidents.
- The reporting of incidents will be moving away from lists of specific incident types in order to improve the ability to learn and target improvements at the right areas.

Impact of COVID-19 and intention for safety recommendation

The investigation report was finalised during the COVID-19 pandemic. At the time, much of HSIB's and key stakeholders' work was necessarily redirected to supporting frontline services and focusing on issues specifically related to COVID-19.

HSIB intends to develop and issue a safety recommendation around identifying medicines that present a high risk if inadvertently retained in a cannula and/or extension line, and to assess and strengthen the mitigations in place for each identified medicine. HSIB has identified a potential stakeholder to lead on this work; however, the stakeholder's capacity to discuss a recommendation is currently limited owing to COVID-19 pressures.

Given the importance of the findings in this report, HSIB decided to publish the findings, safety recommendations and safety observations so far and to issue a further safety recommendation in due course.

HSIB makes the following safety recommendations

Safety recommendation R/2021/115:

HSIB recommends that the Royal College of Anaesthetists and Centre for Perioperative Care work with relevant stakeholders, such as the Association of Anaesthetists, College of Operating Department Practitioners, and Association for Perioperative Practice, to review, update and integrate new guidance on the surgical safety checklist 'SignOut' process. Specifically, the guidance should be updated in relation to the flushing of cannulae and extension lines by strengthening the current administrative barriers, considering the hierarchy of hazard control, and the issues identified by the HSIB investigation.

Safety recommendation R/2021/116:

HSIB recommends that the Royal College of Anaesthetists reviews its 'Guidelines for the provision of anaesthetic services' regarding the planning and oversight of perianaesthetic care in non-theatre settings. This should include:

1. guidance to assist anaesthetic departments to consistently plan for short-notice or emergency cases which take place in the non-theatre setting
2. planning which considers and mitigates against unexpected changes in conditions.

HSIB makes the following safety observations**Safety observation O/2021/098:**

It may be beneficial for healthcare trusts to adopt the programme provided by Health Education England for intravenous (IV) skills, which supports the competency requirements published by the Nursing and Midwifery Council.

Safety observation O/2021/099:

It may be beneficial to increase the use of body maps to record the presence of all indwelling items, such as cannulae, catheter and drains, during an anaesthetic procedure. The body map could be used as part of an enhanced sign-out and to provide instructions for the management of each indwelling item in the postoperative period.

Safety observation O/2021/100:

It may be beneficial for manufacturers to further standardise product specifications to design out the potential for errors. For example, items such as Y-connectors, extension lines and needle-free connectors often look similar but may have differing specifications.

1 Background and context

1.1 Intravenous cannulae and associated items

1.1.1 An intravenous cannula is a thin tube inserted into a vein. One of its primary functions is to provide a way through which medicines are administered. Medicines administered through the intravenous (IV) route can act very quickly as they enter the bloodstream immediately.

1.1.2 Cannulae are manufactured in various sizes and to a standard sizing specification (International Organisation for Standardization, 2015). The size of the lumen (that is, the width of the tube) ranges from very small cannulae intended for pre-term babies, through to wide-bore cannulae used for rapid administration of blood or giving large volumes of IV fluids to adult patients.

1.1.3 Cannulae have a Luer lock connector on the rear of the device and some have an injection port on the top of the device. Cannulae with an injection port may be referred to as ported (**see figure 1**) and those without, non-porting (**see figure 2**). The port on a ported cannula is designed to accept the tip of a syringe for injecting medicines.

Fig 1 Image of ported cannula

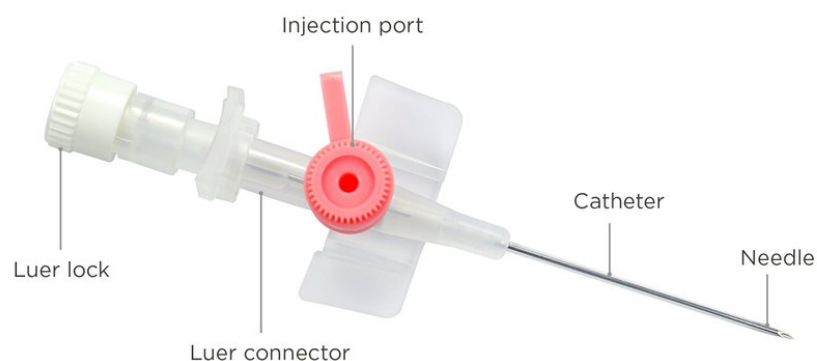


Fig 1 Image of ported cannula

Fig 2 Image of non-ported cannula



Fig 2 Image of non-ported cannula

1.1.4 It was reported by anaesthetists that they preferred to use ported cannula because the drug administration port allowed them to give drugs with one hand. This allowed them to conduct another task, such as supporting a mask providing oxygen, with the other hand during the induction of anaesthetic. Non-ported cannula with an extension piece attached required two hands to administer a drug; one to hold the extension piece, the other to inject.

1.1.5 Luer lock connections allow an infusion (drip) to be secured to the cannula by means of a threaded section on the male and female aspects of each item.

1.1.6 A range of items can be attached to a cannula via the Luer lock (**see figure 3**), including; three-way taps (valves for switching between different infusions), extension line (to extend the length of the infusion line to assist with drug administration, commonly used if the patient is under surgical drapes), Y-connectors/multi-limb connectors (which allow flow from multiple infusions into a single cannula).

Fig 3 Examples of items that can be attached to a cannula

Extension line with three-way tap

Single, 'Y' and multi-limb extension lines



Fig 3 Examples of items that can be attached to a cannula

1.1.7 Extension lines may be equipped with a needle-free connector, in-line clamps, non-regurgitation/one-way valves or 'anti siphon' valves. Extension lines and other devices may vary in lumen size (width of tube) and have varying types of clamps and valves depending on the individual product.

1.2 General anaesthesia

1.2.1 General anaesthesia is 'a state of controlled unconsciousness. During a general anaesthetic, medications are used to send you to sleep, so you're unaware of surgery and don't move or feel pain while it's carried out' (NHS, 2018). The medications used include a combination of analgesia (pain relief), anaesthetic agents and, in some cases, neuromuscular blockade (to induce paralysis). Together, these create a state in which the patient is unconscious, unable to move, and unable to recall any events during the period of anaesthesia. Where neuromuscular blocking agents (NMBAs) have been administered, the patient will not be able to breathe and their breathing will need to be supported in some way by the anaesthetist caring for the patient.

1.2.2 There are safety standards in place for anaesthesia, developed by a range of stakeholder groups, including the Royal College of Anaesthetists, NHS England and NHS Improvement, the Medicines and Healthcare products Regulatory Agency, and the Association of Anaesthetists. These organisations work together via the Safe Anaesthesia Liaison Group and publish

guidance on safe anaesthetic and sedation practice. Around one patient dies for every 100,000 anaesthetic procedures each year in the UK (Royal College of Anaesthetists, 2016) so despite the overall safety measures in place, anaesthesia has a level of risk.

1.2.3 The Royal College of Anaesthetists and the Association of Anaesthetists publish guidance on all aspects of anaesthesia and sedation which covers its use in practice in all settings. This includes anaesthesia undertaken outside of the usual operating theatre environment, such as in endoscopy suites, pre-hospital care, and imaging settings.

1.3 Neuromuscular blocking agents (NMBAs)

1.3.1 NMBAs (also known as muscle relaxants) are a class of drug used when anaesthetising patients during an operation. When administered, the neuromuscular blocker produces paralysis of all skeletal muscle including those controlling the vocal cords – this allows an endotracheal tube (breathing tube) to be placed in the trachea (windpipe), in addition to providing muscle relaxation during surgery to aid surgical access.

1.3.2 NMBAs also paralyse the muscles required to breathe until the effects of the paralysing agent have ceased; in this period, breathing requires external support. NMBAs need to be given with an anaesthetic to prevent the patient being awake and unable to move or breathe.

1.3.3 NMBAs are not always required to facilitate an anaesthetic or surgical procedure. The 5th National Audit Project (Royal College of Anaesthetists and Association of Anaesthetists of Great Britain and Ireland, 2014) reported that 46% of the general anaesthetics administered in the UK include the use of an NMBA.

1.3.4 During the induction of anaesthesia, acutely ill patients requiring an urgent or emergency procedure are at higher risk of inhalation of gastric contents (solids or fluid from the stomach) than patients having elective (planned) surgery. A method of anaesthetic induction, referred to as a rapid sequence induction (RSI), is performed to minimise this risk. 1.3.5 An RSI requires a fast-acting NMBA to achieve conditions to allow the patient's airway to be protected as quickly as possible. Suxamethonium is an NMBA with a rapid onset that can be used for this purpose. Suxamethonium is manufactured, distributed, and administered in a high-concentration, low-volume format (100mg in 2ml).

1.4 Sodium chloride flush

1.4.1 Sodium chloride 0.9% (saline solution or 'salty water') is a licensed medicine which is available in different volumes depending on its intended use. In small quantities (5ml to 20ml) it is used to flush IV cannulae and other medical devices and is also used to dilute medicines.

1.4.2 In the patient safety incident examined for this investigation, sodium chloride was administered via the IV route, and as such should be treated as a prescription-only medicine according to The Prescription Only Medicines (Human Use) Order 1997. Prescriptiononly medicines are licenced pharmaceutical products that must either be prescribed by a doctor or non-medical prescriber or administered/supplied using an alternative legal mechanism.

1.4.3 The Royal Pharmaceutical Society informed the investigation that sodium chloride flushes should be documented.

1.5 World Health Organization surgical checklists

1.5.1 The World Health Organization (WHO) developed the original surgical safety checklist in 2009 as a way to improve team communication and consistency of care, and therefore reduce complications and deaths associated with surgery (Haynes et al, 2009).

1.5.2 The WHO checklist is a 19-item checklist which lists a range of tasks and prompts, each specifically designed to address known safety risks. The checklist is intended to be applicable to all environments and types of surgery.

1.5.3 The WHO stated that 'adaptation of the Checklist is encouraged to better fit the needs and processes of care in specific environments and surgical disciplines' (World Health Organization, n.d.). Where the checklist is used without modification, it can bear the WHO logo. However, the WHO states that in cases where the checklist has been locally adapted, its logo cannot be used and a citation should be added stating that the local version is:

'Based on the WHO Surgical Safety Checklist, <http://www.who.int/patientsafety/safesurgery/checklist/en/index.html>, © World Health Organization 2009. All rights reserved.' (World Health Organization, 2009c)

1.5.4 The checklist is used at three points during a patient's operative pathway:

- **Sign In:** Completed when the patient arrives in the operating department (usually in the anaesthetic room, or operating theatre if an anaesthetic room is not used) to ensure that the indicated procedure is being carried out on the correct patient.
- **Time Out:** Following the induction of anaesthetic but prior to the commencement of the surgical procedure, to again ensure that it is the correct patient and that the indicated procedure is being carried out in the correct location (for example, left or right side of the body).

Sign Out: Completed at the end of the procedure prior to the patient leaving theatre.

1.6 Nephrostomy undertaken by interventional radiologists

1.6.1 A nephrostomy is a surgical procedure which is performed to allow for drainage of the kidney and prevent damage from occurring while the cause of a blocked ureter (the tube connecting the kidney to the bladder) is addressed. It involves creating a surgical opening in the patient's side through which a catheter (tube) is passed through which the urine can drain (British Society of Interventional Radiology, 2018).

1.6.2 Nephrostomies are performed by interventional radiologists. The procedure is usually undertaken in the interventional radiology department. Sometimes the patient will be under sedation during the procedure (that is, they are given relaxant and painkilling drugs, but remain conscious). Some patients who are more unwell may require a general anaesthetic for the procedure. Where an anaesthetic is required, the procedure may still be undertaken in the interventional radiology department or in a radiology operating theatre in the main operating department, depending on the hospital.

1.7 Infection prevention and control

1.7.1 Cannulae are a potential route of infection and a series of studies have been carried out in response (Loveday et al, 2014). These studies have informed the choice of cannulae used in healthcare, aimed at minimising healthcare associated infections.

1.7.2 The WHO defines infection prevention and control (IPC) as: '... a scientific approach and practical solution designed to prevent harm caused by infection to patients and health workers. It is grounded in infectious diseases, epidemiology, social science and health system strengthening. IPC occupies a unique position in the field of patient safety and quality universal health coverage since it is relevant to health workers and patients at every single healthcare encounter.' (World Health Organization, 2020)

1.7.3 All healthcare providers are required to have IPC procedures in place and to work to reduce/ prevent healthcare acquired infections and the harm these can cause to patients.

1.7.4 Typically, healthcare providers such as acute hospital trusts will have a team of infection control leads and practitioners working to quality standards issued by the National Institute for Health and Care Excellence (National Institute for Health and Care Excellence, 2014).

1.7.5 NHS organisations are required to report their infection rates nationally, and these are published centrally by NHS England and NHS Improvement. Some infections are reported on specifically, such as *Clostridium Difficile* (C. Diff) and MRSA (methicillin resistant staphylococcus aureus).

1.7.6 This report includes reference to specific infection control measures associated with IV cannulae.

1.8 Residual medicines in cannulae and extension lines

1.8.1 After the administration of a drug through a cannula either directly or via an extension line, the residual drug will remain in the cannula system 'dead space' (within the lumen of the extension line and the cannula itself) unless it is flushed or another drug is administered. Flushing involves the administration of a volume (usually 5 to 10 ml) of sodium chloride solution using a syringe. The effect of the residual drug on the patient will depend on:

- **The amount of drug required to produce an effect:** The pharmacological effect of the drug will be affected by the weight of the patient; consequently the dosage of many drugs is given based on weight (there are also additional factors, such as age, on which dosage is based). For example, suxamethonium is a drug which is presented in a relatively high concentration in a relatively low volume (100mg in 2ml), which means small volumes of the drug have the potential for a clinically significant effect, especially on smaller patients due to their lower body mass.
- **Attachment of extension line:** An extension line attached to the back of a cannula will allow the drug to be given through it (**see figure 3**). More of the drug would be present in an extended system, and hence have an increased effect when flushed.
- **When and where the flushing occurs:** If the residual drug was an NMBA and it was flushed just after the main dose is administered (during the induction period of anaesthesia) then the added effect would be negligible as it would essentially form part of the total dose given at that time. If the drug was given later during the procedure while the patient was still under anaesthetic, any effect would likely be picked up by the anaesthetist and managed accordingly. If the extension line was flushed after the procedure had finished, when the patient was awake, this would lead to a degree of awake paralysis – that is, the patient would be conscious but their ability to move would be affected. The degree of the effect would depend on the dose remaining in the extension line and the patient's size. As NMBAs paralyse the breathing muscles, prompt detection and management by an appropriately trained and experienced clinician would be required to prevent life-threatening low oxygen levels.

1.9 History of safety alerts relating to residual drugs in cannulae

1.9.1 In 2009, a National Patient Safety Agency alert was issued following harmful incidents involving children after the flushing of residual drugs in cannulae (National Patient Safety Agency, 2009). The trigger incident was a serious event where a baby suffered a cardiac arrest (their heart stopped). Although successfully resuscitated, the baby suffered significant brain damage. Local investigation suggested that the NMBA used during the operation remained in the cannula system dead space, which was then administered inadvertently when antibiotics were later given intravenously.

1.9.2 The Medicines and Healthcare products Regulatory Agency issued a medical device alert pertaining to intravenous extension sets with multiple ports. It describes the risk of back-tracking when an IV line has multiple access ports (as part of the extension set). This can lead to under-infusion of a drug or inadvertent delivery of the drug when the extension line is subsequently flushed (Medicines and Healthcare products Regulatory Agency, 2010).

1.9.3 NHS Improvement issued a patient safety alert in 2014, after it was identified that there had been several incidents of cardiac or respiratory arrest (where a patient's heart or breathing stops) due to residual anaesthetic drugs in cannulae (NHS England, 2014).

1.9.4 Since the 2014 alert, 58 incidents involving either anaesthetic or sedative drugs in adults or children have been reported to the National Reporting and Learning System (the central database of patient safety incident reports). Eighteen were reported as causing respiratory arrest and the remaining incidents described effects including temporary paralysis, muscle spasms, and difficulty breathing (NHS Improvement, 2017).

1.9.5 NHS Improvement (2017) issued a patient safety/directive alert requiring all organisations to embed changes to procedures by adding prompts to existing procedure documentation. This was intended to confirm that all cannulae and IV lines that may contain residual drugs have been fully flushed or removed. This included an extra question in the Sign Out part of the WHO checklist, asking the anaesthetist if all cannulae and IV lines have been flushed or removed.

1.9.6 The NHS Improvement (2017) patient safety alert also states actions for what is to be included in local documentation for patient handover from procedural areas to recovery, and to the subsequent place of care. This includes the requirement for documented and verbal confirmation that IV lines not in active use have been removed and multi-lumen connectors and cannulae removed or flushed.

2 The reference event

This investigation used the following patient safety incident, referred to as 'the reference event', to examine the issue of residual drugs in intravenous (IV) cannulae and extension lines.

2.1.1 The patient involved in the reference event, Spencer, has a complex health history and is a double amputee. He was 42 years old at the time of the reference event.

2.1.2 Spencer began to feel unwell, suffering from back pain and a raised temperature. Due to his worsening condition, he was admitted to hospital as an emergency at 17:00 hours on 4 February. He was diagnosed with a kidney infection.

2.1.3 Following an assessment by his doctors the next morning, it was decided that Spencer needed an urgent procedure to drain his infected kidney (a nephrostomy).

2.1.4 A request was made to the anaesthetic department to provide an anaesthetist and operating department practitioner [1] (ODP) to attend the interventional radiology [2] (IR) suite to provide a general anaesthetic that same day.

2.1.5 Shortly before the time that Spencer was due to be taken to the IR suite for his nephrostomy, a doctor attempted to take a blood sample. The doctor found it difficult to find a vein to draw blood from and it took several attempts over the following 90 minutes to obtain the sample. An IV cannula was inserted into a vein in Spencer's right hand through which the blood sample was taken. The cannula was left in situ (in place). The nephrostomy commenced approximately 90 minutes later than originally planned.

2.1.6 The anaesthetist decided that as establishing IV access had proven challenging while taking blood earlier, they would use the cannula that had been inserted on the ward to administer the anaesthetic drugs. It was planned to insert another cannula after Spencer was anaesthetised. The cannula already in situ was nonported and had a dual-lumen extension line attached (**see figure 5, 4.3.4**).

2.1.7 A rapid sequence induction of general anaesthesia commenced at 14:45 hours. Anaesthesia was induced using fentanyl (a strong painkiller similar to morphine) and propofol (an anaesthetic induction agent). Following this, a neuromuscular blocking agent (NMBA) (muscle relaxant) called suxamethonium was given (concentration: 100mg in 2ml).

2.1.8 Once Spencer was anaesthetised, a ported cannula was inserted in his left arm. This was used during the nephrostomy procedure to administer further anaesthetic drugs and fluids.

2.1.9 Spencer was partially turned onto his right side to allow access to the area where the surgical procedure would take place. The nephrostomy was conducted without any complications and concluded at approximately 16:10 hours.

2.1.10 Spencer remained in the IR suite while the post-procedural tasks were completed, such as removing equipment and drapes, until he started to wake from the anaesthetic.

2.1.11 The hospital trust where the incident took place (referred to in this report as 'the Trust') used an adapted World Health Organization (WHO) surgical safety checklist, 'Interventional radiology complex cases'. This checklist was completed and signed by members of the surgical and anaesthetic team. This involved two steps before the procedure was undertaken (Sign In and Time Out) and a final step (Sign Out) after the procedure was completed. Part of the Sign Out requires confirmation that all IV cannulae are flushed. The Sign Out record was completed to reflect that the flushing had taken place.

2.1.12 Once awake and stable, Spencer was moved to the recovery area within the IR suite. The standard practice at the Trust was to have a post-anaesthetic recovery practitioner from the main operating theatre in attendance.

2.1.13 The anaesthetist and ODP were made aware that a recovery practitioner would not be attending to take over Spencer's care while he recovered from the anaesthetic. Due to the time of day and the lack of a post-anaesthetic recovery practitioner, it was decided to attempt to move Spencer to a post-anaesthetic care unit (PACU) in one of the hospital's operating theatre departments.

2.1.14 The ODP was tasked with making the arrangements for Spencer's recovery. This required several telephone calls to be made to the two PACUs in the hospital. Both units were full and were not able to accept patients. This left the anaesthetist and ODP on their own with the patient without a post-anaesthetic recovery practitioner and distanced from other clinical support.

2.1.15 The consultant anaesthetist and ODP were informed there was no space in the day surgery or main operating theatre PACUs. However, the consultant anaesthetist decided that it would be safer to relocate Spencer to the main operating theatre PACU and he was transferred there.

2.1.16 Spencer remained in the operating theatre PACU for a short period of time. He was not formally admitted to PACU as they were not expecting him and the area was full. The anaesthetist reported that Spencer was seen and that his observations (routine checks such as heart rate, breathing rate, blood pressure and temperature) were assessed to be within the expected range; therefore he was sent to the surgical assessment ward.

2.1.17 At around 18:00 hours, Spencer complained of feeling unwell and was reviewed by a urology registrar who documented in the medical notes a diagnosis of 'post nephrostomy sepsis'. The urology registrar prescribed IV antibiotics to treat the infection and IV paracetamol to treat the pain and fever.

2.1.18 A member of the nursing team gave the antibiotics and set up the IV paracetamol infusion according to the prescription. However, at approximately 19:00 hours, it was identified that Spencer's IV paracetamol being administered via the left arm cannula had 'stopped working'. The agency nurse who was caring for Spencer was not trained to administer IV drugs and sought an IV-trained nurse to assist.

2.1.19 The IV-trained nurse arrived from another ward area to assist her colleague with the infusion. The IV-trained nurse flushed both cannulae to restore the administration of the paracetamol before leaving to resume the medicines round they had been undertaking previously.

2.1.20 One of the doctors who had previously examined Spencer was in the bay at the time. The doctor reported that shortly after the flush and IV paracetamol were administered, Spencer became distressed and shouted that he could not breathe before going limp. The doctor identified that Spencer was in respiratory arrest (no longer breathing). The doctor acted promptly by placing a “crash call” by to summon a specialist support team, and initiating ventilation via a bag-valve-mask (a hand-held device to manually provide ventilation to patients who are not breathing).

2.1.21 After approximately two minutes, Spencer started to breathe spontaneously. Based on the nature of the episode, the recent anaesthetic, and lack of other signs and symptoms, it was concluded that the incident was likely to have been caused by residual suxamethonium being flushed into Spencer when his IV therapy was recommenced. The hospital’s emergency response team arrived soon after Spencer recommenced breathing for himself and he required no further resuscitation.

2.1.22 Spencer remained on the surgical assessment unit after his episode of apnoea (pause in breathing) and subsequent recovery. The ward staff, junior doctor and anaesthetic team provided aftercare following the event. He was assessed later that evening and over the next 24 hours, prior to being discharged as planned a few days later. Spencer did not suffer any permanent physical harm as a result of the event. The Trust apologised immediately following the event and has offered Spencer ongoing support. Spencer has reported significant psychological impact and is suffering from both nightmares and flashbacks.

3 Involvement of HSIB

3.1 Notification of reference event

3.1.1 HSIB was notified of a patient safety incident by the anaesthetic department of a district general hospital. The incident (referred to in this report as ‘the reference event’) involved a patient who had stopped breathing while on a ward, several hours after having a procedure under general anaesthetic. The referrer was concerned that a quantity of the neuromuscular blocking agent (NBMA) (a muscle relaxant) used during the general anaesthetic had been retained in the extension lines or within the intravenous cannula and was later unintentionally administered to the patient.

3.2 Decision to investigate

3.2.1 Following a preliminary investigation, HSIB’s Chief Investigator authorised a national investigation based on the HSIB patient safety risk criteria:

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

- Where a period of apnoea (when breathing temporarily ceases) occurs and is not acted upon, the patient is at risk of brain injury or death as a result of a lack of oxygen reaching the brain.
- Patients who receive an unintended dose of an NMBA when general anaesthesia is not being delivered will be awake and aware. The level of paralysis may vary and range from a feeling of heaviness through to full paralysis and inability to breathe. The psychological impact on patients is significant and can lead to distress or harm in the short, medium or long term.

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

- High-concentration, low-volume drugs, which can induce a clinically significant effect in small doses, are frequently used in anaesthetic procedures. These drugs could be life threatening if inadvertently administered, especially outside of the operating theatre environment. Between 2014-2017, 58 incidents involving residual anaesthetic or sedative drugs in cannulae and extension lines with adults or children have been reported to the National Reporting and Learning System (the central database of patient safety incident reports) (NHS Improvement, 2017).
- Cannulae, extension lines and other types of consumable items, such as three-way taps and Y-connectors, are used extensively in hospitals for a range of different types of treatment.
- The focus on the potential infection control risks associated with different types of cannulae (ported and non-ported) and associated items can vary within a hospital. For example, medical wards may convert to using non-ported cannulae, whereas operating departments commonly continue to use ported cannulae. This variation may mean that staff could be unfamiliar with devices sited in patients being transferred to their clinical area.
- The number of general anaesthetics taking place outside the operating theatre environment has increased due to more procedures which require anaesthetic support being undertaken in other areas, such as interventional radiology.

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

- The investigation is an opportunity to understand how and why drugs could be retained in IV cannulae and associated consumables.

- The human factors associated with the existing safeguards to prevent/reduce the risk of patient safety events relating to the retention of residual drugs in cannulae can be explored.

3.3 Scope of investigation

3.3.1 After preliminary investigation, it was agreed that the national investigation would:

- explore the design, procurement and change management of IV consumables, such as cannulae and extension lines
- observe how the World Health Organization surgical safety checklist is used in the operating theatre and in non-theatre settings to ensure that cannula flushing is undertaken
- examine medicines safety, management and governance arrangements – this may include prescribing arrangements, record keeping, medicines dosage and presentations, and reporting of incidents
- develop safety recommendations.

3.4 Method

Investigative approach

3.4.1 HSIB uses a standard process in all its investigations:

- gather all relevant evidence
- establish the factual circumstances leading up to the reference event
- analyse the evidence
- identify which safety factors are contributory to the reference event
- identify which safety issues are likely to contribute to future, similar events, nationally. These inform the wider investigation (**see section 5**)
- develop safety recommendations and safety observations to reduce identified safety risks.

Evidence gathering and verification of findings

The investigation was informed by the following:

- review of the patient's clinical records, Trust policies, procedures and practice relating to care for patients receiving general anaesthetics
- interview and telephone conversations with the patient
- interviews with staff at the Trust where the reference event occurred
- liaison with subject matter advisors in the area of anaesthetics and pharmacy/medicines safety

- interviews in person and by telephone with relevant national organisations and subject matter advisers. For example, senior leads from the Royal College of Anaesthetists, Association of Anaesthetists of Great Britain and Ireland, and NHS England and NHS Improvement
- observations at the Trust where the reference event occurred to understand the processes and environments in which care was provided
- visits to three trusts to observe care for patients undergoing procedures under general anaesthetic
- review of the independent Serious Incident report commissioned by the Trust
- review of published guidance and literature relevant to the safety risk.

Analysis of the reference event

3.4.2 The Accident Route Matrix (ARM) (Harris, 2011) was used to support the analysis of the reference event. The ARM is a human factors investigation tool, created in 2009, to support military human factors air accident investigations (Harris, 2016; Revell et al, 2014; Harris, 2011). The ARM is based on the Swiss Cheese Model (Reason, 1990) and the Human Factors Analysis and Classification System (Wiegmann and Shappell, 2003). In addition, more than 30 actual air accident investigations were used to both develop the framework and refine it (Harris, 2011). The ARM enables evidence to be plotted by both type (factors at the organisation, supervision, equipment, environment or operator level) and by time of effect (factors that occurred prior to the day of the incident or factors that occurred on the day of the incident). HSIB has worked with its own human factors specialists to modify the ARM for use in healthcare investigations. A generic HSIB modified ARM is shown in figure 4.

Fig 4 Residual drugs

	Pre-existing conditions Factors that exist in the years, weeks, months, days prior to the incident – what should and usually happens?	On-the-day factors		
		Planning and preparation Were staff ready/prepared to conduct their tasks?	On-task events What actually happened on that task/day?	Hazard management Timeline of the sequence of events from hazard onset
Organisation	Resource management Organisational climate Organisational process Regulation			
Supervision	Training Procedures Information management Leadership Oversight of tasks Scheduling	Supervision during planning and preparation	Supervision on-task	
Task	Workload Number of tasks Type and complexity of tasks	Planned for task	Tasks performed and task changes	
Equipment	Equipment and interface design Medical tools and devices Checklists Packaging	Planned for equipment and accepted serviceability	Environment conditions on-task	
Environment	Noise, temperature, light Infrastructure Room and equipment layout Clutter, debris, slippery surfaces	Planned for environment conditions	Equipment performance on-task	
Behaviours, actions & interactions	Teamwork and communication Mental models, habits, norms Risk judgement Rest, nutrition and hydration	Pre-task acts	On-task behaviour and actions	
Condition of staff	Adverse mental states Human performance limitations Adverse physiological conditions	Planned for task	Condition of staff on-task	1. Hazard 2. Hazard Detection 3. Rescue 4. Post incident
Patient factors	Clinical condition Social, psychological & safeguarding factors Physical factors	Planned for equipment and accepted serviceability	Patient factors on-task	

3.4.3 The aim of the ARM is to identify which factors, and at which point each factor, contributed to the following:

- **Hazard** – the hazardous situation the patient and/or staff were in.
- **Hazard detection** – how, when, where and by whom, the hazardous situation was detected (if detected).
- **Rescue** – the response and actions taken to deal with the hazardous situation.

4 Analysis and findings from the reference event

The investigation examined the perioperative pathway in relation to the reference event including:

- preparation for emergency anaesthetic procedures in the non-theatre setting
- patient care during the procedure
- post-procedure, handover, and aftercare.

Section 4 details, in chronological order, the relevant analysis and findings for each phase of Spencer's perioperative pathway.

Preparation for emergency anaesthetic procedures in the non-theatre setting

4.1 Formation and preparation of the anaesthetic team

4.1.1 At 09:30 hours, a decision was made for Spencer to have an urgent nephrostomy, which was to be conducted that same day. This procedure required Spencer to be under general anaesthetic and so a request was made to the operating theatre co-ordinator to arrange for an anaesthetist and operating department practitioner (ODP) to attend the interventional radiology (IR) suite at the agreed start time.

4.1.2 For 'same day' cases, the anaesthetic team was formed dynamically, using staff who were on call or were available. It was reported that only experienced anaesthetists and ODPs would be sent to a non-theatre setting such as IR. This was because it was located away from the main operating theatres with limited 'back-up' if assistance were required. The IR was perceived by staff and described to the investigation as a "hostile environment"; that is, it was a more difficult setting to work safely in compared to the main operating theatres.

4.1.3 Most procedures in IR did not require general anaesthetic. Consequently, when attending IR, the anaesthetic team joined an already formed IR team, who were likely unfamiliar to them. An ODP reported that when asked to attend a case in IR, they would feel like a “visitor” and that it could feel “a bit disorganised”. The planning for urgent cases, such as Spencer’s case, was ad hoc with limited consideration for potential risks or mitigations.

4.1.4 The anaesthetist reported that at the time of the request they were supervising a colleague in the operating theatre. When the anaesthetist was asked if they would be happy to take this case, they agreed. The anaesthetist and the ODP departed for IR, taking the required equipment and drugs with them from the operating theatre department.

4.1.5 The anaesthetist reported that they had not worked in IR in the last two years, they were not familiar with the IR team and as such felt they were “on the back foot”. They had also assumed a post-anaesthetic recovery practitioner was arranged (to care for Spencer after the procedure) and so did not anticipate that they would have to personally organise this later.

4.1.6 Summary

- The anaesthetist and ODP experienced different team dynamics and environmental challenges when working in IR, compared to when working in operating theatres. They did not feel part of the IR team.
- The anaesthetist had limited recent experience of working in the IR environment and with the IR team.
- There was limited planning of recovery arrangements prior to starting the procedure.

4.2 Delays in commencing the nephrostomy

4.2.1 The team conducting the nephrostomy, including the anaesthetist and ODP, had a team briefing at 13:00 hours and requested for Spencer to be brought to IR. The team members were informed that ward staff were not ready to bring Spencer down. They waited approximately 30 minutes before calling again, to be told that the ward staff were still not ready.

4.2.2 The reason for the delay in Spencer leaving the ward was because blood samples needed to be taken prior to the procedure. Obtaining intravenous (IV) access to collect the blood sample from Spencer was proving difficult because he had “poor veins” associated with his health history. In total, it took 90 minutes to gain IV access.

4.2.3 The anaesthetist described their frustration with the situation where they had been called to undertake a procedure at short notice; had quickly formed an anaesthetic and radiology team and were ready to proceed, only to be delayed. The anaesthetist stated that the delay added time pressure and created tension. The combination of these factors may have been a source of distraction affecting staffs’ attention during the procedure.

4.2.4 There was no planning around how the delay may impact on the patient's recovery in IR. The IR suite closed at 17:00 hours and the post-anaesthetic recovery practitioner was not available after this time. The team presumed that a post-anaesthetic recovery practitioner would be available.

4.2.5 The delay in commencing the procedure and the limitations in planning for the recovery phase appear to have subsequently impacted on Spencer's care after his procedure.

4.2.6 Summary

- The delay to the procedure caused frustration, tension and time pressure among the team which may have been a source of distraction affecting attention during the procedure.
- The delay in commencing the procedure and limitations in planning for Spencer's recovery impacted on his recovery immediately after the procedure (see section 4.7).

Patient care during the procedure

4.3 Intravenous access (sites and cannulae used)

4.3.1 Different types of cannulae and extension sets were in use throughout the Trust: ported and non-porting with associated extension sets. Ported cannulae (which may have a wide-bore extension attached) tended to only be used in operating theatres and critical care, whereas non-porting cannulae with a narrow twolimb Y-connector attached were commonly used on the wards (see figure 5).

4.3.2 It was reported that anaesthetists preferred ported cannulae (see figure 1 and 1.1.3). The anaesthetist also reported that ported cannulae with a widebore extension line attached were preferred because they enabled IV fluids to be administered at a faster flow rate.

4.3.3 It was reported by staff that the Trust did not use ported cannulae in other areas of the hospital because of a belief that non-porting cannulae posed less infection risk than ported cannulae (see section 5). It was reported there had historically been some debate between operating theatres and the infection prevention and control department about the introduction of non-porting cannulae across the Trust and the impact this would have on anaesthetists. The anaesthetics department negotiated to retain the use of ported cannulae in operating theatres.

4.3.4 Spencer arrived at the IR with the non-porting cannula with a Y-connector extension line (as shown in figure 5) in place. It had been inserted while he was on the ward, before he was sent for his procedure.

Fig 5 A non-porting cannula with Y-connector extension line attached



Fig 5 A non-ported cannula with Y-connector extension line attached

4.3.5 The anaesthetist decided to administer the anaesthetic drugs (which included the neuromuscular blocking agent (NMBA), suxamethonium) through the existing cannula that had been placed while Spencer was on the ward.

4.3.6 It was reported that it is not unusual to induce anaesthesia through a pre-existing cannula and then to add another cannula afterwards, especially if a patient is difficult to cannulate. It was deemed better for the patient and easier for the anaesthetist to insert a second cannula once the patient was asleep.

4.3.7 Following the administration of general anaesthetic, a second ported cannula was inserted, and a wide-bore extension line attached.

4.3.8 Spencer was turned to a position so that he was “laying face down with arms in either the ‘superman position’ [one arm above the head] or by their side, and with head turned to the side”. Surgical drapes were placed over Spencer and it was reported that the nonported (ward) cannula was under the drapes and not used for the remainder of the procedure. The anaesthetist gave additional medicines through the newly sited ported cannula.

4.3.9 Summary

- Different types of cannulae and extension sets were used in ward and operating theatre settings owing to infection control guidance and task requirements for each department.

- The ward cannula was used for the induction of anaesthetic, which included the administration of suxamethonium, an NMBA.
- A second cannula was sited after induction of anaesthetic and was used to administer medicines after the patient was positioned for the procedure.

4.4 Use of neuromuscular blocking agent (NMBA)

4.4.1 Spencer's nephrostomy was an urgent case, and so he had not fasted before the procedure. As such a rapid sequence induction (RSI), was required to minimise the risk of aspiration from regurgitation (stomach contents going into the airway). An RSI requires a fast onset NMBA and so suxamethonium (succinylcholine) (British National Formulary, 2020a) was used.

4.4.2 Suxamethonium's pharmacological properties do not make it appropriate for ongoing muscle paralysis after induction of anaesthesia. A longer-acting NMBA is used to maintain muscle paralysis if it is required after induction where suxamethonium is used. In the reference event, a single dose of the NMBA atracurium (British National Formulary, 2020b) was used after suxamethonium to maintain paralysis. However, atracurium was administered through the second (ported) cannula.

4.4.3 Suxamethonium is a drug which is presented in a relatively high concentration in a relatively low volume (100mg in 2ml). Small volumes of the drug have the potential for a clinically significant effect, especially on patients with a smaller body mass.

4.4.4 When any drug is administered through either a ported or non-porting cannula, unless a subsequent flush (or another drug) is administered, a volume of that drug will remain in the extension line and/or cannula (dead space). The investigation was informed that research undertaken by the Trust suggested that up to 37% of a full dose of suxamethonium can be retained in the cannula and extension line.

4.4.5 The investigation considered the sequence in which the drugs were administered and whether this could have reduced the likelihood of an adverse clinical effect if the drug residue was not flushed. Spencer's general anaesthesia had been induced using fentanyl (a strong painkiller similar to morphine) and propofol (an anaesthetic induction agent). Suxamethonium (100mg in 2ml) was given last and so this drug remained in the cannula and extension line.

4.4.6 A subject matter advisor in anaesthetics told the investigation that fentanyl is usually given first as it takes a couple of minutes to act. The propofol and suxamethonium are then given a minute or two later in quick succession. The reason for giving propofol first is to ensure the patient is asleep before the suxamethonium starts to work. Suxamethonium paralyses a patient within 45 to 60 seconds, but also causes marked fasciculations of the muscles (powerful contractions) while it starts to work, which would be both painful and distressing for the patient.

4.4.7 Summary

- When any drug is administered, unless there is a subsequent flush (or another drug) administered, a volume of that drug will remain in the cannula.
- Spencer's nephrostomy was a short-notice case, and so he had not fasted prior to his procedure. As such a rapid sequence induction (RSI) was required where suxamethonium was used.
- Suxamethonium is presented in a relatively high concentration in a relatively low volume (100mg in 2ml); this means it can have a clinically significant effect in low volumes.
- Suxamethonium is administered last during a general anaesthetic induction, to reduce the likelihood of causing pain and distress to the patient.

4.5 World Health Organization (WHO) surgical checklist

4.5.1 The Trust used locally adapted versions of the WHO surgical safety checklist. The checklists varied between the Trust's departments.

Content of WHO surgical safety checklist in IR

4.5.2 There is national guidance for confirming removal or flushing of lines and cannulae after procedures, which states that surgical checklists should include a confirmation that:

'... before a patient leaves the procedural area:

A All IV administration sets and extension sets without active flow have been removed.

B Any multi-lumen connector without active flow through all its arms is removed; or, if this is not possible because a patient cannot tolerate even brief interruptions to essential drug or fluid delivery, that all arms have been adequately flushed.

C All cannulae have been identified and either removed or adequately flushed.' (NHS Improvement, 2017)

4.5.3 The investigation found that the Trust's locally adapted theatrebased checklist required removal of unnecessary cannulae and extensions lines, and the flushing of all remaining cannulae. However, the checklist in IR only required a check of the flushing of the cannulae.

4.5.4 The Trust's IR checklist was not in line with national guidance. It asked if 'cannulae/giving sets flushed free of medication (if given)'. The checklist also only had a yes or no tick box that this task was complete. There was no space to record if there were multiple ports of entry. For

example, in the reference event there were two cannulae (one of which also had a drug administration port) with two ports on each Y-connector, which meant there were five points of access to flush. The Trust reported that the surgical checklist has since been updated.

4.5.5 The anaesthetist stated that they were aware that all unnecessary cannulae, extensions and connectors should be removed, and if not, that they should be flushed. However, they recalled thinking that Spencer's cannulae were still necessary because he would likely require painkillers and IV antibiotics. As such, a decision was made not to remove the cannulae to prevent Spencer having to be re-cannulated. The anaesthetist thought that the cannulae had been flushed.

4.5.6 Both the national and local guidance allows for discretion for cannulae and extension lines to remain in situ if deemed necessary. As such, in Spencer's case, this placed a greater reliance on the flush of the cannulae and extensions as a barrier for preventing residual drugs remaining.

Timing of WHO checks

4.5.7 The Trust had adopted the WHO surgical safety checklist, adapting it to suit each clinical area in which it was used (for example, in operating theatres, IR, MRI and maternity). Anaesthetists worked in surgical areas across the Trust, and so reported using different adaptations of the checklist depending on where they were working.

4.5.8 It was reported that the adapted surgical checklists at the Trust did not always suit the anaesthetic workflow. The Sign Out section of the checklist (conducted at the end of the procedure) included a confirmation that cannulae had been flushed. It was reported that the timing of this check would often occur when the safety-critical final flushing of the cannulae and extensions lines had not yet been performed. Anaesthetists reported that they would respond to this check by saying that they "will do".

4.5.9 According to the Trust's WHO surgical safety checklist policy, the Sign Out section was to be conducted before the end of the surgery prior to skin closure with the whole team present, including surgeon and anaesthetist. However, the Trust's policy also described five tasks that are part of the Sign Out process, some of which were required after skin closure. The original WHO surgical safety checklist (World Health Organization, 2009a) states that the final part of the checklist is to be completed 'before the patient leaves the operating room'; however it later states that this can coincide with wound closure (World Health Organization, 2009b). As such, the timing of the Sign Out for the Trust's adapted policy was in line with WHO guidance.

4.5.10 It was reported that conducting the WHO Sign Out section could be challenging, as often the surgeon in charge would leave the operating theatre once the main aspects of the surgery were complete. According to the Trust's WHO safety checklist policy, the surgeon/operator was

responsible for the completion of the Sign Out section of the WHO checklist. However, because they often left prior to all of the sign-out tasks being completed, the duties and responsibilities outlined in policy did not align with the operating theatre process and how the WHO checklist was used in practice.

4.5.11 As a result of the timing of the checklist Sign Out, the confirmation that cannulae had been flushed no longer served as a 'check' item, to ensure this safety-critical task had not been missed. While in theatre, there were no further controls in place to ensure the flushing of cannulae and extension lines.

4.5.12 The Trust reported that it was designing an extra section of the checklist to mitigate the issue of the timing of the Sign Out. The Trust informed the investigation that it intended to add a section focusing on anaesthetic tasks such as flushing and/or removing cannulae and extension lines conducted after Sign Out, once the patient was extubated (breathing tube removed), and prior to the patient leaving the operating theatre. The investigation was told that this process had been formally trialled across the Trust.

Confirmation that the checklist item has been completed

4.5.13 It was reported that the confirmation of the flush checklist item having been conducted was done verbally. The anaesthetist would be asked if they had flushed the cannula and extension lines, to which they would respond that they either had or were about to complete the task.

4.5.14 The physical task of performing the flush was not formally observed and there were no visual indicators that confirmed the flush had been performed. As such, reliance was placed on the anaesthetist's memory that the task had or would be actioned.

4.5.15 Recall of events is prone to error; details of events can be forgotten, altered or falsely added into memory (British Psychological Society, 2010). For example, an anaesthetist may intend to flush the cannula, or know they usually perform this task, which can then falsely form a memory that it has been performed. Use of the WHO surgical safety checklist in practice

4.5.16 The investigation observed some of the challenges of undertaking an emergency IR procedure at the Trust. It observed that the initial team briefing involved the team members stating their name and job title, allocating roles for the procedure, discussing what would happen, and making sure key emergency contact numbers were on the whiteboard.

4.5.17 Despite the team briefing, some members of the team remained unclear on job roles and did not know who everyone was. While the emergency necessitated a quick response owing to the nature of the patient's condition, the team briefing was similar to non-emergency briefings observed in other trusts.

4.5.18 The IR suite was observed to be busy and the room layout and equipment presented some logistical challenges. For example, the investigation observed:

- anaesthetic tubing getting tangled and caught up when moving the patient to the operating table
- the anaesthetist tripping over tubing
- difficulties entering and leaving the IR suite because staff had to move around obstacles such as chairs and trolleys
- one telephone, with different members of the procedure team needing to use it at the same time.

4.5.19 One of the team members carried out the WHO surgical safety checklist. While they were reading out and confirming that checklist items had been conducted, the IR suite was noisy and staff were moving around, conducting tasks, donning gowns, and entering and leaving the room. It should be noted that the emergency scenario witnessed was reported to be unusual; however, it is in such circumstances that the checklist becomes even more important as a barrier to prevent safety-critical tasks being missed.

4.5.20 Once the interventional radiologist had completed their tasks, the majority of staff left the IR suite leaving the anaesthetic team and IR nurses to finish their aspects of the procedure.

4.5.21 Summary

National and local policy allows for clinical discretion to keep cannulae and extension lines used during a procedure in situ after it is complete. This places a greater importance on flushing cannulae and extension lines following the procedure to prevent residual drugs remaining.

- The WHO surgical safety checklist Sign Out would often occur when the task of flushing the cannulae and extensions lines had not yet been performed. There were no further controls in place to ensure the flushing of cannulae and extension lines.
- The anaesthetist was not formally responsible for the WHO checklist Sign Out despite having a safety-critical sign-out task.
- The physical task of performing the flush was not formally observed and there were no visual indicators that confirmed the flush had been performed.

4.6 Flushing of cannulae/ extension lines

Factors affecting flushing of cannula/extension lines

4.6.1 The investigation explored potential factors that may have influenced the process of flushing cannulae and extension lines and the subsequent outcome where residual suxamethonium was retained in Spencer's cannula and extension line. The investigation considered two possible scenarios of how residual suxamethonium remained:

- the cannula and extension line had not been flushed
- the cannula and extension line had been flushed but residual drug remained.

4.6.2 The investigation identified the following factors that could contribute to a situation in which the cannula and extension lines were not flushed:

- **Skill-based task that is prone to error.** Flushing cannulae and extension lines is a routine task that is performed frequently (**see appendix**). As such, it is likely that the action of flushing a cannula and extension line is an automatic behaviour which requires little conscious attention to perform. These 'skill-based' actions are vulnerable to failures of attention and/or memory (Wiegmann and Shappell, 2003). 'Skill-based errors' are common everyday occurrences for most people, such as forgetting to attach a file to an email.
- **Alertness.** There are numerous daily circadian (biological) rhythms such as blood pressure, body temperature, hormone levels and the sleep/wake cycle which oscillate over a 24-hour cycle (Ishida et al, 1999). The time at which the flush could have been missed occurred at a time of day (between 14:30 hours and 17:00 hours) when levels of alertness reduce due to the body's natural circadian rhythm. The investigation also considered what opportunity the staff had to have a rest break on the day of the reference event. The anaesthetist reported having very limited opportunity to rest during the shift and could not recall having lunch. The ODP reported that owing to the delay, the team went for coffee before commencing the procedure. Coffee contains the stimulant caffeine, which, when used strategically, can reduce sleepiness and so improve alertness levels (International Civil Aviation Organization, 2016). Owing to mixed evidence, the extent to which alertness levels were a factor that influenced this incident is unclear.
- **Distraction.** Both the IR and operating theatre environment were reported to have distractions. For example, the time pressures and frustration experienced due to the delays to the procedure were likely to serve as a distraction on the day of the incident. The environment could also be busy. For example, the investigation observed an emergency procedure and it was noted that the IR was noisy, there were multiple simultaneous conversations, staff were moving around, conducting tasks, and entering and leaving the room. Distraction could have resulted in attention being directed away from the task of flushing the cannula and extension line.
- **Cognitive load (the amount of information that people's working memory can hold).** The anaesthetist stated that they had not worked in the IR suite for approximately two years prior to Spencer's case. As such, they had a lack of recent experience in the IR

environment and with the team with whom they were working. The anaesthetist also usually used ported cannula with a wide-bore extension and was less familiar with using non-ported cannula with narrow lumen extensions, which Spencer had. Working in an unfamiliar environment and with less familiar equipment is likely to increase cognitive load when compared to working with more familiar environments and equipment, increasing the likelihood of an error being made (Wickens, 1984).

- **More than one cannula.** A second cannula was sited soon after Spencer had been anaesthetised. As a result, attention was likely to have shifted to the newly sited cannula. The original cannula used to administer suxamethonium was then reported to no longer be visible when the surgical drapes were placed over Spencer. As such, there was an increased risk that attention would no longer be directed at the original cannula and that the flush could be forgotten.
- **Flush not always given immediately.** During observations of procedures involving anaesthetic, the investigation observed that the task of flushing cannulae and extension lines was sometimes delayed. Often, a series of drugs would be given in close succession before being followed up with a flush, particularly when inducing anaesthesia. The investigation observed that during a procedure, drugs would be administered with no subsequent flush using a syringe. This may be due to the anticipation that further drugs would be given or that saline solution would be running via a drip and flush any residual drugs through. The variation in sequence for administering the flush may have increased the likelihood of error where the step of flushing is missed or forgotten in the process.

4.6.3 The investigation identified the following factors that could contribute to a situation in which the cannula and/or extension lines were flushed but residual drug remained:

- **Backtracking (regurgitation).** There is the potential that the suxamethonium backtracked or was displaced into the other limb of the extension line. The potential for backtracking has been highlighted in research (McAtamney and Campbell, 2015), a patient safety alert (NHS Improvement, 2017) and a medical device alert (Medicines and Healthcare products Regulatory Agency, 2010).
- **Knowledge and usability of equipment.** The extension lines had slide clamps attached to them which could be opened and closed (**see figure 6**).

Fig 6 Extension line with slide clamps



Fig 6 Extension line with slide clamps

Representatives from the manufacturer stated that the slide clamps should be closed when the cannula was not in use to prevent backtracking. The investigation was informed that the wide-bore extension line the anaesthetist usually used in operating theatres did not have clamps, instead having inbuilt valves to prevent reverse flow. As such they were not familiar with using clamps; this could have resulted in the clamps not being used, making backtracking more likely. Staff reported that the slide clamps were often not used in the ward environment. The clamps were small and fiddly to use, and two clinicians the investigation spoke with perceived that the clamps were not effective. It was reported that training in how all the different types of cannulation and extension line devices should be used was limited, with assumptions being made that clinicians should know.

- Not enough flush to clear cannula and extension line. An ODP at the Trust stated that they provided a steady supply of flushes ready for the anaesthetist to use. There was not a set volume of flush given for each drug administration, and so it was possible that not enough flush was given to clear the cannula and extension line of suxamethonium. However, given the that the extension line could only contain a small volume, this scenario was considered less likely.
- Flushed incorrect extension line. The extension line had two identical limbs, with no visual features to distinguish between them (see figure 6). As such, it was possible that a drug could be administered in one limb and then the flush inadvertently given through

the other limb (thinking it was the same limb through which the drug had been administered), resulting in the drug not being flushed through.

4.6.4 The investigation went on to identify why, in the reference event, it was not detected that there was residual drug in the cannula and extension line or that the flush had been missed:

- **Limited visual cues of drug remaining.** The limbs of the extension lines are transparent, as is the cannula, which allows for the detection of blood at the point of insertion (demonstrating the cannula is correctly sited in the vein). However, the majority of IV drugs, including suxamethonium, are also clear and colourless, and so it is very difficult to detect if there is residual drug in the extension line upon visual inspection.
- **Change of task focus.** The siting of the second cannula meant that attention was no longer directed at the original cannula.
- **Limited mitigation to ensure safety-critical task complete.** Suxamethonium is presented in a relatively high concentration in a relatively low volume (100mg in 2ml) and so if the cannula and extension line is not flushed, the small remaining volume of suxamethonium can have a clinically significant effect. As such, the task of flushing is safety critical in this scenario. There was no distinct moment during the procedure to observe that the task of flushing had been performed, or any requirement to do so. As such, there was limited mitigation to ensure that a highly consequential drug had been flushed through. Further, the timing of completion of the WHO surgical safety checklist provided limited mitigation as it sometimes occurred too early and relied on verbal confirmation, memory and trust that flushing had been conducted (**see section 4.5**). The ODP also reported being somewhat distracted towards the end of the procedure. This was because the delay was about to potentially affect their next task (to cover emergency operating theatres) and so they were arranging for someone else to cover for this task. As such, they may not have been in the IR suite to observe the final flushes of the cannula and extension lines.
- **Limited recording of flushes given.** Sodium chloride 0.9% is a prescription-only medicine (POM) (see 1.4.1 to 1.4.2). The anaesthetic medication chart contained a tick box for 'N Saline Flush', which was ticked. It was reported to the investigation by various operating theatre staff that it was not common practice to record the total quantity of flush administered, how much was given after each drug, or note the number of flushes used. As a result, there was limited evidence of what flushes had been administered.

4.6.5 Summary

- The investigation identified factors that may result in a situation in which the cannulae and extension lines were not flushed. These included that it is a skill-based task that is prone to error; distraction; cognitive load; attention shifting to the newly sited cannula; and variation in sequence for administering the flush.

- The investigation identified factors that may result in a situation in which the cannulae and/or extension lines were flushed but residual drug remained. These included the potential for backtracking; knowledge and usability of equipment; not using enough flush to clear the extension line; and, inadvertently flushing the incorrect extension line.
- The investigation identified that it was difficult to detect whether there was residual drug remaining because of limited visual cues, a change of task focus, limited mitigation to ensure a safety-critical task was complete and limited documented evidence that flushes had been given. Post-procedure, handover, and aftercare

4.7 Recovery in interventional radiology suite

4.7.1 Following a procedure in IR, patients would normally spend some time in the recovery area of the IR department before being discharged home or to the ward.

4.7.2 According to the Association of Anaesthetists of Great Britain and Ireland (2013), 'No fewer than two staff (of whom at least one must be a registered practitioner) should be present when there is a patient in the PACU [postanaesthetic care unit] who does not fulfil the criteria for discharge to the ward'. Most IR procedures were not conducted under general anaesthetic and so the IR team relied on post-anaesthetic recovery practitioners from main operating theatres to be sent to the IR suite for patients having general anaesthetic.

4.7.3 By the time Spencer's procedure was complete at 16:10 hours, there was limited time available to recover Spencer in the IR suite as it closed at 17:00 hours. It was reported that the IR staff did not usually remain after 17:00 hours. It was reported that because the procedure was carried out at short notice, no arrangements had been made for post-anaesthetic recovery practitioners to come from theatres. The anaesthetist 'is responsible for ensuring that this transfer [handover from theatre to recovery team] is accomplished safely' (Association of Anaesthetists of Great Britain and Ireland, 2013) and so the anaesthetist and the ODP tried to formulate a plan to recover Spencer.

4.7.4 The anaesthetist reported that they discussed that it was "not a good idea" for just the anaesthetist and ODP to remain alone in the IR suite with Spencer as they would be isolated with minimal support. The ODP called the main operating theatre's post-anaesthetic care unit (PACU) and asked if Spencer could be recovered there instead. The ODP was informed that the PACU was full and to contact the day surgery PACU. The PACU for day surgery informed the ODP they closed at 19:00 hours and that Spencer was better off in the main operating theatre PACU. Spencer was taken to the PACU at the main theatres.

4.7.5 The Association of Anaesthetists of Great Britain and Ireland (2013) has outlined criteria that patients need to meet prior to being transferred to a recovery area to ensure their safety. One of the criteria is that 'All lines should be flushed to remove any residual anaesthetic drugs if

necessary and checked to be patent, adequately secured and protected'. The investigation noted that this national safety guidance for anaesthetists does not align with NHS Improvement's (2017) guidance to remove unnecessary extension lines.

4.7.6 The anaesthetist and ODP highlighted the frustration they experienced on the unexpected difficulty of having to negotiate a safe place to take Spencer. The ODP reported that there was no policy to follow to help guide them in this situation. The difficulty, frustration and 'on the spot' decision making meant that attention was unlikely to be directed to the cannulae and extension lines at this time.

4.7.7 Summary

- Owing to limited recovery planning, there was no mitigation for the absence of the postanaesthetic recovery practitioner.
- The anaesthetist's and ODP's focus was on finding a safe area to recover Spencer, and so attention was not directed to the cannulae and extension lines at this time.

4.8 Handover in the operating theatre PACU and ward

4.8.1 On arrival at the main operating theatre's PACU, the anaesthetist reported that they initially had to wait for a member of staff to become available. Spencer was not formally admitted to recovery as they were not expecting him and the area was full. The anaesthetist reported that Spencer was seen and his observations assessed to be within the expected range; he was sent to the ward.

4.8.2 The immediate post-operative pathway for the PACU was reported to usually be more formal, including handover, admission, assessment, monitoring and discharge. As part of this process, Trust guidance outlined that IV cannulae should be flushed by the anaesthetist. If the flush had been administered in the operating theatre, then the flush should be verbally confirmed at handover. A witnessed flush would then also take place in the recovery area or PACU. Because Spencer was not formally admitted to the operating theatre PACU, and therefore the usual processes were not followed, this mitigation was missed.

4.8.3 The investigation was told that the best place to detect and manage the effects of residual suxamethonium being flushed later (causing apnoea) would be in the operating theatre. Although not ideal, the next best place to manage an apnoea episode would be in the PACU. Recovery is part of the perioperative pathway and the PACU staff are familiar with complications and have the skills and equipment to deal with them. Patients are also supervised more closely compared to the ward environment.

4.8.4 Summary

- The standard processes for patient recovery, including flushing of cannulae, were omitted due to a lack of recovery planning, resulting in a deviation from the usual perioperative pathway.
- The best place to detect and manage the effects of residual suxamethonium being flushed later (causing apnoea) would be in the operating theatre. The next best place to manage an apnoea episode would be in the PACU. In both these places, patients are supervised more closely compared to the ward environment.

4.9 Intravenous drug administration on the ward

4.9.2 Spencer's apnoea episode occurred around 19:00 hours when his IV paracetamol had 'stopped working'. The agency nurse who was caring for Spencer was not trained to administer IV drugs and sought an IV-trained nurse to assist in rectifying this issue.

4.9.3 The IV-trained nurse reported that they flushed both cannulae to attempt to restore the flow of Spencer's IV paracetamol, and that the first cannula they tried to flush was not working. They recalled that the two cannulae were different, with one extension set having a wider bore than the extension lines they used on the ward. They could not recall which one they flushed first. A junior doctor documented that the cannula on the right was flushed. Seconds after the nurse left Spencer's bed space, Spencer shouted that he could not breathe, collapsed, and went into respiratory arrest. The junior doctor and a registrar were present when this event occurred.

4.9.4 The local Trust investigation identified that the cause of Spencer's collapse was residual suxamethonium in the lumen of the right-sided cannula being flushed into his bloodstream. A subject matter advisor in anaesthetics to the HSIB investigation confirmed this as the most likely cause.

4.9.5 The junior doctor reported that when Spencer collapsed, their focus was on dealing with the emergency and supporting Spencer's breathing. The junior doctor later learned that the registrar understood that Spencer's cannula and extension line may have had residual neuromuscular blocking agent (NMBA) remaining due to their previous experience of a similar event.

4.9.6 The nurse called to assist with Spencer's IV paracetamol reported that they were not aware that Spencer had recently returned to the ward after having a general anaesthetic. At the time of the incident, they thought Spencer may have been experiencing an anaphylactic reaction (a severe allergic reaction) to the paracetamol, as this was a complication that they were aware of from previous training.

4.9.7 The nurse had received IV training which was delivered locally based on a broad nationally agreed curriculum. It was reported that the IV training did not highlight the different types of cannulae and extension lines, nor some of the potential complications that may be encountered such as residual anaesthetic medicines. It was reported by the Trust that training did not include previous safety alerts about the potential risk of residual anaesthetic drugs remaining in extension lines.

4.9.8 Summary

- The nurse was not aware of the potential and actual risks associated with Spencer's cannula (that it had previously been used to administer anaesthetic drugs) and stated that they had not received training on the risks of residual anaesthetic drugs as part of their IV training.
- The IV training did not cover the risks associated with different types of cannulae or specific risks associated with cannulae that may have been used in other clinical settings (for example, anaesthetics).

4.10 Patient outcome

4.10.1 Spencer was deeply upset and traumatised by the events that had occurred. He could recall not being able to breathe, being manually ventilated and hearing the emergency response team working around him. Spencer has been psychologically affected by his apnoea experience. The Trust offered him follow-up meetings at the Trust, which he chose not to attend. Spencer has since returned to the Trust for medical treatment but not in relation to the reference event.

5 Analysis and findings from the wider investigation

The investigation explored the risks identified in the analysis and findings of the reference event in the wider national context. As part of this, mitigations which could reduce the risk of residual drugs in cannulae and extension lines at the various levels of the hierarchy of hazard control (most effective to least effective) (**see figure 7**) were considered. The hierarchy of hazard control is used by those in industry who plan and implement mitigations to reduce risks that have been identified in the workplace. Risks should be reduced to the lowest practicable level and the hierarchy helps decision makers assess and prioritise mitigations that are more likely to be effective (Health and Safety Executive, 2019).

Fig 7 Hierarchy of hazard control

Adapted from Health and Safety Executive (2019) and Leadership and Worker Engagement Forum (2011).

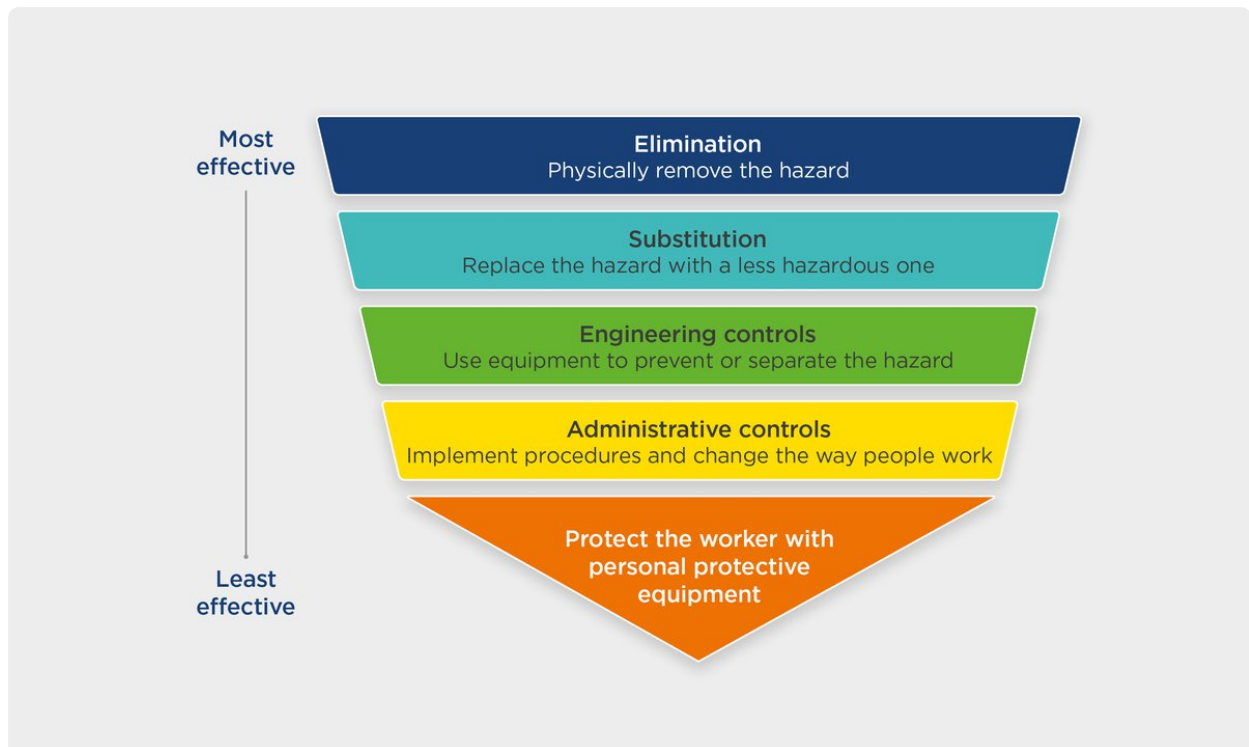


Fig 7 Hierarchy of hazard control

The analysis and findings are structured in relation to the hierarchy of hazard control, starting with the most effective mitigations and moving through to the least effective.

5.1 Reducing risks associated with drugs which have a clinically significant effect in low volumes

5.1.1 One of the key risk factors associated with residual drugs in cannulae and extension lines is the risks associated with the drug itself. As an example, suxamethonium is presented in a relatively high concentration in a relatively low volume (100mg in 2ml) where a small remaining volume in a cannula and extension line can have a clinically significant effect.

5.1.2 One of the main mitigations to prevent residual drugs in cannulae and extension lines is to flush them with sodium chloride 0.9% after drug administration (see 1.4.1). However, flushing as mitigation for preventing the risk of residual drugs in cannulae and extension lines sits at the 'administrative controls' level of the hierarchy of hazard control, towards the 'least effect' end of the control spectrum. More effective controls would be to remove the risk itself, in this instance suxamethonium, or to 'substitute' it with a drug that is less hazardous.

5.1.3 The investigation was told that there are other neuromuscular blocking agents (NMBAs) (muscle relaxants), aside from suxamethonium, which allow for rapid intubating (insertion of breathing tube) conditions such as those required during a rapid sequence induction (RSI). For

example, it was reported that there is a move towards using rocuronium. However, there are differences between suxamethonium and rocuronium. The anaesthetist subject matter advisor reported that a normal dose (0.6mg/kg) of rocuronium has a slower speed of onset than suxamethonium of 1 to 2 minutes versus 45 to 60 seconds. However, the speed of onset for rocuronium can be increased to 60 to 70 seconds by increasing the dose to 1mg/kg to 1.2mg/kg. It was also stated that rocuronium could be reversed, where suxamethonium cannot be reversed. The paralysis induced by suxamethonium is also short lasting (5 to 10 minutes), whereas rocuronium has a longer duration of 30 to 90 minutes, depending on the dose used (Davies, 2012). There may be instances where it is more clinically appropriate to administer a shorter-duration NMBA.

5.1.4 There is debate about whether suxamethonium needs to be used; it can be a problematic drug owing to its potential side effects and alternatives are available (Davies, 2012; Lee, 2008). However, a systematic review which explored rocuronium versus suxamethonium for RSI (Tran et al, 2015) found there is moderate- quality evidence to show that suxamethonium provides excellent intubation conditions more reliably than rocuronium. The review stated it should still be used as a first-line muscle relaxant for RSI. Therefore, it may not be appropriate to remove suxamethonium from clinical practice. However, suxamethonium is not the only drug that could cause an adverse effect if a residual quantity is inadvertently left in a cannula or extension line. The investigation did not identify each of these drugs and whether they had safer alternatives.

5.1.5 Replacing the medicine with a less hazardous one could also be achieved by manufacturing high-risk medicines, such as suxamethonium, in a lower concentration to volume ratio. This would mean that any residual amounts remaining in a cannula and/or extension line would be less likely to cause a significant clinical effect.

5.1.6 The investigation learned that procuring medicines in a lower concentration to volume ratio has been achieved previously. For example, one consultant told the investigation about an incident where a large dose (10mg) of metaraminol (a medicine used to increase blood pressure during anaesthesia) was inadvertently administered at once. The medicine was presented in a high-concentration to low-volume format (10mg in 1ml) and was diluted up into 20ml so that 0.5 mg/ml of medicine was given at a time. Rarely would the entire 20ml be given, especially at once. Following the reference event, the Trust procured metaraminol in pre-diluted glass vials with 5ml at 0.5mg/ml concentration. This meant only 2.5mg could be given by mistake, instead of 10mg, decreasing the risk of an adverse outcome. However, the investigation acknowledges that for some medicines, there may be clinical reasons for presenting a drug in a high-concentration to low-volume format. For example, it was reported by the anaesthetist subject matter advisor that one of the reasons suxamethonium is presented in a high concentration is because it can be administered intramuscularly (directly into muscle tissue) and into the tongue where there is no intravenous (IV) access.

5.1.7 The investigation also explored whether a trust could dilute the concentration of the drug itself. The investigation spoke with anaesthetists during observation visits about the risks associated with residual quantities of NMBAs left in cannulae following a procedure, and if dilution was ever considered. Anaesthetists commonly accepted the presence of the risk, but considered it a “rare event”, which was extremely unlikely to occur during routine anaesthetics.

5.1.8 Routine anaesthetics were commonly described as patients having planned procedures and who arrive in the operating department without an IV cannula in situ. Routine anaesthetics less commonly require top-up doses of NMBA due to the duration of the case. NMBAs given during induction of anaesthesia are often followed by other medicines through the single cannula which has been inserted.

5.1.9 The topic of dilution of NMBAs was also discussed with subject matter advisors for anaesthetics and pharmacy/medicines safety. The investigation heard that some NMBAs can be diluted, as described in the manufacturers’ guidance, whereas other NMBAs cannot. One specific example regarding suxamethonium was given which stated that “with reference to the stability of the product once opened, injections are sterile products and once opened the product becomes unsterile. So, the product information recommends the product is administered immediately once opened”. A pharmacist subject matter advisor stated that dilution is not possible for certain NMBAs, such as suxamethonium, as it would result in them being used off-licence (that is, outside of the uses for which the drug has been licensed by the national regulatory body). However, the investigation was also told that many anaesthetic drugs are used off-licence and that one laboratory was supplying diluted suxamethonium to a trust.

5.1.10 There was a consensus that relying on anaesthetists to dilute the drug could present a safety issue. Anaesthetists suggested that adding the task of dilution of NMBAs during the preparation of medicines for an anaesthetic adds a further step which could also be subject to errors, including diluting the wrong drug and mislabelling, leading to greater risk of error. It would also require changing the staffs’ perception of the unique syringe size used for a particular NMBA. Ideally, if it is possible to dilute medication, it should be done by the supplier.

5.1.11 The potential for enhancing safety by providing NMBAs in diluted form in pre-filled syringes was discussed, following this being raised by an anaesthetist in an earlier observation visit. The subject matter advisor for pharmacy told the investigation that pre-filled syringes are significantly more expensive than drugs which are provided in glass vials, commonly costing around eight times more. This level of increased spend may be costprohibitive for trusts. However, the investigation was told that one trust used prefilled glass vials of suxamethonium and found this to be more cost effective as it reduced waste. This was because suxamethonium was being drawn up as an emergency medicine but then would rarely be used and subsequently discarded at the end of the procedure.

5.2 Design of equipment

5.2.1 The investigation explored how the risk of residual high-risk medicines in cannulae and extension lines could be reduced by applying engineering controls through the design of equipment. The investigation noted it would not be practical to remove cannulae from healthcare and there is no cannula design that does not require flushing after drug administration. Therefore, the investigation considered ways to minimise the residual drug that remains.

5.2.2 One way in which the residual drug remaining could be minimised is to remove extension lines from clinical practice, thus minimising the amount of dead space where a drug could remain. However, this is unlikely to be practical when multiple entry ports are required. A cannula would have to be inserted into the patient for each entry port required, leading to multiple cannulae being in place which would present various other risks such as infection. In addition, the dead space within a cannula can still be large enough for a high concentration/low-volume drug to have a clinically significant effect.

5.2.3 If the amount of dead space could not be minimised, the investigation considered ways to improve the detection of any residual drugs. This could be achieved by colouring the drug itself. However, the investigation learned that this is not possible for some drugs and may cause an allergic reaction in some patients.

5.2.4 The investigation found it was possible to administer a drug through one limb of an extension line and then inadvertently flush the other because there were no visual features to distinguish between them. The investigation considered the potential of colour coding limbs to help reduce the risk of inadvertently flushing the wrong limb. However, the investigation was told that colour coding limbs could create new risks and add to a clinician's cognitive load in interpreting what the colour meant. Colour coding is already used in several ways in IV consumables and medications. For example, colour distinguishes:

- the route of a medication (for example, intravenously, through the mouth or through the spine)
- the class or type of medication (see BS ISO 26825:2020)
- the cannula size (clinicians often refer to a 'pink' or 'green' cannula).

Colours are also used in manufacturers' branding and there are also issues to consider including colour blindness, reduced lighting levels in some clinical environments, and that memory recall would still be required to know which colour limb had been used, and so errors could still occur.

5.2.5 Overall, the investigation found that designing out the risk of residual drugs in cannulae and extension lines is challenging, and unintended consequences of redesign need to be considered.

5.3 Flushing cannula/extension lines as a safety-critical task

5.3.1 As stated previously, one of the main mitigations to prevent residual drugs in cannulae and extension lines is to flush them with sodium chloride 0.9% after drug administration. The investigation explored the task of flushing and the administrative controls that are currently in place to mitigate the risk of residual drugs in cannulae and extension lines.

5.3.2 The investigation met with representatives from a manufacturer of cannulae and extension lines and spoke with clinicians and a subject matter advisor to establish what the reasons for flushing were. The reasons included:

- to check the cannula is correctly located and check that fluid is passing freely through it
- to prevent incompatible drugs mixing in the extension lines when drugs are given in succession
- to flush drugs through the lumen of the device(s)
- to ensure the full dosage of the drug is administered to the patient, particularly for paediatric patients
- to ensure there is no residual drug left in the cannula and extension line.

5.3.3 The investigation conducted a Hierarchical Task Analysis (Annett, 2004) of perioperative care, focusing on the aspects where flushing can occur. As shown in the appendix, there are multiple tasks to be conducted during the perioperative phase, and multiple sub-tasks at each stage of the process, such as drug administration.

5.3.4 Flushing occurs multiple times during the life cycle of a cannula and its purpose alters depending on the task being conducted. For example, before administering a drug, the flush can be used to assess the patency of the line (that is, how well fluid is passing through it), whereas later it prevents mixing of drugs and then ensures the drug has been fully administered.

5.3.5 The safety-critical nature of the flushing task can also alter depending on the purpose of the flush, the drug being used and the type of patient to whom it is being administered (for example, adults or children). Missing a flush after a bolus dose of IV antibiotics is unlikely to have an adverse effect on the patient if a residual amount remains in the line and is flushed through later. Failing to flush a potent NMBA, as seen in the reference event, could cause severe harm or death.

5.3.6 The investigation was informed that for most medicines, the flushing of cannulae and extension lines is not safety critical. As such, flushing is not generally regarded among clinicians as a critical or consequential task in its own right. Flushing is often coupled to another task (as in, flushing blood from the cannula after insertion, patency check prior to drug administration, to push the drug through the cannula/line after administration, and so on).

5.3.7 The investigation witnessed variation in flushing practice during site visits to observe anaesthetic care in main operating theatres. Sometimes a flush was given immediately after a drug was administered, other times it was not. In all observations, there appeared to be no differentiation between a routine flush and a flush that was safety critical. It was also difficult to discern when the final flush had been undertaken prior to the patient leaving the operating theatre to go to the post-anaesthetic care unit (PACU). There was no clearly defined moment or acknowledgement that the task had been completed. The task of flushing is functionally the same and there are limited additional steps or process alterations that mark the flushing of a consequential drug versus flushing to maintain a cannula's patency. Use of the World Health Organization (WHO) surgical safety checklist

5.3.8 Using adapted versions of the WHO surgical safety checklist is an example of an administrative control that trusts have implemented to ensure that task of either removing or flushing cannulae and extension lines following an anaesthetic procedure is completed. However, as demonstrated in the reference event and the hierarchy of hazard control, this mitigation is not always effective.

5.3.9 During observation visits, many staff involved in all aspects of perioperative care (including those involved with procedures under anaesthetic in the non-theatre setting) agreed that the WHO checklist was an important part of their work routine. However, some senior staff expressed frustration and concerns regarding the use of the WHO checklist. One consultant anaesthetist told the investigation that, while generally supportive of the concept, there was "too much information on these kinds of things". Another consultant anaesthetist in another trust said that "[we] don't take it seriously anymore" as it contained "redundant questions" and contained too many "tick boxes". The investigation noted that the contents of locally amended WHO checklists contained many more items than the standard version and did not clearly highlight or differentiate safetycritical tasks.

5.3.10 In some trusts, the checklist varied by setting (for example, modified versions of the checklist were used in non-theatre settings) whereas others had a single version of the WHO checklist. All the hospitals visited had modified the checklist in some way. The investigation noted that the modifications can make the checklist more relevant for certain specialties. However, the variability between checklists can also cause unfamiliarity for staff who work across different departments or trusts.

5.3.11 In all hospitals visited by the investigation, anaesthetic teams undertook briefings and safety huddles [3] to review the cases of patients due to be treated during each period of work. Those in attendance introduced themselves by name and role, the consultant anaesthetist discussed each patient, and all team members were encouraged to speak up. It was noted that at all sites visited, this process was not rushed, took place in a quiet environment, and was (with one justified exception) never interrupted.

5.3.12 The investigation observed the WHO checklist in use many times during visits to trusts, and in a range of clinical settings and for different procedures. It was observed that during Sign In and Time Out, the checklist process was closely adhered to and all staff were silent and focused on the verbalisation of each phase of the checklist. By contrast, the Sign Out was nearly always carried out without the same level of attention.

5.3.13 The WHO checklist does not, by design, cover the whole of the perioperative pathway. Perioperative care is defined as 'Integrated care across the full patient pathway before, during and after surgery' and 'is the practice of patient-centered, multidisciplinary, and integrated medical care of patients from the moment of contemplation of surgery until full recovery' (Centre for Perioperative Care, n.d.). The WHO checklist only covers the period from the commencement of the Sign In to the completion of the Sign Out and does not include processes to support the handover of patients to the PACU or back onto the ward.

5.3.14 A HSIB national learning report which examined the findings of previous investigations into **Never Events** (Healthcare Safety Investigation Branch, 2021) made the following observations in relation to checklists, based on the existing literature and findings from previous national safety investigations. 'The healthcare checklist has become a ubiquitous tool, often implemented in response to incidents as an administrative barrier to prevent recurrence. Checklists offer assistance to staff when carrying out tasks by reducing the reliance on memory and attention. There is evidence that checklists do improve patient outcomes, and improve secondary outcomes such as communication, when they are used and followed thoroughly (Bergs et al, 2014; Thomassen et al, 2014). However, to be effective, the rationale for their use, their design and how they are implemented within complex sociotechnical systems need to be considered. 'Checklists work best when they are used at critical moments and should be specific to the tasks being undertaken (Catchpole and Russ, 2015). They require motivated teams whose members are already familiar with the tasks and processes. They should lead to physical changes or actions at the critical points; they are not designed to be team-building tools. They also require a local culture that empowers staff to speak up when they have concerns and ensures they are listened to when they do so. 'The nature of checklists evidenced in HSIB's investigations is that they act just before the potential point of an error occurring. For example, the wrong patient may have been brought to theatre, but it is only identified at the point that the anaesthetic is about to begin. Greater emphasis needs to be placed on preventing situations such as this rather than relying on checklists to identify them. Checklists can also

have consequences that increase the risk of incidents happening. They may increase automaticity – the mindless checking that results in missed steps (Catchpole and Russ, 2015). They also take time, make cases take longer and therefore put added pressure on staff. To be done thoroughly checklists need time and cannot be rushed. However, there is often a trade-off of thoroughness for efficiency. Checklists are administrative barriers. They are not strong and systemic barriers and will therefore not always prevent Never Events.’ (Healthcare Safety Investigation Branch, 2021)

5.3.15 The items on the WHO checklist act as prompts for expected actions or tasks, and do not include second/independent checks or other hazard control activities proportionate to the risks being addressed by the process. Furthermore, the lack of stratification of tasks in the checklist means that there is a single level of importance for all tasks. This may lead to a loss of opportunity to assess individual sub-tasks and reduce associated risks to be ‘As Low As Reasonably Practicable’ (ALARP). ALARP attempts to reduce the risk of harm as far as possible.

5.3.16 The task of flushing cannulae and extension lines is not generally safety critical and it is not specifically highlighted as being safety critical in the checklist. Even in systems where checklists are used extensively (**see 5.3.8 to 5.3.16**) the importance of flushing as a safety-critical task is not highlighted.

Sign Out phase of the WHO surgical safety checklist

5.3.17 Reflecting the prompt in the Sign Out, one consultant anaesthetist commented that “patients should leave theatre with as few points of [IV] access as possible” but conceded that this is sometimes overlooked or is not possible.

5.3.18 The Association of Anaesthetists of Great Britain and Ireland (2013) has outlined criteria that patients need to meet before being transferred to a PACU to ensure their safety. One of the criteria is that ‘All lines should be flushed to remove any residual anaesthetic drugs if necessary and checked to be patent, adequately secured and protected’. The investigation noted that this national safety guidance for anaesthetists does not align fully with NHS Improvement’s (2017) guidance to remove unnecessary extension lines.

5.3.19 Staff commonly reflected the issue that the content of the WHO checklist, and the Sign Out phase in particular, became rote learned. One theatre clinician told the investigation that “items on the list are anticipated; you hear, but don’t listen; [you] don’t take it in”. A similar comment was made during HSIB’s investigation into the **implantation of wrong prostheses during joint replacement surgery** (Healthcare Safety Investigation Branch, 2018a). An operating theatre staff member stated they tended to “switch off the brain” because of the repeated checks. HSIB’s investigation into the **insertion of an incorrect intraocular lens**

noted that, on observing operating theatre practice, 'not all members of the team were actively participating in the checks and the [WHO checklist] form was completed retrospectively' (Healthcare Safety Investigation Branch, 2018b).

5.3.20 The reduced attention to checklist items was compounded by the differences observed between the Sign In and Time Out phases of the checklist versus the Sign Out phase. The Sign In and Time Out, were undertaken at the same point during the perioperative pathway, in silence and to the exclusion of almost all other tasks, whereas the Sign Out was observed frequently as taking place at slightly different moments after the procedure was completed, with other tasks being conducted concurrently.

5.3.21 On several occasions during observations in different trusts, significant variation was noted in the way the Sign Out was undertaken. On one occasion, the Sign Out was almost omitted; the team was prevented from leaving the operating theatre by the theatre team leader and the Sign Out was performed. Sign Outs were commonly performed in parallel with other tasks and lacked the silence and attention observed during Sign In and Time Out.

5.3.22 The investigation commonly observed that at the end of a procedure, there appeared to be an urgency to move the patient to the PACU and to prepare for the next case. Staff were observed as often breaking into two broad groups; those responsible for caring for the patient as they woke and were being prepared for transfer to the PACU, and those who were clearing instruments and cleaning the operating theatre in readiness for the next patient. This rapid turnaround and the change in team dynamics may account for the undertaking of tasks in parallel, and the lack of focus on the Sign Out by all staff present. This practice was also observed during an HSIB investigation exploring the **detection of retained vaginal swabs and tampons following childbirth** (Healthcare Safety Investigation Branch, 2019a) which found that:

'... towards the end of the procedure there was a focus on the next task. Soon after the baby/ babies were born the theatre teams would fragment, focusing on their own tasks such as clearing up the theatre, measuring the baby's cord blood gases, weighing the baby and monitoring the mother's vital signs'. (Healthcare Safety Investigation Branch, 2019a)

5.3.23 The investigation was told that factors such as time pressure, size of operating theatre lists (that is, the number of patients due to have surgery), and availability of staff affected the integrity of the Sign Out process. This is supported by a study regarding time pressures affecting focus on Sign Out, which stated:

'Five centres reported that items could be ticked off even when items were not checked because of time constraints. Items were ticked only to comply with the management audit; therefore, in this situation, checklists failed to improve patient safety.' (Fourcade et al, 2012)

5.3.24 Staff commonly left the operating theatre prior to Sign Out. On one occasion where the Sign Out was observed by the investigation, the ODP who led the process stated that “we have the same team” but in fact the surgical registrar who carried out the procedure had left the theatre and a different surgical registrar was present, ready to commence the case they were going to perform. Team members departing the operating theatre prior to Sign Out is not unique to this investigation. The ‘Detection of retained vaginal swabs and tampons following childbirth’ report also found that: ‘... there were occasions when those who were present for the procedure were not all present for the WHO sign out. The anaesthetist also reported that it was “normal” and not uncommon for surgeons to leave the specialty trainee in theatre to finish off a procedure, such as suturing, if they deemed the trainee competent to do so.’ (Healthcare Safety Investigation Branch, 2019a).

5.3.25 It was not clear during any observation visit who was responsible for instigating the Sign Out. This contrasted with the clarity of the roles for those staff leading the Sign In and Time Out. On one occasion, an ODP was seen to take the Sign Out laminate and commence the process without attempting to get the attention of colleagues. The Sign Out was aborted and recommenced. On another occasion, the Sign Out was almost forgotten due to the nurse in charge becoming distracted by a malfunction with the operating table.

5.3.26 Importantly, and in relation to the reference event, on two occasions on separate observation visits when the question regarding flushing was called out, the response given was positive affirmation that the flush had been given, rather than that it was about to be, or would be, done. In one of these cases, an unlabelled syringe was shown to colleagues by the anaesthetist, indicating that the flush was ready to be given. The investigation did not witness the flush being given due to the amount of activity and movement around the patient during and after the Sign Out was completed. In addition, the frequency of flushing during an ongoing anaesthetic means that reliable recall of whether a flush has been given is reduced.

5.4 Knowledge and usability of equipment

Overview of usability/variability of equipment

5.4.1 The investigation spoke to staff who procure and use IV cannulae and extension lines, and with manufacturers of these items. Discussions with the various stakeholders regarding these items elicited a range of issues, including:

- frequent changes in the types of cannulae, extension lines and other IV consumables procured for use in hospitals
- a presumption that all items have identical specifications
- lack of awareness of the nuances of new items introduced into practice
- limited uptake by trusts of training offered by manufacturers/suppliers

- directives relating to infection prevention and control affecting the selection of cannulae.

Knowledge and training on IV equipment

5.4.2 Many anaesthetists and ODPs spoke about the use of ported cannulae in operating theatres versus the use of non-ported cannulae in other parts of the hospital. It was less common that anaesthetics needed to be carried out using non-ported cannulae as these were not available in operating theatre departments and, where anaesthetics were being undertaken in non-theatre settings, a supply of ported cannulae would be taken with the team to that location (for example, interventional radiology or MRI).

5.4.3 One consultant anaesthetist mentioned the importance of using one-way (non-regurgitation) valves when dealing with “high-risk drugs” such as NMBAs. They mentioned that “Swan locks [needle-free connectors] do not have oneway valves” and that the needlefree connectors on Y-connectors and extension lines do not offer anti-regurgitation protection. Many of these devices appear outwardly similar but, according to the manufacturers’ information, have variable specifications relating to the potential for regurgitation. A consultant anaesthetist told the investigation that these consumable items are often ordered without considering the end-user requirements and the different environments in which they are used. This may mean that certain configurations of IV extension lines are not protected against the backtracking of medicines.

5.4.4 The investigation was told by consultant anaesthetists that there is no guidance on the optimal configuration which minimises risk when setting up an IV line which has multiple components. Variability was observed in relation to the order that consumable items were connected, such as three-way taps and single and/or multiple lumen extension lines. It was reported that different set-ups are required to suit the patient’s needs and so having one standardised set-up for all would not suit all scenarios.

Nursing practice

5.4.5 The investigation was told by senior nurses and infection prevention and control (IPC) leads in hospitals visited, that IV administration training courses for nurses did not highlight the different types of cannulae and extension lines available in their clinical areas. The IV training courses discussed with nursing and IPC leads did not cover the potential complications that may be encountered. Training did not include previous NHS England and Medicines and Healthcare products Regulatory Agency safety alerts about the potential risk of residual anaesthetic drugs remaining in extension lines.

5.4.6 IV administration courses include teaching on common and rare reactions to medicines given by the IV route, for example, anaphylaxis (a severe and potentially life-threatening allergic reaction). The IV cannulation training course includes information about cannulae and

extension lines. Nurses who had undertaken both courses told the investigation that they felt it would be helpful if the information about cannulae and extension lines delivered on the cannulation course was also included on the IV administration courses. This would give nurses who were administering IV medicines more awareness of a wider range of potential adverse events.

5.4.7 The Nursing and Midwifery Council publishes standards for nursing competencies which include cannulation and IV administration. Nurses should be able to 'recognise and respond to adverse or abnormal reactions to medications' (Nursing and Midwifery Council, 2018). The standards do not specify the types of reactions which may be anticipated depending on the clinical setting. For example, nurses should be aware of the risk of residual drugs in cannulae in the clinical setting in which they are working.

5.4.8 The investigation was made aware of a resource published by Health Education England on the e-Learning for Healthcare website which provides a modular programme for healthcare professionals in the key aspects of IV therapy. The 'IV Therapy Passport' is intended to provide a consistent national programme for all clinicians providing IV treatment to patients and seeks to 'provide and develop the underpinning knowledge, required by healthcare professionals to administer intravenous medication (IV)' (Health Education England, n.d.). This resource was not mentioned during any investigation visits.

5.4.9 There appears to be an inconsistent approach at individual trust level to the content of IV cannulation and administration training courses for nurses and other healthcare professionals across the country. This variation means that, contrary to the intentions outlined in the IV Therapy Passport, when nurses move between hospital trusts their IV skills may not be consistent with the practices at the new trust.

HSIB makes the following safety observation

Safety observation O/2021/098:

It may be beneficial for healthcare trusts to adopt the programme provided by Health Education England for intravenous (IV) skills, which supports the competency requirements published by the Nursing and Midwifery Council.

Change management and procurement of intravenous consumables

5.4.10 The investigation was told by several staff in the hospital trusts visited that it was common for cannulae and associated consumables, such as extension lines, to be changed without informing the end users in advance. While these items are functionally the same, there

are subtle differences which the user should be made aware of, and which should be risk assessed. Similar situations where trusts have changed equipment without consulting or informing the end user (the clinicians) have been identified in previous HSIB investigations (for example, Healthcare Safety Investigation Branch, 2020; 2019a, 2019b, 2017).

5.4.11 All hospitals visited had previously changed from using only ported cannulae to having both ported and non-porting cannulae. A commonly reported reason for doing so was infection prevention and control (IPC). However, only staff working in IPC teams were able to articulate the reasons for change. This supports the issue which was reported during observation visits that there were “not enough stakeholders involved [with the process of change]” and that the evidence for moving away from ported cannulae was not shared with end users.

5.4.12 Ported cannulae had been retained in the operating department of all trusts visited during the investigation. The reason for retaining ported cannulae was that anaesthetists had expressed concerns regarding how using non-porting cannulae would negatively impact on their practice during critical phases of care. Specifically, injecting a drug into a ported cannula is a one-handed operation, whereas non-porting cannulae require two-handed drug administration (**see 1.1.4**).

5.4.13 The investigation spoke with a consultant microbiologist who had liaised with colleagues nationally and reported that the drivers for changing to non-porting cannulae, and the method by which changes were made, were “locally determined in different trusts”. The investigation was made aware of the epic3 national evidence-based guidelines for preventing healthcare-associated infections in NHS Hospitals in England (Loveday et al, 2014). The guidelines recommended using cannulae with ‘the minimum number of ports or lumens essential for management of the patient’. However, the investigation was unable to find a national directive requiring trusts to move to non-porting cannulae.

5.4.14 A consultant anaesthetist told the investigation that in their trust the change to non-porting cannulae was done “unilaterally, based on advice from IPC” and that it had been challenging to achieve the reintroduction of ported cannulae into clinical settings where anaesthesia was carried out. It was stated that the selection of items requiring change had been made by the “office-based IPC team working with procurement” and that the lack of engagement with clinicians led to a period of time where remedial action was needed (to reintroduce ported cannulae). It was reported that a risk assessment was done after the change to non-porting cannulae and that the change management process was not inclusive. This did not allow for the infection risks of ported cannulae to be considered in the context of other risks, which were subsequently used to justify the re-introduction of ported cannulae in specified parts of the hospital.

5.4.15 The consultant microbiologist suggested that there was “not much data to support [growth of bacteria in cannulae] versus common sense” and pointed out that the “evidence base was often not strong in infection control – you only know when you get it wrong”. These comments supported the imperative to move away from ported cannulae due to the need to mitigate all risks for hospital acquired infections (HAI) and specific infections relating to indwelling intravenous cannulae. A consultant anaesthetist stated that in relation to HAIs, there is “difficulty proving source of bacteraemia” and that there was therefore appreciation of the need to change, but that other risks (which have now been considered) should have been taken into account before the changes took place.

5.4.16 All of the trusts visited by the investigation had overcome the issues with ported versus non-ported cannulae. They were now working with a shared understanding between IPC teams and clinicians working in the perioperative and critical care functions of each trust.

5.4.17 However, staff commonly reported that when consumable items were changed, such as cannulae, extension lines, three-way taps and caps/valves, these items appeared without any communication or training. While the core specification of these items is outwardly the same, staff reported identifying differences in features such as one-way valves and in-line clamps, and that training was rarely, if ever, offered when items of this type were swapped out. This differed to changes made to larger pieces of equipment, such as syringe drivers, which required training before use. However, at one trust it was reported that the change process included liaison with the clinical education team, a trial being undertaken, and anaesthetists being engaged with.

5.4.18 A representative of a manufacturer of IV products told the investigation that the company offers training to organisations that change to its products, but this is rarely taken up. The representative expressed concerns regarding the practice of changing equipment such as cannulae and extension lines without staff being made aware of any differences. Differences between products often include changes to insertion technique, volumes of residual contents, types of clamps and valves, and issues that may affect the performance of the device.

5.4.19 Another perceived driver cited by clinicians regarding the regular changing of consumable items was cost. One anaesthetist told the investigation that there are risks regarding replacing “needle-free devices which are known to be safe” with cheaper products which may have either different specifications or be of lower quality. They expanded on this point to explain that “needle-free ports are not one-way valves but may be mistaken as being so” and that this could be particularly problematic if a clinician is familiar with a product which is then exchanged for one with a different specification.

5.5 Documentation of flushing of IV lines

5.5.1 Another administrative control is to document the flushing of cannulae and extension lines. Sodium chloride 0.9% flushes are prescription-only medicines and may be documented or prescribed by an anaesthetist using a check-box or pre-printed part of the anaesthetic chart. However, the investigation observed that flushes were not reconciled on prescription charts in adult perioperative care in the same way other medications or paediatric medication charts are (**see 5.5.10 to 5.5.13**).

5.5.2 Where a flush was needed, it was observed that the ODP or anaesthetist would draw up the required volume and inject this as needed. On one occasion, an anaesthetist was observed to use a labelled syringe, previously used to give an anti-sickness medicine, to draw up a small amount of flush to give after administering a top-up dose of an NMBA.

5.5.3 Staff spoken to during observation visits stated that documenting each flush would be an additional task and therefore create a resource burden. ODPs commonly reported that their role included keeping flushes “topped up” in case the anaesthetist needed to administer a flush after giving an IV drug. Flushes are not kept in medicines cupboards and are not regarded by staff in the same way as other medicines. This means that there is no way of establishing if or when a flush was given following the administration of an IV drug. Practice was different between adult and paediatric care regarding the recording and reconciliation of flushes (**see 5.5.10 to 5.5.13**).

5.5.4 Specific to drugs such as NMBAs, which can induce a clinically significant effect in low volumes, there is no ‘forcing’ function which ensures that a flush of sufficient volume is given following the administration of these medicines. This in turn may give rise to an error being detected many hours later when the patient is on the ward, as illustrated by the reference event.

5.5.5 Flushing is a task within the WHO surgical safety checklist at the Sign Out stage. In the investigation’s observations, the response to this prompt was always observed as being affirmative, but no evidence was established to support this or to demonstrate to the person leading the Sign Out to accept that they could tick off the task as being completed. On more than one occasion, the responses were equivocal; for example, one ODP was heard to reply saying “just about to” and on another occasion “I think so”. In the context of NMBA use, flushing is a safety-critical task and yet lacks systemic assurance of the completion of the task with clear evidence or documentation.

Documentation of cannula sites

5.5.6 The risk of residual drugs in cannulae may increase where more than one cannula (or other IV access routes) is used and/ or multiple extension lines and Y-connectors are used. This risk was highlighted in a patient safety alert about residual anaesthetics drugs in cannulae and intravenous lines. It stated that ‘The insertion of two cannulae during anaesthesia has also been identified as a potential risk factor, as only one may be subsequently flushed’ (NHS England, 2014).

5.5.7 A paediatric anaesthetist who spoke to the investigation said that in their experience, residual NMBAs had occurred most often in patients with multiple IV access devices in situ. This was echoed by other anaesthetists spoken to during observations, suggesting a potential increased risk for patients who arrive for their procedure with existing IV access and who require further cannulae to be inserted. It was noted by another consultant anaesthetist that a “GA with a single IV cannula has little risk, if any, of [containing] residual drugs” versus patients with multiple lines in situ.

5.5.8 In one hospital, the anaesthetic documentation included a body map for recording the sites of cannulae and other points of intravascular access (access to blood vessels) (see figure 8). The process of recording/mapping these devices was not seen as onerous by the anaesthetic team, and it was reported that when used in combination with the Sign Out prompt regarding the removal of unnecessary lines, it reduced the risk of items being missed. Having documentation relating to vascular access sites was reported as beneficial and assisted with preventing line flushing being omitted. The use of body maps is not explicitly included in the WHO Sign Out process.

5.5.9 The investigation heard that patients with multiple IV access devices were least likely to be suitable to have these removed during Sign Out. Discussions about this point suggested that there were many contributing factors. These commonly included issues such as the patients being sicker; coming to the operating department (or non-theatre setting) from critical care or other units that treat very sick patients, or patients needing ongoing IV therapy. Anaesthetists and other operating theatre staff reported cannula removal as a rare event as prompted during the WHO Sign Out.

Fig 8 Example of a body map with IV access and urinary catheters marked

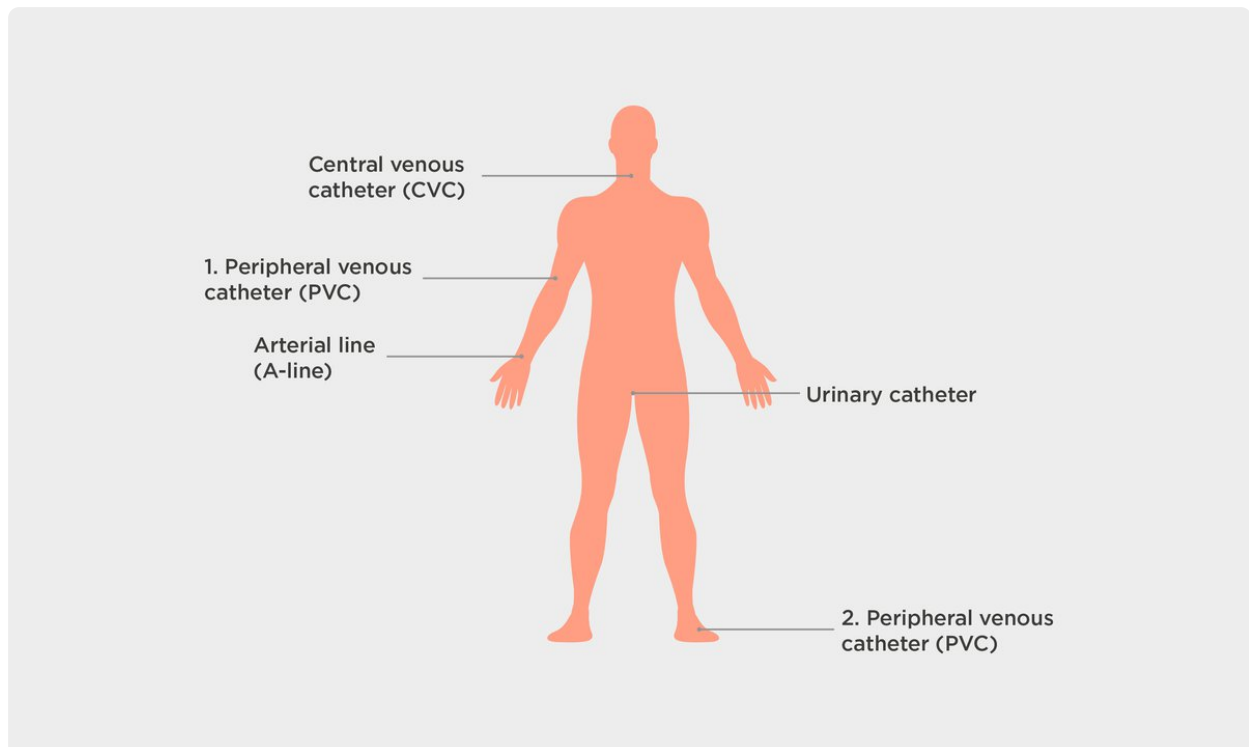


Fig 8 Example of a body map with IV access and urinary catheters marked

HSIB makes the following safety observation

Safety observation O/2021/099:

It may be beneficial to increase the use of body maps to record the presence of all indwelling items, such as cannulae, catheter and drains, during an anaesthetic procedure. The body map could be used as part of an enhanced sign-out and to provide instructions for the management of each indwelling item in the postoperative period.

Documentation of flushes in paediatrics

5.5.10 The investigation spoke with paediatric anaesthetists during observation visits to explore whether any differences existed in practice for children. Two areas of difference from adult anaesthetic practice were identified.

5.5.11 This first difference in paediatric anaesthesia, especially for smaller children, is that the doses of drugs are much smaller than for adults. While child-sized IV cannulae are also smaller, the amount of a drug which can be retained in the lumen, linked to the volume of the drug

needed to elicit a pharmacological response, means that the “dose is contingent” on flushing the drug after administration. Failure to provide sufficient doses of anaesthetic drugs could lead to the patient having awareness and/or feeling pain while anaesthetised.

5.5.12 The other difference reported to the investigation was that the volume of sodium chloride flushes can, in smaller children, have an impact on the overall management of the patient's fluid balance. In an adult, receiving five individual 10ml flushes would not be physiologically significant, but in a small child, particularly for a newborn infant, this could be significant. Therefore, flushes are recorded alongside the other fluids being infused to give a total volume given.

5.5.13 The context of these differences is clear, and the reasons that paediatric anaesthetists apply this level of diligence is specific to their patient group. Several subject matter advisors articulated to the investigation that they believed residual drugs in the cannulae of children being anaesthetised was extremely rare as a result.

5.6 Summary and conclusion of sections 5.1 to 5.5

5.6.1 The investigation explored mitigations which could reduce the risk of residual drugs in cannulae and extension lines at the various levels of the hierarchy of hazard control. The investigation found:

- One of the key risk factors associated with residual drugs in cannulae and extension lines is the concentration and risks associated with the drug itself.
- This is particularly the case for drugs that can cause a clinically significant effect in low volumes.
- Flushing is a key mitigation for preventing the risk of residual drugs in cannulae and extension lines. However, it sits at the ‘administrative controls’ level of the hierarchy of hazard control, towards the ‘least effect’ end of the control spectrum (**see figure 7**).
- There are issues associated with the design of IV equipment which increase the risk of residual drugs in cannulae and extension lines. There may be opportunities to improve equipment design to design out the potential for errors. The unintended consequences of redesign would need to be considered.
- Where certain drugs are used during an anaesthetic, such as NMBAs and some strong opioids, flushing becomes a safety-critical task. However, the task of flushing is functionally the same and there are limited additional steps or process alterations that mark the flushing of a consequential drug versus flushing to maintain the flow of fluid through a cannula.
- The WHO surgical safety checklist is an administrative control used to mitigate residual drugs in cannulae and extension lines following anaesthesia. Items on the WHO checklist act as prompts for expected actions or tasks, and do not include second/independent

checks or other hazard control activities proportionate to the risks being addressed by the process.

- Greater attention and focus are given to the Sign In and Time Out phases of the WHO checklist compared to Sign Out. The Sign Out process appears to compete with other tasks and processes and is often rote-learned and anticipated. This presents the risk that the purpose of the checklist is lost, and safety-critical checks overlooked.
- There is variation between IV devices and associated equipment. Many of these devices appear outwardly similar but, according to manufacturers' information, have variable specifications relating to the potential for regurgitation.
- Consumable IV equipment may be subject to change for a range of reasons which may include availability, cost, newer/better variants, and quality. Training and awareness of these changes is rarely provided, but there is a risk that staff are not made aware of changes to specification and/or device performance.
- Healthcare trusts acted upon the epic3 guidelines to minimise the number of ports on cannulae several years ago. The change management process at the time did not consider a wide range of stakeholders, including the end users.
- Healthcare providers are required to reduce the instances and risk of hospital acquired infections. The introduction of non-ported cannulae was not effectively communicated to end users and this affected the introduction of these items.
- In adult care, administration of flushes is rarely reconciled or recorded on perioperative documentation.
- Patients with multiple IV access sites are believed to be at greater risk of residual drugs in cannulae and extension lines. Recording of IV sites is not consistent.
- Paediatric anaesthetic practice differs from adult practice as flushes are prescribed and reconciled due to the specific additional considerations when anaesthetising very small children.
- Many of the hazard controls currently used to reduce the risk of residual drugs in cannulae and extension lines sit at the 'administrative controls' and less effective levels of the hierarchy of hazard control. The investigation considered that there may be stronger and more effective solutions that could be put in place. For example, physically removing the hazard (the drug) from clinical practice, replacing the hazard with a less hazardous drug, or reducing the concentration of the drug.

Impact of COVID-19 and intention for safety recommendation

HSIB intends to develop and issue a safety recommendation on identifying medicines that present a high risk if inadvertently retained in a cannula and/or extension line, and to assess and strengthen the mitigations in place for each identified medicine. HSIB has identified a

potential stakeholder to lead on this work; however, the stakeholder's capacity to discuss a safety recommendation is currently limited owing to COVID-19 pressures. HSIB anticipates issuing a safety recommendation in due course.

HSIB makes the following safety recommendation

Safety recommendation R/2021/115:

HSIB recommends that the Royal College of Anaesthetists and Centre for Perioperative Care work with relevant stakeholders, such as the Association of Anaesthetists, College of Operating Department Practitioners, and Association for Perioperative Practice, to review, update and integrate new guidance on the surgical safety checklist 'SignOut' process. Specifically, the guidance should be updated in relation to the flushing of cannulae and extension lines by strengthening the current administrative barriers, considering the hierarchy of hazard control, and the issues identified by the HSIB investigation.

HSIB makes the following safety observation

Safety observation O/2021/100:

It may be beneficial for manufacturers to further standardise product specifications to design out the potential for errors. For example, items such as Y-connectors, extension lines and needle-free connectors often look similar but may have differing specifications.

5.7 Planning for and delivery of emergency procedures in the non-theatre setting and transitions of patient care through the perioperative pathway

Planning for short-notice or emergency procedures under general anaesthetic

5.7.1 During observation visits, the investigation observed the booking of emergency operations and other procedures. The processes observed or described were broadly recognisable when compared between trusts and followed the guidance in the 'Guidelines for the provision of anaesthetic services' (GPAS) (Royal College of Anaesthetists, 2020).

5.7.2 While minor variations were common, all observation sites used a duty anaesthetist (described in the GPAS guidance as an 'emergency theatre coordinator'). Typically, this was a senior anaesthetist who received same-day requests for cases taking place in operating theatres (for example, emergency operations) and non-theatre settings (such as interventional radiology) and allocated the case to an available colleague.

5.7.3 The role of the duty anaesthetist typically extended to identifying and tasking the anaesthetic team. In one trust visited, the anaesthetic department had a 'duty floor anaesthetist' who managed all on-day requests for urgent cases. This role included co-ordinating anaesthetic teams and supported peri-anaesthetic planning, including recovery arrangements. This was not observed in all trusts visited.

5.7.4 GPAS guidance regarding the role of the emergency theatre co-ordinator is limited, stating they could actively manage the prioritisation of cases and patient flow (Royal College of Anaesthetists, 2020). The guidance does not provide advice regarding support and oversight of all emergency cases. Specifically, the standards exclude information supporting end-to-end care for emergency cases.

5.7.5 There are limited standards for planning anaesthetics for short-notice cases in any clinical setting. The 'National safety standards for invasive procedures' (NHS England, 2015) has a section which describes the safety briefing that should take place before a procedure commences. Relevant to this investigation, it states that: 'The expected duration of each procedure, to include anaesthetic procedures, should be identified. This should promote a discussion about agreed plans if it appears that the duration of the planned procedures will exceed the time allocated. Any additional concerns from an operator, anaesthetic or practitioner perspective must be discussed, and contingency plans made.' (NHS England, 2015)

5.7.6 No planning documentation was observed during visits to trusts. None of the hospitals visited (except those that recover patients in the operating department following a procedure in a nontheatre setting) described the requirement to deliver a recovery plan. As a result, there was limited consideration of environmental and logistical considerations for cases taking place away from main operating theatres. Anaesthetists do undertake careful planning of the actual anaesthetic being carried out at each stage (such as assessment, induction, maintenance, and critical care requirements). Where an adverse event occurs, such as changes to the availability of the post-anaesthetic recovery practitioner, as described in the reference event, the absence of a clear plan can result in limited mitigation and contingency.

5.7.7 In hospitals where patients are recovered in the non-theatre department setting following their procedure, recovery staff based in the operating department told the investigation that they were not made aware of these cases. When the reference event was discussed with post-anaesthetic recovery practitioners, a range of responses were given in terms of what each post-

anaesthetic recovery practitioner would do in similar circumstances. No hospital trust had guidance or plans for accepting unannounced arrivals in the PACU. Staff working in the perioperative setting commonly said that awareness of all patients being anaesthetised would be helpful, although no evidence was presented as to how this awareness would prevent adverse events.

5.7.8 The investigation was told by a PACU manager that in their PACU, staff are informed of all emergency cases which take place in the main operating theatre, so that a bed is available for that patient. This is not the case for procedures performed under general anaesthetic taking place in non-theatre settings.

5.7.9 The GPAS guidance for provision of anaesthetic services in the non-theatre environment (Royal College of Anaesthetists, 2020) states that 'A PACU or equivalent should be available for each patient at the end of the procedure'. It also states that:

'Patients recovering from anaesthesia or sedation in an isolated unit should receive the same standard of care as that required in an operating theatre post anaesthetic care unit (PACU). For major vascular surgery, transfer to the main PACU by appropriately trained personnel may be required.' (Royal College of Anaesthetists, 2020)

5.7.10 A subject matter advisor (anaesthetics) told the investigation that consideration should be given to using "an end-to-end planning process/ document for non-theatre general anaesthetic cases. This should include who to call for help if required as well as the planned location for post anaesthetic care".

5.7.11 Creating an end-to-end plan in safety-critical industries, such as aviation, is common. Pilots create and log a flight plan which describes their intentions for the flight under expected conditions, but also considers a range of responses to anticipated changes in conditions, such as weather and onboard medical emergencies. This may include identifying alternative airports in range throughout the journey. This could be considered as analogous to the need to consider potential events during procedures under anaesthetic in non-theatre settings, such as recovery arrangements, equipment failure, or changes in staffing. Team dynamics and logistics

5.7.12 Several anaesthetists and ODPs spoke about the differences between undertaking general anaesthetics as part of a surgical team within the operating theatre versus non-theatre settings. Anaesthetists reported feeling part of a cohesive unit when working with surgeons in operating theatres, whereas in settings such as interventional radiology and MRI suites, they reported feeling like "hired help". This was cited as a factor which affected team dynamics and impacted on communication and situation awareness.

5.7.13 Non-theatre settings were often less well equipped and stocked compared to main theatres. While equipment was suitable and met the criteria for relevant standards, such as the guidelines for immediate post-anaesthesia recovery (Association of Anaesthetists of Great Britain and Ireland, 2013), GPAS (Royal College of Anaesthetists, 2019) and Anaesthesia Clinical Services Accreditation (Royal College of Anaesthetists, 2019), it often differed from the equipment in the operating department. Unlike when working in operating theatres, in other settings the anaesthetic machine and other items needed to be taken out of storage and positioned in the setting in which they were being used (such as an interventional radiology (IR) suite). These tasks added a time pressure when preparing for a short-notice or emergency case.

5.7.14 The investigation was told by anaesthetists and ODPs that they routinely brought certain medications with them to nontheatre settings to ensure that they had what they needed. Even where medicines cabinets were installed in locations such as IR suites, anaesthetic teams often brought their own supplies from the operating department to provide assurance that they could access specific medicines should an adverse event occur.

5.7.15 Staff spoke of operating theatres having standardised layouts and storage facilities, whereas non-theatre settings varied. Equipment in non-theatre settings was used less frequently and was less likely to be routinely checked. This placed a further burden on staff who said that this compounded the existing risks of undertaking a general anaesthetic outside of the operating department setting. 5.7.16 Conversely, in one trust visited, where general anaesthetics were not carried out in the IR department, a senior radiology nurse mentioned a disadvantage of undertaking IR procedures in a hybrid theatre (a combined operating theatre and IR suite) within the main operating department. It will include full operating theatre equipment alongside high-quality imaging facilities. They said that when working in the operating department they felt isolated from their main (IR) department and were “treated like guests”, which could affect the dynamic of the team. Communication and handover of care

5.7.17 During the observation visits it was noted that despite differences in environmental conditions and flow through operating departments or procedural unit (such as IR or MRI), communication was clear and structured throughout the patient journey.

5.7.18 There are many transitions between care settings associated with operations or other procedures done under general anaesthetic. These include:

- transfer from ward/unit to the operating department
- moving from the operating theatre receiving area (where applicable) to the anaesthetic room (where applicable)

- after being anaesthetised (or other anaesthetic procedure such as a regional block, which involves anaesthetising part of a patient's body with the patient remaining conscious), movement to the operating theatre
- following the operation/ procedure, transfer to the PACU (or critical care unit)
- transfer back to the ward/unit from the PACU.

5.7.19 On arrival in the anaesthetic room (or operating theatre in trusts where anaesthetic rooms are not used), the WHO surgical safety checklist Sign In process is used to sign the patient in. This was observed in every instance where a procedural anaesthetic was performed. Similarly, the Time Out section of the checklist was used in every case prior to the commencement of the actual operation/procedure. When it was time to undertake these stages of the process, staff fell silent and observed closely each step of the process as it was verbalised.

5.7.20 When the operation was completed, the Sign Out was undertaken (see section 4.5). While still structured, the communication observed during Sign Out was less formal and more distractions were noted.

5.7.21 At one trust, the investigation noted that on arrival at the recovery unit, there was no checklist or prompt used to structure the handover of the patient's care. Recovery staff told the investigation that the expertise of the anaesthetic team and the recovery team meant that the pertinent information was either volunteered or requested from either party; therefore, a checklist would be of little value. Recovery staff told the investigation that they are familiar with anaesthetic techniques and the type of medicines which pose the most risk.

5.7.22 At another trust, recovery staff said that they follow a clear process for patients who are cared for in their unit. While specific processes varied, staff in different trusts reported a clear method for admitting patients to recovery, which included a verbal handover, monitoring and assessment of the patient, and a process for identifying when a patient is ready to go back to the ward (described by some staff as being "discharged" from recovery).

5.7.23 Post-anaesthetic recovery practitioners in two observation sites specifically mentioned the importance of the admission, monitoring and discharge processes undertaken in recovery.

5.7.24 The WHO surgical safety checklist includes sections which cover the transition between phases of perioperative care. One consultant anaesthetist said that "nurses in recovery are more vigilant" and therefore do not need checklists to support handover, and that there would be little appetite for checklists to be used in this context. The lack of reported incidents occurring within the recovery environment supports the view that recovery nurses and ODPs

have expertise and contextual knowledge of anaesthetics and surgery. However, having a limited structured process may allow for errors to be carried forward and impact on a patient many hours later, as seen in the reference event.

5.7.25 A subject matter advisor (pharmacist) highlighted that patients on the perioperative care pathway are “transitioning environments, but also transitioning systems” and this has a potential impact on the awareness of different medicines used and the potential risk of residual drugs in lines. For example, many hospitals use paper charts in the operating theatre, but use electronic prescribing and medicines administration (EPMA) systems in recovery and the wards.

Anaesthetic drugs are rarely transcribed into EPMA systems, and anaesthetic records are physically added to the patient’s case notes. While not always relevant to the risks of NMBAs being retained in cannulae, other risks may arise when patients and their information move between systems during their care. For example, the lack of collation of medicines given during an operation into a single system could result in subsequent medicines, such as anticoagulants (blood thinners) and antibiotics, being omitted or repeated in error.

Summary

- There is limited guidance on the planning process for undertaking anaesthesia in the non-theatre setting. This may impact on the follow-up actions should an adverse event occur.
- Guidance from the Royal College of Anaesthetists promotes the use of co-ordinators in the booking of emergency cases, but there is a lack of specific guidance on oversight of patients throughout the perioperative pathway, particularly for cases in the non-theatre setting.
- Anaesthetists report different team dynamics in non-theatre settings compared to working as part of a surgical team in the operating department.
- Medicines given during perioperative care may not be transcribed into the patient’s main drug chart/record.

HSIB makes the following safety recommendation

Safety recommendation R/2021/116:

HSIB recommends that the Royal College of Anaesthetists reviews its ‘Guidelines for the provision of anaesthetic services’ regarding the planning and oversight of perianaesthetic care in non-theatre settings. This should include:

1. guidance to assist anaesthetic departments to consistently plan for short-notice or emergency cases which take place in the non-theatre setting

5.8 Reporting of incidents

5.8.1 The reporting of inadvertent administration of NMBA's or other medicines of consequence used in anaesthesia is challenging. Awareness under general anaesthetic is a well-understood phenomenon (Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland, 2014) where a patient is not fully asleep and may feel pain and/or be unable to move during their operation. Awareness events are generally thought to occur during the administration of an anaesthetic, but in the reference event, the unintended administration of an NMBA did not take place during the anaesthetic procedure and so was not reported as an awareness event.

5.8.2 A subject matter advisor (pharmacy/medicines safety) told the investigation that reporting of events similar to the reference event was limited. Patients are commonly only mildly physically affected and/or the effects only last a very short period. These events may either not be detected or not classified as an anaesthetic awareness event, and are therefore not reported as such.

5.8.3 A senior anaesthetist told the investigation that "[we] don't know what we don't know" regarding these kinds of events. Discussion was had about whether medical or nursing staff would be able to reliably recognise a change in a patient's condition caused by the infusion of a residual dose of an NMBA or other drugs. A consultant anaesthetist told the investigation that some patients are reported as having "a funny turn" following an anaesthetic (either in the PACU or on the ward later) and that serious adverse events such as respiratory and/or cardiac arrest are extremely rare. Where mild reactions or other adverse events resolve rapidly and spontaneously, their cause is rarely explored or reported.

5.8.4 Anaesthetists who spoke to the investigation reported having experienced near misses which may have led to occurrences similar to that in the reference event. Typically, these occurred in the operating theatre or PACU and were detected prior to the patient leaving these settings and so were not reported. Not reporting near misses may have a negative impact on the opportunity to learn from these events and to raise awareness of the potential for patient harm.

5.8.5 Hospital trusts are required to have a centralised incident reporting system which uses a standardised code set (a predefined list of codes for incident types) but which can be adjusted to suit local contexts. It is understood that there is no code in the national reporting code set which specifically describes an event relating to the administration of residual drugs in a cannula following an anaesthetic.

5.8.6 As previously discussed in 5.4.5, nurses and midwives who receive IV training are not made aware of the specific complication of the inadvertent administration of residual anaesthetic drugs in cannulae. In the context of the reference event and the patient not being in an anaesthetic environment, events may not be accurately detected and therefore correctly reported. Improvements in reporting accuracy will require awareness of this risk to be promoted during training.

5.8.7 The investigation was told by NHS England and NHS Improvement that the way in which incidents are reported will be changing and moving away from lists of specific incident types.

5.8.8 Instead, the classification system will ask a more nuanced set of questions about what happened, what things were involved, and the ways in which things went wrong, alongside information about the patient outcome, level of harm, and so on. It is anticipated that this will allow for a shift of focus away from the outcome of an incident, and towards the points at which things went wrong, which is where any interventions to improve safety would need to be targeted.

Summary

- The reporting of incidences of awareness under general anaesthetic is well established but the circumstances of the reference event may not fulfil the published definition. Such events may either not be detected or not classified as an anaesthetic awareness event, and are therefore not reported as such.
- The reporting of incidents will be moving away from lists of specific incident types to improve the ability to learn and target improvements at the right areas.

6 Summary of HSIB findings, safety recommendations and safety observations

Key findings associated with mitigations which could reduce the risk of residual drugs in cannulae and extension lines

The investigation found:

- One of the key risk factors associated with residual drugs in cannulae and extension lines is the concentration and risks associated with the drug itself. This is particularly the case for drugs that can cause a clinically significant effect in low volumes.
- Flushing is a key mitigation for preventing the risk of residual drugs in cannulae and extension lines. However, it sits at the 'administrative controls' level of the hierarchy of hazard control, towards the 'least effect' end of the control spectrum (see figure 7).

- There are issues associated with the design of intravenous (IV) equipment which increase the risk of residual drugs in cannulae and extension lines. There may be opportunities to improve equipment design to design out the potential for errors. The unintended consequences of redesign would need to be considered.
- Where certain drugs are used during an anaesthetic, such as neuromuscular blocking agents (NMBAs) and some strong opioids, flushing becomes a safety-critical task. However, the task of flushing is functionally the same and there are limited additional steps or process alterations that mark the flushing of a consequential drug versus flushing to maintain the flow of fluid through a cannula.
- The WHO surgical safety checklist is an administrative control used to mitigate residual drugs in cannulae and extension lines following anaesthesia. Items on the WHO checklist act as prompts for expected actions or tasks, and do not include second/independent checks or other hazard control activities proportionate to the risks being addressed by the process.
- Greater attention and focus are given to the Sign In and Time Out phases of the WHO checklist compared to Sign Out. The Sign Out process appears to compete with other tasks and processes and is often rote-learned and anticipated. This presents the risk that the purpose of the checklist is lost, and safety-critical checks overlooked.
- There is variation between IV devices and associated equipment. Many of these devices appear outwardly similar but, according to manufacturers' information, have variable specifications relating to the potential for regurgitation.
- Consumable IV equipment may be subject to change for a range of reasons which may include availability, cost, newer/better variants, and quality. Training and awareness of these changes is rarely provided, but there is a risk that staff are not made aware of changes to specification and/or device performance.
- Healthcare trusts acted upon the epic3 guidelines to minimise the number of ports on cannulae several years ago. The change management process at the time did not consider a wide range of stakeholders, including the end users.
- Healthcare providers are required to reduce the instances and risk of hospital acquired infections. The introduction of non-ported cannulae was not effectively communicated to end users and this affected the introduction of these items.
- In adult care, administration of flushes is rarely reconciled or recorded on perioperative documentation.
- Patients with multiple IV access sites are believed to be at greater risk of residual drugs in cannulae and extension lines. Recording of IV sites is not consistent.

- Paediatric anaesthetic practice differs from adult practice as flushes are prescribed and reconciled due to the specific additional considerations when anaesthetising very small children.
- Many of the hazard controls currently used to reduce the risk of residual drugs in cannulae and extension lines sit at the 'administrative controls' and less effective levels of the hierarchy of hazard control. The investigation considered that there may be stronger and more effective solutions that could be put in place. For example, physically removing the hazard (the drug) from clinical practice, replacing the hazard with a less hazardous drug, or reducing the concentration of the drug.

Impact of COVID-19 and intention for recommendation

The investigation report was finalised during the COVID-19 pandemic. At the time, much of HSIB's and key stakeholders work was necessarily redirected to supporting frontline services and focusing on issues specifically related to COVID-19.

HSIB intend to develop and issue a safety recommendation around identifying medicines that present a high risk if inadvertently retained in a cannula and/or extension line, and to assess and strengthen the mitigations in place for each identified medicine. HSIB has identified a potential stakeholder to lead on this work, however, the stakeholder's capacity to discuss a recommendation is currently limited owing to COVID-19 pressures.

Given the importance of the findings in this report, HSIB decided to publish the findings, safety recommendations, and safety observations so far and to issue a further recommendation in due course.

HSIB makes the following safety recommendation

Safety recommendation R/2021/115:

HSIB recommends that the Royal College of Anaesthetists and Centre for Perioperative Care work with relevant stakeholders, such as the Association of Anaesthetists, College of Operating Department Practitioners, and Association for Perioperative Practice, to review, update and integrate new guidance on the surgical safety checklist 'SignOut' process. Specifically, the guidance should be updated in relation to the flushing of cannulae and extension lines by strengthening the current administrative barriers, considering the hierarchy of hazard control, and the issues identified by the HSIB investigation.

HSIB makes the following safety observations

Safety observation O/2021/098:

It may be beneficial for healthcare trusts to adopt the programme provided by Health Education England for intravenous (IV) skills, which supports the competency requirements published by the Nursing and Midwifery Council.

Safety observation O/2021/099:

It may be beneficial to increase the use of body maps to record the presence of all indwelling items, such as cannulae, catheter and drains, during an anaesthetic procedure. The body map could be used as part of an enhanced sign-out and to provide instructions for the management of each indwelling item in the postoperative period.

Safety observation O/2021/100:

It may be beneficial for manufacturers to further standardise product specifications to design out the potential for errors. For example, items such as Y-connectors, extension lines and needle-free connectors often look similar but may have differing specifications.

Key findings associated with planning for and delivery of emergency procedures in the non-theatre setting

The investigation found:

- There is limited guidance on the planning process for undertaking anaesthesia in the non-theatre setting. This may impact on the follow-up actions should an adverse event occur.
- Guidance from the Royal College of Anaesthetists promotes the use of co-ordinators in the booking of emergency cases, but there is a lack of specific guidance on oversight of patients throughout the peri-operative pathway, particularly for cases in the non-theatre setting
- Anaesthetists report different team dynamics in non-theatre settings compared to working as part of a surgical team in the operating department.
- Medicines given during peri-operative care may not be transcribed into the patient's main drug chart/record.

HSIB makes the following safety recommendation**Safety recommendation R/2021/116:**

HSIB recommends that the Royal College of Anaesthetists reviews its 'Guidelines for the provision of anaesthetic services' regarding the planning and oversight of peri-anaesthetic care in non-theatre settings. This should include:

1. guidance to assist anaesthetic departments to consistently plan for short-notice or emergency cases which take place in the non-theatre setting
2. planning which considers and mitigates against unexpected changes in conditions.

Key findings associated with the reporting of incidents

- The reporting of incidences of awareness under general anaesthetic is well established but the circumstances of the reference event may not fulfil the published definition. Such events may either not be detected or not classified as an anaesthetic awareness event, and are therefore not reported as such.
- The reporting of incidents will be moving away from lists of specific incident types to improve the ability to learn and target improvements at the right areas.

7 Endnotes

[1] Operating department practitioners (ODPs) are healthcare professionals registered with the Health and Care Professions Council and primarily qualified in peri-operative care (care of patients before, during and after an operation). They may work as part of the anaesthesia or surgical teams and in post-anaesthesia recovery care.

[2] Interventional radiology suites/departments are specialist units within hospitals where interventional radiologists undertake advanced imaging and surgical techniques to diagnose and treat a range of diseases.

[3] A safety huddle is 'a short multidisciplinary briefing, held at a predictable time and place, and focused on the patients most at risk. Effective safety huddles involve agreed actions, are informed by visual feedback of data and provide the opportunity to celebrate success in reducing harm' (NHS England, 2019).

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9 Appendix

Process for perioperative care in anaesthesia

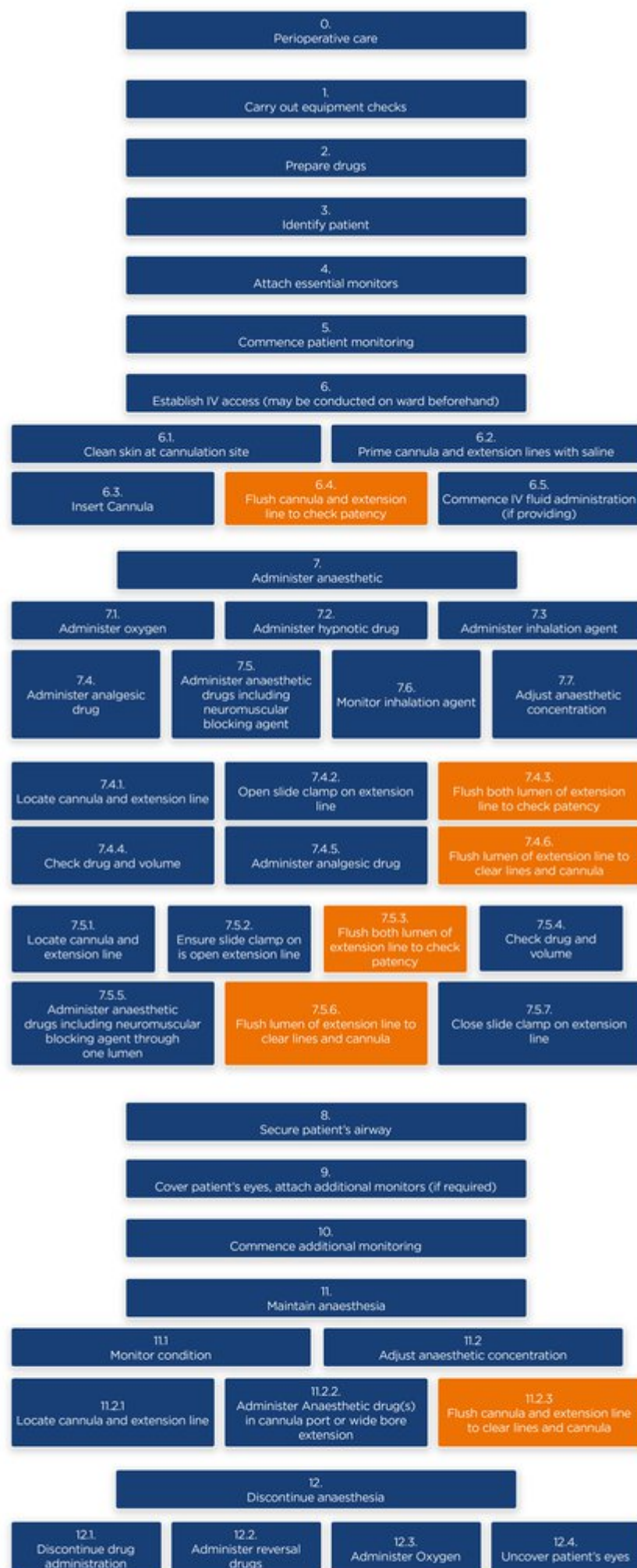
The investigation conducted a Hierarchical Task Analysis (HTA) (Annett, 2004) of perioperative care in anaesthesia, focusing on the aspects where flushing can occur (shown in figure 9). The HTA was developed using data from two research papers (Lane et al, 2006; Phipps et al, 2008) and observations from investigation site visits. The HTA was not intended to be exhaustive, but

to provide a sufficient level of detail (relevant to this investigation) of the tasks and sub-tasks anaesthetists are likely to be undertaking during a procedure. The sequence of tasks may also vary between anaesthetists and from patient to patient.

The HTA shows the overall process that was under analysis (perioperative care), which was broken down into 14 key task goals. Four of these goals which were relevant to flushing were then explored further, identifying the various sub-tasks that are required to achieve the goal. Three subtasks were broken down further to identify the smaller steps required to achieve the sub-task.

The HTA shows that flushing:

- occurs at numerous points during the perioperative process
- is a routine task that may occur frequently during the perioperative process
- can vary in its purpose throughout the perioperative process
- sits among many other anaesthetic tasks, especially when considering that each key task goal can be decomposed into numerous sub-tasks.



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