INADVERTENT ADMINISTRATION OF AN ORAL LIQUID MEDICINE INTO A VEIN
I2017/009

Independent report by the Healthcare Safety Investigation Branch

April 2019 Edition
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ABOUT HSIB

The Healthcare Safety Investigation Branch (HSIB) conducts independent investigations of patient safety concerns in NHS-funded care across England. Most harm in healthcare results from problems within the systems and processes that determine how care is delivered. Our investigations identify the contributory factors that have led to harm or the potential for harm to patients.

The recommendations we make aim to improve healthcare systems and processes, to reduce risk and improve safety. Our organisation values independence, transparency, objectivity, expertise and learning for improvement. We work closely with patients, families and healthcare staff affected by patient safety incidents, and we never attribute blame or liability.

OUR INDEPENDENCE

We are funded by the Department of Health and Social Care and sponsored by NHS Improvement, but we operate independently. In 2018, a draft Bill for establishing the Health Service Safety Investigations Body (HSSIB) was approved by Parliament and is expected to be introduced in the near future. The Bill will establish our full statutory independence and enshrine our right to conduct national safety investigations under protected disclosure. This provision, commonly known as ‘safe space’, enables staff to share their experience of a patient safety incident without fear of reprisal. It will not prevent us from sharing important details with families, regulators or organisations about an incident or to address immediate risks to patient safety. The Health Service Safety Investigations Bill will also establish our responsibility for NHS maternity investigations that meet specific criteria, though the maternity investigations are exempted from protected disclosure. Full information about the draft Bill is available on the Department of Health and Social Care website

ANONYMITY

The gendered pronouns and the grades of the staff referred to in the report may have been changed to protect the anonymity of the staff involved.
OUR INVESTIGATIONS

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

We undertake patient safety investigations through two programmes.

NATIONAL INVESTIGATIONS

Our national investigations can encompass any patient safety concern that occurred within NHS-funded care in England after 1 April 2017. We consider potential incidents or issues for investigation based on wide sources of information including that provided by healthcare organisations and our own research and analysis of NHS patient safety systems. We decide what to investigate based on the scale of risk and harm, the impact on individuals involved and on public confidence in the healthcare system, and the learning potential to prevent future harm. We welcome information about patient safety concerns from the public, but we do not replace local investigations and cannot investigate on behalf of families, staff, organisations or regulators.

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

- safety recommendations based on information derived from the investigation or other sources such as safety studies, made with the intention of preventing future, similar events; and
- safety observations which are made for wider learning in healthcare, or to a specific individual or organisation for consideration, when there is insufficient information to support a safety recommendation but still warrant attention.

Our reports also identify actions taken during an investigation to immediately improve patient safety. Organisations subject to our recommendations must send their response to us within three months, which is published on our website.

More information about our national investigations including in-depth explanations of our criteria, how we investigate, and how to refer a patient safety concern is available on our website.

MATERNITY INVESTIGATIONS

From 1 April 2018, we became responsible for all NHS patient safety investigations of maternity incidents which meet criteria for the Each Baby Counts programme (Royal College of Obstetrics and Gynaecologists, 2015). The purpose of this programme is to achieve rapid learning and improvement in maternity services, and to identify common themes that offer opportunity for system-wide change. For these incidents HSIB’s investigation replaces the local investigation, although the trust remains responsible for Duty of Candour and for referring the incident to us. We work closely with mothers and families, and healthcare staff and organisations during an investigation. Our reports are provided directly to the families and to the trust. Our safety recommendations are for actions to be taken directly by the trust.

We will be operating in all trusts by 1 April 2019. Our longer-term aim is to make safety recommendations to national organisations for system-level improvements in maternity services. These will be based on common themes arising from our trust-level investigations. More information about our maternity investigations is available on our website.
EXECUTIVE SUMMARY

The reference event
A nine-year-old child was admitted to a hospital day-case ward for an elective renal biopsy, which involves taking a small piece of kidney using a special needle. The procedure can be frightening and is sometimes painful. At the reference site, to calm a child, a sedative drug called midazolam is usually injected slowly into a vein until the patient is sleepy.

A Specialty Trainee (ST1-3) doctor in training prescribed the midazolam to be given intravenously (IV). The ST1-3 doctor waited approximately 15 minutes until a nurse was available to prepare the medicine. The nurse and doctor agreed the dosage and subsequently went together to the ward treatment room’s controlled drugs cupboard to draw up the medicine. In the controlled drugs cupboard, ampoules of midazolam for IV injection were kept beside a bottle of midazolam oral suspension for administration by mouth. The nurse had only ever used oral midazolam and drew some of the oral midazolam up into a purple syringe marked ‘enteral’ with the expectation of it being given via the mouth.

The nurse and ST1-3 doctor followed a two-person checking process designed to ensure that the correct drug at the correct dose was administered in the correct way during the scheduled procedure. However, the two-person checking process did not provide a warning to the doctor that the nurse had drawn up oral midazolam or alert the nurse that the doctor had prescribed an IV drug.

The doctor took the purple syringe into a side room on the ward, where the procedure was being performed, and passed it to a second, more senior doctor (a Specialist Trainee doctor (ST6-8)) who attempted to administer the medicine. However, the ST6-8 doctor could not connect the purple syringe to the intravenous line, and so asked the ST1-3 doctor to put the midazolam into a ‘normal’ IV syringe. With the contents of the purple oral/enteral syringe decanted to an IV syringe, the latter was connected to the patient’s IV line.

The ST6-8 doctor realised that the wrong drug was being administered when she began to inject it into the vein and some spilled. It was sticky and smelled sweet. She flushed the cannula with a saline solution and sent the ST1-3 doctor out of the room to clarify if the medicine that had been prepared was intravenous. The procedure was paused while this clarification was being sought. The nurse who had prepared the enteral syringe realised that an error had been made when she noticed the doctor was carrying an IV syringe. The procedure was stopped.

Subsequently, the patient’s mother was informed of what had happened. The patient remained in hospital and was monitored for the next 24 hours for any adverse effects. The patient then underwent the procedure under general anaesthetic and was later discharged having suffered no apparent adverse effects from the inadvertent administration of oral midazolam into the vein.

The national investigation
The Healthcare Safety Investigation Branch (HSIB) was made aware of a patient who inadvertently had an oral liquid medication injected into a vein, via the national reporting and learning system. This is classed as a wrong route medication error. Administration of medicine via the wrong route is defined as a ‘Never Event’ in the NHS. HSIB staff gathered additional information and assessed the incident against its investigation criteria. The HSIB’s Chief Investigator decided to progress to a national investigation focusing specifically on the inadvertent administration of an oral liquid medication into a vein and the potential for national learning for improvement.

The investigation reviewed the effectiveness of the current processes for the storage of medicines, equipment design, and the prescribing, preparation, checking and administration of medication. It also considered the contextual, environmental and human factors that influenced the inadvertent administration of an oral solution into a vein.

The effectiveness of current processes for implementation of local safety standards for invasive procedures was also considered.

A human factors expert was involved in the investigation and a dedicated report was written based on the evidence reviewed, a reconstruction of the event and a simulation of what should have happened. The human factors report is supplementary to this report – see Appendix A.

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1 The Trust at which the incident occurred.
2 Purple coloured or purple barrel syringes are intended for oral or enteral (for example nasogastric, jejunal) administration, that is, for administering liquids into the gastric system rather than for injection use.
3 Never Events are defined as ‘Serious Incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers’ (NHS Improvement, 2018a).
Reference event findings
In summary, there was a lack of knowledge of the medicines being used by inexperienced nursing staff, unfamiliarity with enteral syringes by medical personnel, and decanting of medicines from enteral to Luer lock syringes thus bypassing the physical barriers designed to prevent these errors.

1 An experienced practice nurse educator (a registered nurse who has several years of nursing experience and an interest in teaching) who normally oversaw the process and prepared the necessary medication was absent on the day of the procedure.

2 The registered general nurses on the day-case ward who were helping with the procedure were only familiar with oral preparations of midazolam.

3 The oral and intravenous midazolam were stored on the same shelf within the controlled drugs cupboard.

4 The doctors prescribing and administering the medication were unfamiliar with the design and use of oral/enteral syringes.

5 The nurse who dispensed the oral medication did not accompany the prescribing doctor to the side room where the medication was administered, and the team proceeded in her absence.

6 There was not a local standard operating procedure for invasive procedures incorporating renal biopsy; no structured process existed to ensure each team member understood their own role and the roles of colleagues.

7 Local medicines policies were not followed or possibly not understood.

8 There was not a local safe sedation policy for children.

National investigation findings
1 Human factors can hinder the correct prescribing, preparation, verification and administration of medicines.

2 Administration of medicine via the wrong route is defined as a Never Event in the NHS, however, consistent human interactions are required to prevent it.

3 Using purple oral/enteral syringes doesn’t always prevent wrong route administration of medication.

4 Decanting medication from an oral/enteral syringe into an IV syringe is not an isolated event.

5 Some safeguards are in place on wards to reduce the risk of wrong route administration of medication, but these may fail due to local anomalies, such as staff shortages and lack of training.

6 Medication administration is complex with cognitive demands made on staff during critical stages. For example, interruptions, distractions and multi-tasking in the medicine administration process are common.

7 There is no national standard for second-person checking of medication preparation and administration.

8 There appears to be a lack of understanding about the use of oral/enteral syringes among doctors.

9 There appears to be a lack of understanding about the purpose of the colour coding of syringes among doctors.

10 The training of medical students and qualified doctors in the preparation and administration of oral and IV medicines is variable, with no formal mandatory standard drug administration training for doctors in hospitals.

11 While the national Prescribing Safety Assessment is now a mandatory requirement for medical students to graduate, it does not cover practical competencies such as the manipulation and administration of medicines.

12 IV syringes are used when oral/enteral syringes are not available.

13 IV syringes have been used when oral/enteral syringes are available.

14 Practice varies between healthcare facilities in how medicines and syringes are stored.

15 There is significant variation in how existing safety standards are implemented and continually monitored.

* A Luer lock syringe allows fixation by screw fitting to administer intravenous medication.
There has been no national assessment of the effectiveness of the Patient Safety Alerts regarding the introduction of oral syringes.

There is variation in the time available and grade/experience of individuals designated as Medication Safety Officers. There has been no national assessment of the effectiveness of Medication Safety Officer roles.

Implementation strategies to support the integration of new systems and devices, for example training needs analysis and hazard identification exercises, are not systematically used and consistently applied.

The practice of labelling of syringes with the contents of the medicine is inconsistent.

Many organisations, including NHS Improvement, Health Education England, royal colleges and professional regulators, play a substantial role in medicines safety. However, the current system is confused and complex with a lack of clarity of the roles of these organisations and their responsibilities for system-wide implementation of safety standards and the dissemination of messages concerning safety. This is despite the enthusiasm and commitment of the healthcare professionals and national bodies the investigation team consulted.

Interventions to improve medicines safety are challenging as they attempt to address complex interrelated human factors.

Recommendations identified in previous publications on improving medicines safety, dating back over a decade, appear to be challenging to implement and remain outstanding.

Guidance and standards on prescribing, preparation, checking and administration of medicines are fragmented and divided between a range of professional and NHS regulatory bodies.

Local medication policies and guidelines do not follow a consistent core framework linking the various strands of medicines use within the NHS.

Reference site actions
The Trust carried out a local Serious Incident investigation and made several recommendations which included:

1. A local safety standard for renal biopsy and other invasive procedures (as required) should be developed and implemented.

2. Compliance with National Institute for Health and Care Excellence Clinical Guideline [CG112], Sedation in under 19s: using sedation for diagnostic and therapeutic procedures, should be assessed and improved as required.

3. A policy and procedure for the administration of safe sedation in children should be developed and implemented.

4. The medicines policy regarding preparing, checking and administration of medication should be reinforced with staff and level of compliance with the policy should be assessed.

5. Awareness of barriers to prevent wrong route administration of medication including Trust policies should be increased via education.

6. Ward nursing staff should be trained in the processes for undertaking a renal biopsy.

HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATIONS

Recommendation 2019/028:
It is recommended that NHS Improvement, through the National Patient Safety Alert Committee, set standards for all issuers of patient safety alerts which make clear that alert issuers should assess for unintended consequences of the actions in the alert, the effectiveness of barriers created by these actions, and provide appropriate advice for providers on implementation, include ongoing monitoring.

Recommendation 2019/029:
It is recommended that NHS Improvement support the development of necessary knowledge, skills and capacity for the effective operationalisation of hazard identification and risk analysis at a national, regional and local level, as an integral part of the National Patient Safety Strategy.

Recommendation 2019/030:
It is recommended that the Royal College of Physicians, in collaboration with the Royal Pharmaceutical Society, British Pharmacological Society, Royal College of General Practitioners, Royal College of Paediatrics and Child Health,
NHS Improvement, the professional bodies for the professions regulated by the Health and Care Professions Council, Royal College of Nursing and Royal College of Midwives, provide leadership in recommending the postgraduate learning needs and activities to standardise professional development in medicines safety processes.

Recommendation 2019/031:
It is recommended that NHS Improvement undertake a formal evaluation of banding, time and resource given to the Medication Safety Officer role across England and publish its findings and mandate minimum resources and standards.

HSIB MAKES THE FOLLOWING SAFETY OBSERVATIONS

Observation:
It is recommended that staff with a responsibility for medicines safety, for example Medicines Management and Chief Pharmacists, Clinical Governance Leads, Heads of Medicines Optimisation and Medication Safety Officers are familiar with the contents of the existing National Institute for Health and Care Excellence clinical guidance on medicines optimisation and can demonstrate how they have implemented the quality standard on medicines optimisation [QS120] and quality statement 3, ‘Learning from medicines-related patient safety incidents’.

Observation:
It would be beneficial to define a national standard for independent two-person checking when preparing high-risk medication for administration to minimise medication errors associated with high-risk medications.

Observation:
Availability of oral/enteral syringes in all clinical areas (in accordance with the requirements contained in the National Patient Safety Agency’s Patient Safety Alert 19) is inconsistent. A national audit tool may be helpful to organisations.

Observation:
Colouring of high-risk and/or oral liquid medications (such as midazolam) may have a justifiable role in improving safety as it will offer a signal to differentiate oral from parenteral preparations.

Observation:
It would be beneficial if potential interventions designed to reduce wrong route administration medication errors were subjected to human factors testing, review, evaluation and modification prior to being introduced at scale; this includes standards, processes, and the design of medication and administration devices.

Observation:
SCRIPT is an eLearning programme to improve safety and competency among healthcare professionals around prescribing, therapeutics and medicines management. It would be beneficial to roll out SCRIPT as a mandatory requirement for all prescribers.

Observation:
There is an opportunity with the new General Medical Council Medical Licensing Assessment to mandate additional therapeutic practical skills for example, the practical aspects of medicines administration, as part of the Clinical Practical Skills Assessment.

SAFETY ACTIONS CARRIED OUT AND/OR IN PROGRESS

Safety action:
The Trust where the reference event occurred removed an inaccurate notice affixed to the inside of a controlled drugs cupboard and reviewed its storage arrangements.

Safety action:
In January 2019 the Specialist Pharmacy Service published its Medicines Governance Do Once Programme, which includes a plan to develop national templates for medicines-related policies for adaptation and adoption within NHS organisations and other publicly funded commissioned services.

Safety action:
The Royal Pharmaceutical Society has produced and published professional guidance on the administration of medicines for use by all healthcare professionals.

Safety action:
NHS Improvement is working towards a formal launch of the National Medicines Safety Programme in April 2019.
Safety action:
The reference event site has acted upon the requirement for a Local Safety Standard for Invasive Procedures (LocSSIP):
‘...a Local Safety Standard (LocSSIP) should be developed for all invasive procedures including renal biopsies and any other procedures that include sedation. Including minimum staffing/skillmix required’.

Safety action:
HSIB, supported by a teaching hospital, has produced a reconstruction of events and a simulation of what happened during the reference event along with a supplementary teaching aid to increase awareness of this type of error.

Safety action:
The reference event site has developed a safe sedation guideline for under 19s and reviewed the integrated care pathway for children undergoing a procedure requiring sedation.
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1 BACKGROUND AND CONTEXT

1.1 Medication errors

1.1.1 A medication error is an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient (European Medicines Agency, 2015a). The treatment process includes the prescribing, storing, dispensing, preparation for administration and administration of a medicinal product. Examples of common medication administration errors include giving a medication to the wrong patient, the wrong dose of a medication being given to a patient or forgetting to give a patient a medication that had been prescribed for them (European Medicines Agency, 2015b).

1.1.2 Estimating the prevalence of medication errors presents challenges due to the varying definitions or error and methodologies for gathering the data, something highlighted in the report A Spoonful of Sugar (Audit Commission, 2001).

1.1.3 Medicines may be given by one of several routes: oral, rectal, central or peripheral intravenous, nasogastric, topical, gastrostomy, subcutaneous, epidural, jejunostomy, intramuscular, intrathecal, sublingual, intraocular and transdermal. If a medicine intended for administration by one route is given by a different route, then it can cause serious harm. Medicines administration by injection or infusion is complicated, and there are many opportunities for error (Taxis & Barber, 2003), (McDowell et al, 2010).

1.1.4 Most medication errors cause little or no harm, but they demonstrate failures in the system that do or have the potential to cause fatal errors, and so need to be corrected to protect patients. The impact of medication errors, irrespective of harm, carry human costs for the patient, their family and friends, and for the professionals concerned.

1.1.5 A single failure in the system on its own will very rarely lead to a medication error. The system usually breaks down at several points in the chain of prescribing, dispensing and administration of the medicine (Medicines and Healthcare products Regulatory Agency, 2001). The report To Err is Human (Institute of Medicine, 2000) highlighted medication error as the most frequent failure in care causing injury and death. Multiple interventions to address the frequency and impact of medication errors have already been developed, yet their implementation is variable.

1.1.6 In 2001, the Department of Health (DoH) publication Building a Safer NHS for Patients (Department of Health, 2001) set out in more detail the Government’s plans for improving patient safety. This included an aspiration to reduce by 40% the number of serious errors in the use of prescribed medications. The National Patient Safety Agency, established in 2001, was responsible for improving the safety and quality of patient care through reporting, analysing, and disseminating the lessons of adverse events and ‘near misses’ involving NHS patients.

1.1.7 In 2004 a DoH report on medication safety was published (Department of Health, 2004). It described how the Government had established a clear agenda for improving patient safety in the NHS in England. This report aimed for a 40% reduction in medication errors, however it was not clear how this reduction would be measured given the prior intention to increase reporting of medication errors. Even on 23 March 2018 the Secretary of State for Health and Social Care, when speaking to the BBC, said, “We are seeing four to five deaths every single day because of errors in prescription or dispensing or the monitoring of medications.”

1.1.8 A research study published in 2013 comprised a systematic review and appraisal of empirical evidence relating to the causes of medication administration errors in hospital settings (Keers et al, 2013). The central tenet was that by understanding the causes of these errors, the most appropriate interventions could be designed and implemented to minimise their occurrence. The authors applied Reason’s model of accident causation to medication errors in hospitals (Reason, 2000) (Figure 1).
1.1.9 The World Health Organization (WHO) aims to co-ordinate, disseminate and accelerate improvements in patient safety worldwide. In March 2017, WHO announced its 3rd Global Safety Challenge – Medication Without Harm (World Health Organization, 2017). Medication Without Harm aims to reduce severe avoidable medication-related harm by 50%, globally in the next five years. This will be achieved by encouraging countries and key stakeholders to focus on early action priorities as well as developmental programmes to improve practice and health systems. The WHO report does not give any clarity on how this will be funded or evaluated.

1.1.10 The WHO launch report referred to the fact that errors can occur at different stages of the medication use process. It also contains the statement: ‘Medication errors occur when weak medication systems and/or human factors such as fatigue, poor environmental conditions or staffing shortages affect prescribing, transcribing, dispensing, administration and monitoring practices, which can then result in severe harm, disability and even death.’

1.1.11 In support of the WHO campaign, the Department of Health and Social Care commissioned a review of the evidence base on medication errors in England to assess the extent and scale of medication error. In September 2017 the Short Life Working Group (SLWG) was established. The purpose of this group was to advise on the scope of a programme to improve safety in the use of medicines, including how to reduce medication errors and establish the best way to measure progress.

1.1.12 The objectives of the group were (Department of Health and Social Care, 2018):

- in the context of the WHO Global Patient Safety Challenge Medication Without Harm, advise on the overall strategy and programme required to drive improvement in medicines safety, drawing on work underway across NHS England, NHS Improvement, the Care Quality Commission, the Medicines and Healthcare products Regulatory Agency and in the NHS and academia

- identify those areas in which efforts need to be targeted in the short, medium and long term

- provide clinical and academic expertise and advice on the current barriers and issues in medicines safety, and how these can be overcome

- advise on the best ways to measure medication errors and medication safety.
1.1.13 The SLWG considered the roles of both health professionals and patients, and particularly considered high-risk groups of patients, high-risk medications, and high-risk situations. The SLWG discussed the use of technology and how the industry can improve safe use of medicines.

1.1.14 Between September and December 2017, the SLWG met four times. It highlighted key recommendations and 15 priority areas for improvement in medicines safety (Department of Health and Social Care, 2018).

1.2 Prevalence of medication error

1.2.1 Research published in February 2018 (Elliott et al, 2018) estimated that 237 million medication errors occur at some point in the medication process in England per year. While this is a large number, 72% have little or no potential for harm. The researchers estimated that 66 million potentially significant errors occur per year.

1.2.2 The research included two systematic reviews, one on the incidence and prevalence of medication errors, and the other on the costs of health burden associated with errors. Additionally, economic modelling estimated the number of errors occurring in the NHS in England each year, their costs and health consequences.

1.3 Never Events

1.3.1 Never Events are defined as ‘Serious Incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers’ (NHS Improvement, 2018a).

1.3.2 Administration of medication via a wrong route is a Never Event if the patient is given one of the following:

- intravenous chemotherapy by the intrathecal\(^5\) route
- oral/enteral medication or feed/flush by any parenteral\(^6\) route
- intravenous administration of an epidural\(^7\) medication that was not intended to be administered by the intravenous route (see Never Event framework for further clarification (NHS Improvement, 2018a)).

1.4 Midazolam

1.4.1 Midazolam is in a class of medicines called benzodiazepines. Midazolam is classified as a schedule 3 controlled drug and is exempt from the requirements relating to safe custody. Legally, midazolam is not required to be stored in a controlled medication cabinet.

1.4.2 A rapid response patient safety alert was issued in 2008 that restricted the use of concentrated midazolam injections (National Patient Safety Agency, 2008).

1.4.3 Midazolam is widely used for conscious sedation. It is given to children (and adults) before medical procedures or before anaesthesia for surgery to make them sleepy, relieve anxiety, and prevent any memory of the event. Intravenous midazolam should be given slowly and in small quantities until it has the desired effect. There is not a licensed preparation of oral midazolam for conscious sedation in the UK (British National Formulary for Children & National Institute for Health and Care Excellence, 2018), (DailyMed, 2018), (NHS Business Services Authority, 2018). Therefore, the use of the licensed midazolam preparation Buccolam\(^8\) (for seizures) would be ‘off-label’ if used for conscious sedation.

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\(^5\) Intrathecal administration is a route of administration for medicines via an injection into the spinal canal, or into the subarachnoid space.

\(^6\) ‘Parenteral’ means any route that does not come through the digestive system, for example medications that are injected in to the veins, skin or muscle.

\(^7\) An epidural is an injection of medication into the space around the spinal cord known as the epidural space to provide temporary or prolonged relief from pain or inflammation.
2 SETTING THE LEGISLATIVE FRAMEWORK AND REGULATORY CONTEXT

2.1 National and professional guidance

2.1.1 The medicines process is governed by medicines and pharmacy legislation and professional standards. Many professional groups are involved in the complex tasks of medicines management and professional standards and guidance including prescribing, order communication, product labelling, packaging, nomenclature (naming of medicines), compounding, dispensing, distribution, administration, education, monitoring and use.

2.1.2 Figure 2 has been adapted, with permission, from the Royal Pharmaceutical Society, to help visualise where standards and guidance from professional bodies sit in relation to relevant legal frameworks and core standards that are required by ‘systems’ regulators, the professional regulators and for controlled drugs, the Home Office.

2.2 Legislation

2.2.1 The sale and supply of medicines is governed by the Medicines Act 1968 and the main domestic legislation for medicines in the UK is the Human Medicines Regulations 2012 (legislation.gov.uk, 1968).

2.2.2 The Medicines Act 1968 is up to date with all changes known to be in force on or before 18 January 2019 (legislation.gov.uk, 2019). Other relevant regulation includes:

- Misuse of Drugs Act 1971 (legislation.gov.uk, 1971) (includes the management of controlled drugs)
- Prescription Only Medicines (Human Use) Order 1997 (legislation.gov.uk, 1997)

2.2.3 The Medicines and Healthcare products Regulatory Agency (MHRA) (Medicines and Healthcare products Regulatory Agency, 2018) regulates medicines, medical devices and blood components for transfusion in the UK. The MHRA is an executive agency of the Department of Health and Social Care in the United Kingdom and is responsible for ensuring that medicines and medical devices work and are acceptably safe.

2.3 Professional regulatory bodies

2.3.1 In addition to the regulators, there are also professional regulatory bodies that aim to ensure that proper standards are maintained by health and social care professionals and act when they are not. All health and social care professionals must meet the standards given in the code of conduct or code of practice for their profession.

2.3.2 A summary of each organisation can be found in Appendix B, with a description of its purpose and relevance to the investigation.

2.4 Non-regulatory professional bodies

2.4.1 In addition to the regulatory bodies, there are other non-regulatory professional bodies that set standards relevant to the investigation.

2.4.2 These have been summarised in Appendix C, with a description of their purpose and relevance to the investigation.
3 THE REFERENCE INCIDENT

3.1 The incident

3.1.1 A nine-year-old child was admitted to hospital for an elective renal biopsy, a procedure in which a tiny piece (sample) of kidney is removed from the body. The procedure had been planned in advance. The patient was admitted on the day of the procedure to a day-case ward and the biopsy was to be performed in a side room on the ward. The patient’s mother was present and gave consent for the procedure. Preparations were made for the renal biopsy, which included the insertion of a cannula.

3.1.2 The procedure was to be carried out under conscious sedation. This was to ensure that the patient was as comfortable as possible during the procedure, without the requirement for a general anaesthetic. The medication was prescribed by a Specialty Trainee (ST1-3) doctor in training for intravenous administration. The paper medication chart included the date, the medication name, ‘Midazolam’, above the word midazolam were written the words ‘max dose 10 mg’, the route was written as ‘IV’. Underneath was written the medication ‘Flumazenil’. Directly underneath was written ‘10 micrograms/kg max 200 micrograms rpt @ 1 min intervals max 1 mg’. The route was written as IV.

3.1.3 A nurse prepared the medication in the treatment room with the prescribing doctor who had the paper medication chart. The nurse used a bottle of oral midazolam and prepared the medication using an oral syringe thinking the prescription was for oral medication. The concentration of the oral medication was midazolam (Amsed®) 2.5 mg/ml oral liquid (100 ml). The IV concentration of midazolam was 1 mg/ml.

3.1.4 The plunger of the syringe was purple, and the syringe was labelled ‘enteral’. Purple coloured or purple barrel syringes are intended for oral or enteral (for example nasogastric, jejunal) administration, that is administration into the gastric system rather than for injection use.

3.1.5 The prescribing doctor and nurse checked the medication. This two-person checking process (see paragraph 5.11.16) did not warn the nurse that the doctor had prescribed the medication intravenously (for the medication to be administered via the cannula). In addition, the checking process did not alert the doctor that the nurse had prepared the medication with the intention of it being given orally using the enteral syringe.

3.1.6 The nurse who prepared the medication was not present in the side room in readiness for, or during, the procedure. The prescribing doctor entered the side room with the medication and handed the enteral syringe to a second, more senior doctor (an ST6-8 doctor in training) – the administering doctor – who clarified the prescribed dose of the medication. The administering doctor then attempted to administer the medication, via the intravenous route.

3.1.7 The enteral syringe would not connect to the cannula and therefore the administering doctor clarified with the prescribing doctor whether the medication in the purple syringe was the intravenous preparation. Having been told that the medication was the IV preparation, a request was made by the administering doctor to the prescribing doctor to decant the contents of the enteral syringe into a “normal” IV syringe (meaning a clear plastic syringe used for intravenous medication administration). The contents of the purple enteral syringe were then decanted into an IV syringe by the prescribing doctor.

3.1.8 The administering doctor used the IV syringe but stated (at interview) that it felt difficult to push the plunger of the syringe. After administering some of the medication, a small amount leaked on to her hand during this action. The liquid was sticky and smelled sweet; the administering doctor realised that something was wrong and flushed the cannula with a saline solution.

3.1.9 The administering doctor asked the prescribing doctor to find the nurse to clarify whether it was IV midazolam that had been prepared. The procedure was paused while this information was being sought. The nurse questioned why the doctor had an IV syringe

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8 A cannula is a thin tube inserted into the vein to administer medication into a vein.
9 Flumazenil is a medication that can be given to reverse the effects of the midazolam if required.
and the nurse stated, “I gave you oral, we need to stop”. The procedure was stopped.

3.1.10 Subsequently, a consultant informed the patient’s mother what had happened.

3.2 Impact on the child

3.2.1 The patient remained in hospital and was closely monitored for the next 24 hours; no adverse effects were observed. The following day the patient underwent the procedure under general anaesthetic and was later discharged with no known adverse effects from the inadvertent administration of oral midazolam into their vein.
4 INVOLVEMENT OF THE HEALTHCARE SAFETY INVESTIGATION BRANCH

4.1 Selecting the reference event

4.1.1 The HSIB reviewed and analysed the national reporting and learning dataset and medication error, and specifically wrong route error, was identified as having the potential for a safety investigation.

4.1.2 The Trust where the reference event occurred was contacted and preliminary data was gathered about the incident. An initial scoping investigation was launched to determine the learning potential for a national investigation.

4.2 Decision to investigate

4.2.1 Following the initial scoping investigation, the Chief Investigator authorised a full investigation as it met the following criterion:

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

4.2.2.1 There are multiple steps in the process of medication administration involving multiple healthcare professionals. These steps include the prescribing, dispensing, administering, and monitoring of medication. Medication errors very rarely happen as a result of an individual act; usually they are caused by a combination of several different steps within the process of prescribing, dispensing and administration of the medicine (Figure 1). The closer the error is to the administration step, the less likely it is to be intercepted (Ferner, 2000).

4.2.2.2 Although rare, death has been reported due to oral liquid medicine being administered in a vein (National Patient Safety Agency, 2007b), (Pennsylvania Patient Safety Authority, 2013). Other adverse outcomes include psychological harm and prolonged stays in hospital.

4.2.2.3 Studies of medication errors affecting infants, children, and adolescents have been published (Kaushal et al, 2001), (Ghaleb et al, 2010), and the magnitude of medication errors is just being understood (Neuspiel & Taylor, 2013). One parent described the emotional impact of a medication error on a child and its parents/guardians as considerable and that it created an atmosphere of fear around the use of NHS services in the future.

4.2.2.4 In addition to the potential physical, emotional and psychological harm, such errors incur a financial burden and can seriously damage a hospital’s reputation. The emotional impact on staff is significant when they are directly involved in a medical error (Waterman et al, 2007), (Elwahab & Doherty, 2014), (Seys et al, 2013).

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

4.2.3.1 Evidence from both research and national reporting systems demonstrates that wrong route medication incidents continue to occur, despite published guidance aimed at preventing them. A review of incidents reported nationally indicates that during an 18-month period between 1 April 2016 and 30 November 2017, there were 61 reports of wrong route medication errors across England, 36 of which involved oral medication being administered via the wrong route, including 25 cases of oral liquid medication being administered intravenously.

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

4.2.4.1 By reviewing the safety measures currently in place, an HSIB investigation will seek to understand why they do not ensure that medication is administered in the prescribed manner. The reference event provides an opportunity to look at the complexity of the medications process by applying a human factors perspective to aid learning. The wider HSIB investigation would also seek to identify best practice strategies and opportunities designed to reduce the risk of the event happening across the healthcare system with the attendant improvement to patient safety.
4.3 Investigation terms of reference

TERS OF REFERENCE

1 To examine the incident to understand the context and causal factors.
2 To undertake a review of similar incidents of inadvertent administration of an oral liquid medication intravenously to identify common factors.
3 To review the role of the ‘second checker’ in medication preparation and administration.
4 To examine and understand the role of human factors in inadvertent administration of oral liquid medication.

4.3.1 The investigation team did review the opportunities for technological intervention and this included observation of electronic prescribing systems, bar-coded medication administration and conversations with experts in this area. However, another HSIB investigation is focusing on electronic prescribing systems and bar-coded medication administration and therefore the findings obtained by this investigation team have been shared for inclusion in the Electronic Prescribing Medicines Administration Investigation report to prevent duplication.

4.4 Investigation process and methodology

4.4.1 The investigation used a range of methods including:

• Review of the patient’s records, and of policies, procedures and practice regarding medicines storage, prescribing, preparation, administration and monitoring of medication at the hospital where the reference event occurred.

• Observations of medicine storage, prescribing, preparation, administering, and monitoring at the hospital where the reference event occurred and in other acute hospitals.

• Interviews with the Medication Safety Officer, doctors and nurses at the reference event site and with multi-disciplinary staff at the locations visited.

• Interviews and personal communications with doctors, pharmacists, and nurses across England regarding medicines policy, process and safety alert understanding.

• Review of wrong route medication incidents reported on the national reporting system.

• Literature review.

• Review of electronic prescribing systems and observations of them in operation.

• Interviews and personal communications with national organisations and subject matter experts, both clinical and non-clinical, about wrong route medication events.

• Communication with international specialists regarding wrong route medication and implementation of closed-loop administration.

4.4.2 The introduction of purple oral/enteral syringes was an attempt to introduce design-based barriers (NHS Improvement, 2018a) in wrong route medication incidents, however there remains a reliance on human checks. In the reference case, the design-based barrier was bypassed by transferring the medication into an IV syringe. A human factors expert was therefore engaged to support the HSIB investigation.
5 FINDINGS AND ANALYSIS OF THE PATIENT’S MANAGEMENT IN RELATION TO NATIONAL GUIDANCE AND LOCAL POLICY

A review of national guidance and the local Trust’s policies was conducted to establish how these aligned with the actions taken during the reference event. Analysis of the contributory factors that led to the reference event identified a number of safety factors. These have been grouped under three key themes:

• Process for medicines storage, prescribing, preparation, administration and monitoring of use in relation to legislative, regulatory and professional policy and standards.

• Safety culture and priorities when implementing national and local safety standards, particularly in respect to workload and shift patterns, education and training.

• Integration of human factors into the procurement of medicines and the introduction and use of equipment for their administration.

5.1.1 Reference event

5.1.1.1 The Trust had local policies and procedures to guide staff in the safe use of medicines. The main operational policy was the medicines policy (Medicines Management Committee, 2017). This included sections for prescribing, dispensing and supply, storage and security, administration and disposal of medicines. The medicines policy consists of a core operational policy and several additional supporting policies on more specific topics.

5.1.1.2 The overarching purpose of the medicines policy is to ensure that staff involved with any aspect of medicines management are aware of their responsibilities. It is based on relevant legislation and good practice so that:

• staff know how medicines are to be handled

• legislation and good practice are adhered to

• risks associated with the incorrect handling of medicines are reduced to a minimum.

5.1.1.3 An additional 16 supporting policies exist, including an injectable medicines policy and a controlled drugs policy. The investigation team was able to confirm that the local policies reflect national standards and contained relevant references to the legislative, regulatory and professional standards as appropriate.

5.1.1.4 If the local policy had been understood and followed the incident might not have happened. However, the ability to read, digest and comply with the local policies is confounded by several specific factors which are discussed later in this report in section 5.1.3.

5.1.1.5 The investigation team identified deviations from local policy and national standards in relation to medicines storage, prescribing, preparation, administration and monitoring of use.

5.1.1.6 Storage of midazolam

Midazolam is in a class of medications called benzodiazepines. The Misuse of Drugs Regulations 2001 divide controlled drugs (CD) into five schedules corresponding to their therapeutic usefulness and misuse potential (legislation.gov.uk, 2006). Midazolam is classified as a Schedule 3 controlled drug and is exempt from the requirements relating to safe custody. Therefore, legally, midazolam is not required to be stored in a controlled medication cabinet.

5.1.1.7 In the reference event the intravenous and oral forms of midazolam were kept in the ward CD cupboard, on the same shelf (Figure 3).
FIG 3 STORAGE OF MIDAZOLAM

The oral midazolam solution (Amsed®) in the bottle in the foreground was stored next to a plastic tray containing a pack of ampoules of midazolam for intravenous injection.

5.1.8 During a visit to the treatment room where the medication was prepared, a Trust representative alerted the HSIB investigators to a typed sign that was stuck to the back of the CD cupboard. The sign was intended to raise awareness that ‘...there are 2 strengths of Midazolam...’. ‘IV’ (meaning intravenous) had been handwritten on the sign next to the printed word ‘Midazolam’. The two strengths of midazolam specified on the sign were 10 mg/5 ml and 2 mg/ml (Figure 4).

FIG 4 PRINTED SIGN DISPLAYED IN CD CUPBOARD

The sign was misleading and inaccurate; the addition of the handwritten ‘IV’ suggested that only intravenous preparations of the drug were kept in the cupboard, whereas oral midazolam was stored in a bottle in addition to ampoules of IV midazolam. It also did not correlate with the strengths available at the time of the reference event; the strength of the IV midazolam was 1 mg/ml and the oral preparation was midazolam (Amsed®) 2.5 mg/ml oral liquid (100 ml). However, there was no evidence that the sign was referred to during the incident and the Trust has subsequently removed it from the CD cabinet and reviewed its storage arrangements.

Safety action: The Trust where the reference event occurred removed an inaccurate notice affixed to the inside of a controlled drugs cupboard and reviewed its storage arrangements.

- Prescribing of midazolam

5.1.10 A prescription in hospital is a ‘patient specific direction’. It contains detailed instructions on which medicinal product should be given to whom, in which formulation and dose, by which route, when, how frequently and for how long.

5.1.11 Midazolam was the sedative used at the Trust for conscious sedation during renal biopsy procedures. For conscious sedation prior to diagnostic or surgical intervention midazolam can be administered intravenously. The dose must be individualised and titrated and should not be administered by rapid or single bolus injection. The onset of sedation may vary individually depending on the physical status of the patient and the detailed circumstances of dosing (for example, speed of administration, amount of dose). If necessary, subsequent doses may be administered according to the individual need. The onset of action is about two minutes after the injection. Maximum effect is obtained in about five to 10 minutes (Accord Healthcare Limited, 2018).

5.1.12 The child involved in the reference event was nine-years-old and weighed 34 kilograms. The recommended prescribing dose for IV conscious sedation for a child between six and 11 years of age is (British National Formulary for Children & National Institute for Health and Care Excellence, 2018):

- initial dose: 25–50 micrograms/kg (or 0.025–0.05 mg/kg)
- a total dose of up to 0.4 mg/kg to a maximum of 10 mg may be necessary.

In the child’s case, 34 x 0.4 = 13.2 mg, so maximum dose = 10 mg.
The reference event site did not have an electronic prescribing system; prescribing of all drugs was paper-based. The prescription included the medication name (midazolam). The dose was not specified although a maximum dose of 10 mg was written above the medication name. The route was recorded IV, as per the child’s medication chart (Figure 5).

The prescribing doctor described the day-case ward as “chaotic” and she recalled going to the in-patient ward to write the prescription as she wanted “peace and quiet”.

Preparation of midazolam

The prescribing doctor was unfamiliar with the day-case ward and asked a nurse for help to prepare the prescribed midazolam. The nurse was busy. Some time elapsed before the prescribing doctor asked again for help (approximately 15 minutes). During this time the prescribing doctor had gone to a different ward which he had worked on, to obtain flumazenil (a medication that reverses the effects of midazolam if there is a problem) as he believed the day-case ward did not have any.

The nurse and the prescribing doctor referred to the prescription chart to prepare the medication. The route on the chart is specified as IV. The nurse took out a multi-use bottle of oral midazolam from the ward CD cupboard believing that oral midazolam had been prescribed. The nurse recalled at interview holding up the bottle of oral midazolam solution. The prescribing doctor and the nurse verbally checked together the medication name, the expiry date and the dose based on weight per kilogram as per the British National Formulary for Children (BNFc). They did this check together in the treatment room.

The nurse drew 4 ml (10 mg) of clear fluid from the multi-use bottle into the syringe. The quantity was checked by both and the nurse handed the syringe to the doctor. The syringe was not labelled to give an indication of its contents.

The prescribing doctor did not detect or respond to the cue that an enteral syringe with a purple plunger was filled from a multi-use bottle rather than an ampoule and that the medication might not be for intravenous use (Figure 6).

Administration of midazolam

The nurse who prepared the midazolam with the prescribing doctor did not go with the doctor to the side room to check the prescription chart against the patient’s wrist band to confirm the identity of the patient. This was not challenged by the medical staff present in the side room.

In the side room, a more senior doctor in training, ST6-8 (the administering doctor), attempted to administer the contents of the purple syringe. The Trust’s Injectable...
Medicines Policy (Medicines Management Committee, 2016) states, ‘it is not acceptable for a registered practitioner to administer an injectable medicine that has been prepared by anyone else, unless they have been present throughout the whole of the preparation process. The administrator should be the first or second checker not just an observer’. However, the administering doctor had no involvement in either the preparation of the midazolam or the checking process.

5.1.21 The administering doctor could not connect the enteral syringe to the cannula (as they are incompatible). The administering doctor informed the investigation team that she asked for confirmation that the contents of the syringe was IV midazolam, “is this definitely IV?”, which she believed was confirmed. The administering doctor then requested the prescribing doctor to decant the midazolam in to a “normal” IV syringe.

5.1.22 The prescribing doctor decanted the contents of the purple syringe into an IV clear plastic Luer lock syringe (Figure 7).

5.1.23 This was initially attempted by connecting a needle to the enteral syringe. However, when this didn’t work, the transfer of the liquid was achieved by connecting the tip of each syringe together (Figure 8) and transferring from one to the other; this was described at interview as follows: “I just transferred it directly and it flowed straight in, it worked really well”.

5.1.24 A further attempt was made to administer the midazolam. The administering doctor described that, during the attempted administration, it felt “harder to push than usual” and she decided to administer half the amount she had intended to give the child. A small amount of the contents leaked onto her hand. She noticed her hands were sticky and realised from the smell that the medication might not be the IV preparation. She described at interview saying, “that’s just not right – the viscosity of the liquid”.

5.1.25 From the available evidence, it is concluded that approximately 1.5 ml (3.75 mg) of midazolam had been administered to the patient.

5.1.26 The administering doctor disconnected the syringe and flushed the cannula with 15-20 ml of saline.

5.1.27 The reference site investigation timeline was developed from meetings with key staff involved as soon as possible after the incident. At her meeting eight days after the event, the ST6-8 stated that she sent the ST1-3 to talk to with the nurse who had prepared the medication to clarify whether the medication was IV midazolam.
As soon as it became clear that an error had occurred, the nurse who had prepared the oral midazolam with the prescribing doctor notified the nurse in charge and the procedure was stopped.

5.1.2 National review of similar incidents

5.1.2.1 The inadvertent intravenous administration of oral medications, while rarely reported, has contributed to serious patient harm and death (National Patient Safety Agency, 2007b), (Pennsylvania Patient Safety Authority, 2013).

5.1.2.2 In 2007, the National Patient Safety Agency (NPSA) published a report detailing medication errors (National Patient Safety Agency, 2007a). It noted that in the 18-month period between January 2005 and June 2006 there were 59,802 reports relating to medication errors.

5.1.2.3 The investigation team reviewed data from the National Reporting and Learning System (NRLS) reports of medication incidents occurring between 1 April 2013 and 31 March 2018 if reported by 9 August 2018. The search included incidents from England and Wales. The search of the NRLS returned 1,048,594 medication incidents, 88% of which were "no harm" incidents. Table 1 shows the number of medication incidents reported to the NRLS has increased year on year. Over this period, reporting overall to the NRLS has also increased (NHS Improvement, 2018b), as has the number of organisations reporting, including community pharmacies.

### Table 1: Number of Incidents Reported to NRLS by Sub-Type of Incident by Financial Year

<table>
<thead>
<tr>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td>45,146</td>
<td>45,838</td>
<td>46,941</td>
<td>49,405</td>
<td>52,760</td>
<td>240,090</td>
</tr>
<tr>
<td>Omitted medicine/ingredient</td>
<td>33,731</td>
<td>38,333</td>
<td>42,357</td>
<td>44,546</td>
<td>45,690</td>
<td>204,657</td>
</tr>
<tr>
<td>Wrong/unclear dose or strength</td>
<td>23,989</td>
<td>22,610</td>
<td>24,624</td>
<td>27,861</td>
<td>29,713</td>
<td>128,797</td>
</tr>
<tr>
<td>Wrong medication/medicine</td>
<td>16,635</td>
<td>16,666</td>
<td>17,372</td>
<td>19,475</td>
<td>20,734</td>
<td>90,882</td>
</tr>
<tr>
<td>Wrong frequency</td>
<td>13,187</td>
<td>14,086</td>
<td>16,309</td>
<td>17,822</td>
<td>17,472</td>
<td>78,876</td>
</tr>
<tr>
<td>Wrong quantity</td>
<td>11,671</td>
<td>12,011</td>
<td>12,657</td>
<td>13,881</td>
<td>13,928</td>
<td>64,148</td>
</tr>
<tr>
<td>Mismatching between patient and medicine</td>
<td>7,838</td>
<td>7,896</td>
<td>9,069</td>
<td>10,270</td>
<td>9,553</td>
<td>44,626</td>
</tr>
<tr>
<td>Wrong formulation</td>
<td>4,805</td>
<td>4,568</td>
<td>5,086</td>
<td>6,186</td>
<td>6,514</td>
<td>27,159</td>
</tr>
<tr>
<td>Wrong storage</td>
<td>3,494</td>
<td>4,089</td>
<td>4,657</td>
<td>5,487</td>
<td>5,930</td>
<td>23,657</td>
</tr>
<tr>
<td>Unknown</td>
<td>3,832</td>
<td>3,596</td>
<td>4,451</td>
<td>4,199</td>
<td>4,053</td>
<td>20,131</td>
</tr>
<tr>
<td>Contra-indication to the use of the medicine in relation to medications or conditions</td>
<td>2,625</td>
<td>3,110</td>
<td>4,009</td>
<td>4,538</td>
<td>5,265</td>
<td>19,547</td>
</tr>
<tr>
<td>Wrong/omitted/passed expiry date</td>
<td>2,955</td>
<td>3,321</td>
<td>4,047</td>
<td>4,275</td>
<td>4,122</td>
<td>18,720</td>
</tr>
<tr>
<td>Patient allergic to treatment</td>
<td>3,052</td>
<td>3,304</td>
<td>3,527</td>
<td>3,611</td>
<td>3,403</td>
<td>16,897</td>
</tr>
</tbody>
</table>
The wrong route medication incidents noted in Table 1 include incidents where the medication was given via the incorrect route, as described in the reference event, but also include incidents where the medication was given via the prescribed route, but that route was inappropriate for the patient. For example, an oral medicine prescribed for a patient who is ‘nil by mouth’. Of the incidents reported as ‘wrong route’, 88% were no harm incidents. This will include circumstances where the incident was prevented (that is, there was a risk a medication could have been given by the wrong route, but it was not).

Over the five-year period detailed above, wrong route error has the largest percentage increase in reporting. Figure 9 shows the increase in the number of incidents relating to wrong route medication over the last five years with the largest increase in the most recent year. Incidents relating to wrong route medication increased by 23% from 2016/17 to 2017/18.

A review of reported incidents on the Strategic Executive Information System (StEIS) as occurring in the period 1 April 2016 to 31 March 2018 was conducted. The data was accessed on 12 April 2018 at which point the search returned 64 Serious Incidents recorded as ‘Never Events’ and recorded as wrong route administration of medication. Figure 10 shows the majority of reported incidents of wrong route administration of medication occur when oral medicine is administered into a vein. The next largest group of reported Never Events occur when epidural medication is given intravenously followed by oral medicines given subcutaneously. (Note the definition of Never Events has changed during this period (NHS Improvement, 2018a) and only relates to specific types of wrong route administration).

### Table 1: Reported incident sub-category

<table>
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<tr>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong/transposed/omitted medicine label</td>
<td>2,945</td>
<td>2,618</td>
<td>2,823</td>
<td>3,194</td>
<td>3,130</td>
<td>14,710</td>
</tr>
<tr>
<td>Wrong route</td>
<td>2,380</td>
<td>2,460</td>
<td>2,779</td>
<td>2,922</td>
<td>3,608</td>
<td>14,149</td>
</tr>
<tr>
<td>Adverse medication reaction (when used as intended)</td>
<td>1,765</td>
<td>1,994</td>
<td>2,582</td>
<td>3,181</td>
<td>2,989</td>
<td>12,511</td>
</tr>
<tr>
<td>Wrong/omitted verbal patient directions</td>
<td>417</td>
<td>845</td>
<td>1,002</td>
<td>1,140</td>
<td>1,183</td>
<td>4,587</td>
</tr>
<tr>
<td>Wrong/omitted patient information leaflet</td>
<td>266</td>
<td>279</td>
<td>326</td>
<td>283</td>
<td>278</td>
<td>1,432</td>
</tr>
<tr>
<td>Unknown</td>
<td>0</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Total number of reported incidents</td>
<td>184,294</td>
<td>191,525</td>
<td>209,288</td>
<td>227,466</td>
<td>236,021</td>
<td>1,048,594</td>
</tr>
</tbody>
</table>
5.1.2.7 In approximately 40% of the 31 incidents where oral medication was administered into a vein, the medication was drawn up into a clear IV syringe.

5.1.2.8 There were three instances when oral medication was drawn up into an oral, purple syringe but then decanted into an IV syringe.

5.1.2.9 Table 2 shows the breakdown of the reported incidents based on HSIB’s review of free text of these 31 reports.

**TABLE 2**

<table>
<thead>
<tr>
<th>HOW INCIDENT OCCURRED</th>
<th>NUMBER OF INCIDENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drawn up in IV syringe</td>
<td>14</td>
</tr>
<tr>
<td>Not stated/unknown</td>
<td>7</td>
</tr>
<tr>
<td>Purple syringe decanted to IV syringe</td>
<td>3</td>
</tr>
<tr>
<td>Used as flush on a different patient</td>
<td>2</td>
</tr>
<tr>
<td>No purple syringe availability</td>
<td>2</td>
</tr>
<tr>
<td>Oral via syringe driver</td>
<td>1</td>
</tr>
<tr>
<td>Water through PICC not NG</td>
<td>1</td>
</tr>
<tr>
<td>Syringe confusion</td>
<td>1</td>
</tr>
<tr>
<td>Grand Total</td>
<td>31</td>
</tr>
</tbody>
</table>

5.1.2.10 Further detail was obtained from other organisations that had reported inadvertent administration of an oral liquid medicine via the wrong route.

5.1.2.11 Analysis of all the available data indicates that:

- Decanting medication from an enteral syringe into an IV syringe is not an isolated event.
- The availability of oral/enteral syringes can be limited and therefore IV syringes may be used instead. This erodes the distinction between the different functions of the two syringe types.
- In some instances, IV syringes have been used when oral/enteral syringes have been available.
- Labelling of syringes is inconsistent.

- There is inconsistency in the implementation of national safety standards.
- Fatigue, interruptions, distractions and multi-tasking in the medicines administration process are common.
- Knowledge-based errors are common among healthcare professionals involved in the prescribing, dispensing, administering, and monitoring of medication; for example, staff not knowing enough about the medicine they are administering, the administration devices they are using (syringe type, infusion pump, and so on), or about the patients themselves.
- Wrong route error is more common in medications where different medicinal forms of the same medicine exist (for example, oral, intravenous and rectal forms of a single medication such as paracetamol and morphine).
- Emergencies and goodwill to support colleagues may lead to staff carrying out unfamiliar tasks.

5.1.2.12 The investigation team reviewed the recommendations of other Serious Incident investigations reported on StEIS and noted that many of the solutions for improvement at local level focused on individuals. Examples of actions included: reminding people of the ‘5Rs’ (five rights of medication administration), adding additional warning labels, developing local posters raising awareness of product similarities and suggesting to staff to ‘be careful’ and to ‘do this’ or ‘do not do that’.

5.1.2.13 ‘Failure to follow Trust policy’ was a common error cited in these investigations from which flowed remedial measures such as competency assessments, educational campaigns, amendments to policies and procedures and directing staff to follow policy.

5.1.2.14 The investigation team used the above findings to provide focus during its observations of practice. Observation of practice has been used in two ways during the investigation. One method was to witness a reconstruction of the reference event and subsequent simulation of what should happen in the process according to
the Trust’s policy. The second method was through direct observation of staff in their everyday work.

5.1.2.15 The purpose of the direct observation of staff was to better understand the process for medicines storage, prescribing, preparation, administration and monitoring. The investigation had identified a mis-match in terms of how staff describe what should happen in relation to formal procedures and guidelines, (often referred to as ‘work as imagined’) and what happens on the ground, (often referred to as the ‘work as done’), which, with its workarounds and compromises, is very different (European Organisation for the Safety of Air Navigation, 2017).

5.1.2.16 During the observations, the investigation team took note of the environment staff worked in and how this impacted on patient safety. Several intravenous and oral medication administrations were observed and the process for storage, prescribing, preparation, administration, and monitoring of the medicines used was scrutinised.

- **Storage**

5.1.2.17 One source of medication errors is the storage of vials that look similar or have similar sounding names, or medication of differing concentrations, in the same area (Institute for Safer Medicines Practice, 2018). An incorrect look-alike medication can be given in error and potentially cause harm. This was noted in the reference event in terms of the storage of the midazolam and during observations.

5.1.2.18 The storage of medicines and consumables was observed by the investigation team as varied and in some cases the environments were cramped with multiple other distractions, for example a CD cupboard above the ward computer and in the space used for record keeping (see Figure 11, Figure 12, Figure 13 and Figure 14).

5.1.2.19 During one visit, a charge nurse commented to the investigation team that the red storage boxes for items such as water, needles and saline are moved around multiple times. “You come in one day and it’s in one place and the next day it might be on the opposite side of the room.”

5.1.2.20 The investigation noted during an observation that the space for preparing medicines was cramped when two nurses were trying to prepare drugs at the same time in a small area.

5.1.2.21 Cramped working conditions were again evident when investigators visited another ward where there was one treatment room between two wards and staff must leave a ward to prepare medications.
5.1.2.22 Observation of prescribing was limited although the investigators witnessed incomplete prescribing on paper medication charts. In addition, medicines safety experts shared their concerns about paper-based and electronic prescribing. An assessment of the advantages (and unintended consequences) of electronic prescribing systems was undertaken, however, another HSIB investigation is focusing on electronic prescribing systems and therefore the findings obtained by this investigation team have been shared for inclusion in the Electronic Prescribing Medicines Administration Investigation report to prevent duplication.

5.1.2.23 Staff with prescribing responsibilities stated that one of their concerns was not having time and space to think and concentrate when prescribing medication, an issue also identified in the reference event. Figures 14 and 15 illustrate an example where space is limited, and administrative tasks and prescribing are undertaken in the same area.

5.1.2.24 In the reference event, prescribing was undertaken by a Specialty Trainee (ST1-3) doctor in training. Prescribing is a fundamental part of the work of doctors in training, who write and review many prescriptions each day (British Pharmacological Society, 2016).

5.1.2.25 Prescribing is a complex task requiring knowledge of medicines and the diseases they are used to treat, careful judgement of risks and benefits of treatment, and attention to detail. As well as offering the potential for improving health, it is an activity associated with potential hazards; a study sponsored by the General Medical Council (GMC) found that on average 9% of hospital prescriptions contain errors (Dornan et al, 2009). Other research suggests that that is the area of the foundation doctor role that new graduates find the most challenging (General Medical Council, 2014).
5.1.2.26 The Prescribing Safety Assessment is an online assessment of competency in the safe and effective use of medicines, developed by the British Pharmacological Society and the Medical Schools’ Council Assessment (Medical Schools’ Council Assessment & British Pharmacological Society, 2016). It is taken by final-year medical students and Foundation Year 1 doctors. It was originally piloted in 2012 and 2013, before being fully implemented in 2014. The Prescribing Safety Assessment allows candidates to demonstrate their competencies in relation to the safe and effective use of medicines. Medical and foundation school doctors register for the Prescribing Safety Assessment online. Once logged in to the system, students have access to practice papers and further information on the Prescribing Safety Assessment.

5.1.2.27 In addition, to support all prescribers to prescribe effectively, a single prescribing competency framework was published by the National Prescribing Centre/National Institute for Health and Clinical Excellence (NICE) in 2012. The Royal Pharmaceutical Society is responsible for updating the competency framework in collaboration with patients and the other prescribing professions, many of whose professional bodies have endorsed this updated framework. It was last updated in July 2016 with a review scheduled in 2020 (Royal Pharmaceutical Society, 2016a).

5.1.2.28 The GMC has defined prescribing competencies required of new medical school graduates in its document Outcomes for Graduates 2018 (General Medical Council, 2018). On page 20 it states: ‘Newly qualified doctors must be able to prescribe medications safely, appropriately, effectively and economically and be aware of the common causes and consequences of prescribing errors’.

5.1.2.29 As part of the outcome of the report of the Short Life Working Group (SLWG) (Department of Health and Social Care, 2018) the NHS Specialist Pharmacy Service was tasked with building an online repository of examples of good medicine safety practice.

5.1.2.30 Similarly, a set of prescribing indicators has been developed by NHS Digital and NHS Business Services Authority as part of a programme of work to reduce medication error and promote safer use of medicines, including prescribing, dispensing, administration and monitoring (Health and Social Care Information Centre & NHS Business Services Authority, 2018). The purpose of this is to develop indicators that quantify prescribing practice that has a higher risk of harm and is associated with admission to hospital with the aim of promoting safer prescribing and reducing medication error.

• Preparation

5.1.2.31 The search conducted on the national reporting systems (see section 5.1.2) highlighted the types of oral medications involved in wrong route errors. These included oral morphine solution, dispersible aspirin, sodium valproate and oxycodone. Other medicines had been crushed and administered intravenously, including sodium bicarbonate, amitriptyline, lansoprazole and potassium chloride. Additionally, there were reported incidents of medications being prescribed as IV and the IV preparation being administered orally, for example, cyclizine, ondansetron and potassium.

5.1.2.32 Oramorph® (oral liquid morphine) was given intravenously and represented 17 of the 31 oral liquid medications inadvertently given via the vein. It has also been inadvertently given subcutaneously.

5.1.2.33 The Royal College of Emergency Medicine reported in 2017 that in a two-year period, 80% of Never Events that occurred in emergency departments related to two categories of events (Royal College of Emergency Medicine, 2017a), one of which was the inadvertent intravenous administration of oral morphine solution, which accounted for 30%. The other was unrelated to medication. The Royal College of Emergency Medicine produced a safety alert in July 2017 (Royal College of Emergency Medicine, 2017b). The alert included actions to mitigate the risk:

• ‘ONLY USE ORAL SYRINGES TO DRAW UP ORAL MEDICATIONS (this is the main mitigation) – these do NOT FIT onto IV cannulas.

• Only prescribe one route of administration.
Keep oral syringes near to storage of oral medications.

The person who prepares the medication should administer it.

5.1.2.34 In the reference event, the nurse was busy resulting in a delay in being able to prepare the prescribed midazolam with the doctor. The prescribing doctor described the day-case ward as “chaotic” and this was then described as “…noisy, people running around, induction tours [new junior doctors’ induction day]...”.

5.1.2.35 The investigation team observed healthcare professionals preparing medications, with a focus on how the process was affected by interruptions and how and when medication checks are performed and documented. The majority of IV medication administrations were observed between midday and 14:00 hours. There was no observation of a one-off or urgent prescription or of the administration of a controlled drug.

5.1.2.36 Multiple interruptions during medicines preparation were observed. Interruptions to the workflow of healthcare professionals are very common (Healey et al, 2007) and not isolated to the reference event. Indeed, the investigation team witnessed nursing staff carrying out a range of simultaneous tasks including the preparation of medication, attempting to complete medicines rounds for their named patients, answering bleeps, answering on-the-spot queries from other members of the multi-disciplinary team, answering the ward telephone and supervising more junior staff. According to the Institute for Safe Medication Practices, a break in mental concentration can subsequently lead to oral medication being unintentionally administered through the IV route (Institute for Safer Medication Practices, 2012).

5.1.2.37 Distractions can be a contributing factor in medication errors (Reason, 2000). According to Agyemang and White (Agyemang & While, 2010), distractions and interruptions are the most frequent causes of medication errors. There has been research to suggest that the likeliness of a nurse accepting the interruption is based on a hierarchical relationship and how ‘important’ the nurse sees the person interrupting him/her (Flanders & Clark, 2010). Other evidence also noted that the more a nurse is interrupted when conducting a medicines round, the greater the number and severity of errors, because of constant goal switching and the demands on attention exceeding capacity (Westbrook et al, 2010).

5.1.2.38 Summaries of the observations and the distractions and interruptions are highlighted below:

One patient requiring intravenous administration of three IV medications.

The Ward Sister started the preparation process — she took the prescription chart into the treatment room with her, obtained three separate medication vials and put them in a blue tray. She was then asked to make a phone call. She sat at the nurses’ station and phoned another ward to give handover for the patient requiring medications. She was on the phone for 10 - 15 minutes (good handover heard). Whilst she was on the phone, another nurse took her medication keys to get a medication out of the treatment room. She couldn’t find the medication and so went off looking for it elsewhere, taking the keys with her. Whilst the nurse was on the phone, she passed the tray and the medication chart to the nurse who had the medication keys and asked them to check the contents of the tray against the prescription chart. Because she was still on the phone, the nurse in charge (NIC) (a third nurse) took the tray to prepare the medications. The second nurse went and got the water for injection and syringes. The NIC put on gloves and got out more syringes and mixed two of the medications together and then added the water. She moved the third vial which was ranitidine into a white tray. She then took the blue tray to the patient and checked that the patient had an allergy band on and confirmed the allergies the patient had. She asked the patient for her date of birth. Then checked the details on the prescription chart with the wrist band. She flushed the patient’s cannula, gave the intravenous injection, and flushed the cannula again, talking to the patient throughout. She then said there was one more medication to follow. She went back to the trolley, discarded everything in the clinical waste and sharps bin and then prepared the next intravenous injection. She was interrupted by a ward clerk from another ward who asked her for...
some soluble paracetamol as requested by the nurse in charge from their ward.

She stopped what she was doing to help and gave the ward clerk the soluble paracetamol. She then asked the matron passing by to check that the water for injection was in date as all of the other medications had been checked. She then went back to the same patient. She didn’t confirm the patient’s identity before administering the medication.

During administration of the medication, a sister and a porter were preparing the patient for transfer to another ward. The nurse administering the medication was not interrupted although the patient was being spoken to by other people.

The nurse removed her gloves and put them in a tray. She signed the medication chart for all three medicines. She emptied the tray, cleaned it and washed her hands.

5.1.2.39 The HSIB investigation team observed occasions where nurses were trying to save time by preparing medications for multiple patients. The observation notes when observing a nurse prepare the medications for two patients record: ‘Nurse retrieved all consumables for medications preparation e.g. medication, syringe, tray etc for both patients at the same time’.

5.1.2.40 During another observation, one patient required intravenous administration of three IV medications – Pabrinex®, terlipressin acetate and Phytomenadione (vitamin K).

Pabrinex® comes in two vials for one dose and two doses were needed therefore 4 vials, a vial for vitamin K and a vial for terlipressin. The nurse got out IVs and carried them in her hand. She got out a blue tray and put a 100 ml bag of sodium chloride in it. The patient’s medications were due at midday and the time was 13:00 hours. The nurse was six months post qualifying. She checked the sodium chloride bag size with two other nurses as she wasn’t sure if she had enough. A doctor interrupted her and asked how another patient was doing. She left the medications with two other nurses and went to check on the patient the doctor had enquired about. Meanwhile, the two remaining nurses started checking against the prescription chart. The two nurses confirmed the dose with a printed green book (possibly the internal guide?). They then completed a white label to stick to the sodium chloride bag but didn’t stick it on at that point in time. The second nurse helped get out equipment for example the syringes and giving set. She popped the tops off the Pabrinex® which was four vials. The second nurse had left at this point. She then drew the four vials into one syringe and injected the content of the syringe into the bag of normal saline. She then attached the label and signed it. She then attached the giving set and ran the solution to the end of the line. She then drew up the terlipressin and vitamin K in to the same syringe. She was interrupted by another nurse to say the porters were there to transfer her patient. She responded, “I am doing his IVs, they have to wait”. She then went to find the patient to administer the medications. The patient had left the ward for a cigarette and so another nurse was sent to go and get the patient to return to the ward. This was the last part of the observation. The nurse kept the medications with her whilst she waited for the patient to return. I did not observe anything after this point.

5.1.2.41 There were significant interruptions noted during HSIB’s observations of preparations and administrations. Comments from staff included:

“The physios want a handover when [the nurses] are doing their medication rounds in the mornings and I worry that I might be so distracted that I give the same patient two lots of medication.”

“We are often interrupted by other nurses when they need their IVs checking and we are preparing or administering our own.”

5.1.2.42 The NHS publication Releasing time to care 2007 (NHS Institute for Innovation and Improvement, 2008) advocated the wearing of visual signals during the medication round in the form of brightly coloured tabards, vests or sashes, to alert staff to the fact that nurses should not be interrupted. The suggestion that nurses might wear some form of clothing during a medication round to indicate that they should not be interrupted is not new (Kreckler et al, 2008). However, the introduction of wearing such visual cues was reported to be controversial (Beckford, 2011). A subject matter expert in the investigation also commented that there are unintended consequences of wearing a visual signal, for example the unwillingness by patients and other staff
to interrupt, even in clinical emergencies (personal communication, 10 February 2019). In addition, a study on nurses’ perceptions of wearing ‘do not disturb vests’ didn’t align with a nursing culture that values openness and availability for their patients, hence a lack of engagement (Federwisch & Adams, 2014).

5.1.2.43 Disposable red tabards embroidered front and back with ‘Medication round in progress, do not disturb’ and a checklist were introduced and published by the Royal College of Surgeons in Ireland (Uko-Udom, 2014). The purpose of donning a red tabard was to provide a visual cue to alert others that a nurse was doing a medication round, to reduce non-urgent interruptions during medication rounds, reduce the incidents of medication errors, enhance patient safety, save time and promote compliance with professional and national standards on medication management. The result from the nurses’ survey and verbal feedback on the project showed approval of the use of the tabard and checklist and that the measures improved efficiency.

5.1.2.44 Other research has supported the use of visual cues such as warning signs for silence in the medication areas (Thomas et al, 2017).

5.1.2.45 The reference event medicines policy states, ‘Under normal circumstances staff should not be interrupted during the preparation and administration of medicines. It is recommended that staff administering medicines in inpatient areas should wear a tabard denoting that a medicine round is in progress and they should not be disturbed’. Staff were not observed to be wearing a tabard when medicines were being prepared and administered.

5.1.2.46 The investigation heard from staff that had worked or were working in organisations where visible cues such as the tabard had been implemented. Staff reported to the investigation that clinical leadership is key to successful implementation of visible cues.

5.1.2.47 A consultant at the observational site visit informed the investigation team that “nurses should wear a red bib when doing medication rounds” and he commented “this would also be good for doctors doing TTOs [preparing the medication chart and prescribing the required medications for the patient to take out] as they are regularly interrupted”. The investigation team and human factors expert considered that this practice could be deemed as ‘work as imagined’ and not ‘as done’ because the wearing of red bibs by nurses was not observed.

5.1.2.48 During the reference event, staff stated they conducted a two-person checking process. The check was not independent. The check failed to highlight that a wrong formulation had been prepared compared with what was prescribed. With the benefit of hindsight, the prescribing doctor stated: “I completely didn’t twig it was a bottle and not a vial... I SHOULD have realised, oral is a brown bottle, injection is a clear vial”.

5.1.2.49 There appears to be ambiguity about what is meant by two-person checking (or a double check), something observed in academic literature (Hewitt et al, 2015).

5.1.2.50 Although it remains controversial, the importance of the role of two (or more) independent checks in improving safety is reflected in academic literature and was endorsed by a human factors expert. Much of the literature is focused on the impact of double checking on reducing medication errors.

5.1.2.51 The Nursing and Midwifery Council (NMC) Standards for Medicines Management (in use at the time of the reference event although now withdrawn) stated, ‘wherever possible, two registrants should check medication to be administered intravenously...’ (Nursing and Midwifery Council, 2007). In the reference event the nurse thought the medication was to be given orally despite the route being marked as IV. The check does not (usually) consider the formulation, which isn’t specified in the ‘Drug’ box on the chart. Collectively, the research highlights that there are limitations with two-person checking and it is far from infallible in preventing error (Alsulami et al, 2012). As one study described it, second checking requires that one fallible person monitor the work of another imperfect person (Tamuz & Harrison, 2006) and, as such, is subject to psychological...
phenomena such as biases, and ‘auto processing’, where the act of checking is given little active thought, and possible dilution of responsibility.

5.1.2.52 A human factors expert advised that the academic term for this action is ‘self-regulation’, a part of executive control that involves monitoring one’s actions in relation to one’s intentions (paying attention to what you are doing) (Banich, 2009). Executive control is considered a limited resource when it is used; it is used up and must be replenished. It is the reason why situations of fatigue and stress cause people to make mistakes – by making constant demands on attention, they deplete self-regulatory resources. In other words, there are all kinds of stressors that arise from different demands and situations but they all have the same effects on human performance.

5.1.2.53 Double checking is reported as having most value when the checks are conducted independently – that is, when the person who is checking must form an independent judgement without cues from the person doing the initial work or making the initial judgement (Grissinger, 2006). The reference event checking process was not independent.

5.1.2.54 The investigation team heard from people with roles in medicines safety and feedback was predominantly that second checking largely works in some practices, for example pharmacy processes, as it is considered an accuracy check – the intent is to look for errors. This would include independent double checks performed before the preparation of the medication (to check the right medication and delivery devices) and before the administration of the medication when the medication has been reconciled. However generally during medicines administration, the second check is seen as confirmation of accuracy.

5.1.2.55 During the observational visits, two-person checking was rarely seen to be independent. On one occasion, checks were done by three separate people. The continuous presence of the second checker was not always possible; this reinforces observations made in other literature (Evley et al, 2010).

5.1.2.56 The Institute for Safer Medicines Practice (ISMP) produced a list of high-alert medications (Institute for Safe Medication Practices, 2007) and midazolam features in this list. It was anticipated by the ISMP that organisations would use the list to determine which medications require special safeguards to reduce the risk of errors. The report suggested strategies that included limiting access to high-alert medications; using auxiliary labels and automated alerts; standardising the ordering, storage, preparation, and administration of these products; and employing redundancies such as automated or independent double checks when necessary. Contained within the report is the statement, ‘manual independent double-checks are not always the optimal error-reduction strategy and may not be practical for all of the medications on the list’.

5.1.2.57 A hospital Trust that uses an electronic prescribing system (EPS) shared its experience with the investigation. Its EPS is used in 90% of areas within the Trust. The EPS pharmacy team had integrated data analysts who developed a report showing the percentage of intravenous medications used on in-patient areas that were witnessed by two nurses. Some areas showed a particularly poor compliance so in line with their local Trust policy, they decided to investigate the cause for this.

5.1.2.58 Initially, prior to looking at the data, the ward leaders thought that the poor compliance with second checking was due to high bank and agency staff use. The report showed individual performance and performance by medication type. Bank, agency and new starters to the ward had a high percentage of compliance. It was experienced nurses using frequently given medications (such as paracetamol and amoxicillin) that contributed to poor ward performance.

5.1.2.59 The ward leaders consulted their staff to understand the reasons for non-compliance with Trust policy and NMC expectations. Feedback confirmed that the nurses felt that they were familiar with the medications most frequently administered and therefore didn’t need to conduct the checks.
Eighteen months later and following a targeted approach to the importance of second independent checks, compliance is consistently above 99% and individual performance is now reviewed by sisters and matrons at ward level. A reduction in medication errors was reported to have improved patient safety and reduced length of stay, providing a saving financially in bed days and claims against the Trust. This evidence suggests that, when consistently applied, double-checking works. One sister commented that "it was the easiest safety change management she had ever done that had an immediate positive impact for patient safety".

The new Royal Pharmaceutical Society (RPS) Professional Guidance on the Administration of Medicines in Healthcare Settings (Royal Pharmaceutical Society & Royal College of Nursing, 2019), which now supersedes the NMC standards for administration of medicines (Nursing and Midwifery Council, 2007), has been published. The guidance does not specify when or how two-person checking should be followed. It only states that ‘any calculations needed are double checked where practicable by a second person and uncertainties raised with the prescriber or a pharmacy professional’. The new guidance does not discuss a second independent check for intravenous medication. The only other statement that may relate to this is: ‘A risk assessment informs organisational policies/procedures for second signatories, witness requirements and delegating’. Given that local policies are based on national standards, the investigation team felt there remains a gap in terms of robust guidance on when and how independent second-person checking should occur.

During analysis of nationally reported incidents of inadvertent administration of oral drugs into a vein and when talking to staff, the investigation team established that enteral syringes are not always available in clinical areas, and this leads to parenteral syringes being used when preparing and administering oral medicines. In turn this practice increases the likelihood of, and is a common factor in, the inadvertent administration of oral liquid into a vein. This finding is also identified in published literature (Pennsylvania Patient Safety Authority, 2013).

The investigation team concluded that the deviations from policy relating to the administration of medication were not isolated to the reference event site. During interviews and conversations with staff, the investigation team ascertained that multiple factors contributed to the reference event. Many of the factors commonly affect the preparation of medication.

During the observational work it was noted that medication administration occurs during and throughout many other interventions. Examples include:

- doctors’ ward rounds taking place at the same time as medication administration
- lunches being given out
- cleaners passing through with trollies
- stores being left out and sorted at the same time.

An oral administration of painkillers was observed:

Nurse checked medication card against prescribed medications for time of day. Medications were put into a cup. A doctor interrupted the nurse and asked about the patient’s fluid challenge and asked specifically how much the patient had drunk so far today. They had a two-minute conversation about the patient over the medication trolley before the nurse closed the trolley and went to the patient with the medications. The doctor followed the nurse and asked a couple more questions and gave an instruction which the nurse said they had already done. The nurse checked the patient against the medication chart and asked for name, date of birth and allergies. Nurse noted the medication chart said allergy to ibuprofen but the patient did not have a red wristband on. The nurse signed the prescription chart once the medications were all administered. The nurse immediately came back and attached an allergy band to the patient’s wrist.

During HSIB’s observations of the administration process there were examples of medicines policy being followed. However, there were also examples of medicines policy not being followed. The impact of the prevailing environment and level of interruptions on the
wards meant that staff did not fully comply with local and national standards.

5.1.2.67 Lighting levels on the wards, particularly at night, can compromise patient safety during medicines administration. During one site visit, nurses stated that they were not able to see the medication packaging, the consumables, the prescription charts or patient wrist bands very well when the lights were dimmed. Lights are dimmed in this particular area in the evening before the administration of medicines is complete. There is a balance between respecting patients’ (and the matron’s) wishes for maintaining their sleep pattern and restfulness versus ensuring there is adequate lighting to safely prepare and administer medications. A nurse made the following comment to the investigation team: “The ward has a policy of lights off between 10–10:30 pm at night, I feel this makes me unsafe as I am genuinely still doing my IV medications, often finish by about 11 pm but since there is no treatment room to prepare the medications in, we have to do it in the corridor so we can’t see what we are doing. We need lights on to see what we are doing. It is fine to have the bay lights off”.

5.1.2.68 The nurse in the reference event case indicated at interview that her check of the medication process had utilised the “five rights of medicines administration” when presented with the request to prepare the patient’s medication. The five rights are referred to in the local Trust’s policy. The nurse confirmed that she checked the patient name on the medication chart (right patient), the medication prescribed (right medication), the dose against the weight of the patient in the British National Formulary for children (right dose), the route (right route) and the time (right time). Her mental picture fitted the five rights and there was no trigger for her that IV had been clearly prescribed on the paper chart.

5.1.2.69 Analysis of the nationally reported incidents suggested that when a medication error occurred during the administration of a medication, there was often a reference to staff not completing the five rights. Recommendations which highlight non-compliance with the five rights. The Vice President of the Institute for Health Improvement stated that the original intention of the five rights was that it should be accepted as a goal of the medication process and not the “be all and end all” of medication safety.

5.1.3 Analysis

5.1.3.1 The number of reported wrong route incidents relating to the inadvertent injection of oral liquid medications into a vein has increased, despite the introduction of oral syringes. The investigation team was unable to conclude whether safety alerts such as Patient Safety Alert 19 (National Patient Safety Agency, 2007b) have been effective as there had been no formal evaluation.

5.1.3.2 Sharing the outcome of learning from reported incidents among local health and social care providers can lead to better quality improvement initiatives and actions to minimise medication errors. NICE guidance on medicines optimisation (National Institute for Health and Care Excellence, 2015) and specifically, section 1.1 of this guideline, includes recommendations for systems for identifying, reporting and learning from medicines-related patient safety incidents, which should facilitate system improvement. Section 1.1.11 states that health and social care organisations and practitioners should ‘apply and share learning in the organisation and across the local health economy, including feedback on trends or significant incidents to support continuing professional development. This may be through a medicines safety officer, controlled drugs accountable officer or other medicines safety lead’. Discussions with people and a review of actions taken following wrong route medication errors, and specifically inadvertent administration of oral medication into the vein, suggest that learning is rarely shared beyond organisational boundaries. The investigation team was not aware of organisations hosting learning events from their Never Events of wrong route error.

5.1.3.3 A consistent approach to medicines policy development that links to national legislative, regulatory and professional standards and
is based on learning from medicines-related safety incidents may improve medicines safety. This accords with the NICE quality standard on medicines optimisation (National Institute for Health and Care Excellence, 2016a) and specifically Quality statement 3: Learning from medicines-related patient safety incidents (National Institute for Health and Care Excellence, 2016b).

5.1.3.4 The investigation team observed variation in local and national policy in relation to the process for safe administration of medicines, with individual trusts having multiple, often lengthy policy documents with inconsistent formatting. People told the investigation team that they rarely read the policies due to their length, number and complexity. Very few policies seen by the investigation team had a one-page summary document. In a mobile, non-static workforce, the ability to read, digest and comply with local policy is described by staff as “impossible”. A mixed-methods study of policy and practice across 16 hospitals in England concluded that deviation rates and procedural and documentation requirements varied considerably between hospital trusts. The findings revealed that some policies were onerous while others lacked policy in certain areas. Local policy and practice did not align. The authors suggested clearer evidence-based standardisation and local procedures that are contextually practical (Furniss et al, 2018).

5.1.3.5 The investigation team established that adherence to such policies is often examined only after an error has occurred. The outcome of local investigations into medication errors is often a requirement for staff to familiarise themselves with policy.

5.1.3.6 In 2014 a Patient Safety Alert, improving medication and error incident reporting and learning, (NHS England, 2014) was published. It refers to the role of the Medication Safety Officer (MSO) in improving medication error incident reporting and learning within healthcare provider organisations. One of the MSOs’ key roles is to promote the safe use of medicines across their organisations and be the main experts in this area. ‘In addition to improving the quality of reporting, the MSO will serve as the essential link between the identification and implementation of (local and national) medication safety initiatives and the daily operations to improve patient safety with the use of medicines.’ This included reference to assisting in development and review of medication-use policies and procedures. It has also not been possible to obtain evidence on the impact of the Patient Safety Alert on improving medication error incident reporting and learning (NHS England, 2014).

5.1.3.7 In 2016 Lord Carter set the scene for improving both efficiency and productivity across NHS acute hospitals (Department of Health, 2016). The review highlighted where unwarranted variation exists within the NHS and tasked organisations to examine themselves against agreed benchmarking metrics. The report suggested that organisations should ensure that their pharmacists and clinical pharmacy technicians spend more time on patient-facing medicines optimisation activities.

5.1.3.8 In May 2018 Lord Carter’s review published a second report, Mental health services, Community health services (Department of Health, 2018). On page 66 it states, ‘we were struck by the number of activities performed to meet medicines governance requirements that are effectively duplicated in each organisation, and the amount of time dedicated to these activities. Such activities include preparing and reviewing patient group directions, formulary management and medicines policies’. Recommendation 11 of this report included, ‘NHS England’s Specialist Pharmacy Services (SPS) and the regional medicines optimisation committees developing a national ‘do once’ system for organisational medicines governance, including national standardised medicines policies, patient group directions and other essential organisational governance documents during 2018/19’.

5.1.3.9 Following publication of the recommendations, the SPS established the Medicines Governance Do Once (MGDO) Secretariat. This Secretariat provides the oversight for the ‘Do Once’ project; its members are from the SPS Medicines Use and Safety team, NHS Improvement and NHS England. A Medicines Governance Do Once Secretariat Position Paper published on the SPS website in January
provides confirmation that in the first year of the programme its work has focused on Patient Group Directions. The policies work stream will begin in 2019/20. This will involve a review of existing medicines-related policies to enable prioritisation of the work programme. The aim will be to improve the quality and consistency of documentation and reduce duplication of effort and to develop national templates for provider medicines policies (Specialist Pharmacy Service, 2018). The HSIB investigation has therefore not made a specific recommendation about a national framework for the development of local medicines policy and instead notes the following safety action:

Safety Action:
In January 2019 the Specialist Pharmacy Service published its Medicines Governance Do Once Programme, which includes a plan to develop national templates for medicines related policies for adaptation and adoption within NHS organisations and other publicly funded commissioned services.

5.1.3.11 There are competing aims in the storage of medicines. There is a British Standard (BS2881:1989) relating to the storage of medicines in healthcare premises (British Standards Institute, 1989). Officially titled Specification for cupboards for the storage of medicines in health care premises, this act was published in July 1989 and covers both medicine cabinets and controlled drugs cabinets. CD cabinets are also covered by additional legislation. This standard is specifically about the specifications of the cupboard and the room. The structural requirements and technical details with which the CD safe, cabinet and room must comply are detailed in Schedule 2 of the Misuse of Drugs (Safe Custody) Regulations 1973, as amended. When purchasing a safe or cabinet, the purchaser should check with the vendor or manufacturer that the product specifications comply with the requirements stated in the Misuse of Drugs (Safe Custody) Regulations 1973. However, in terms of consumables and environments for storage, the investigation team could not find any evidence of minimum requirements or guidelines.

5.1.3.12 The risk of error may increase when medications are being prepared in busy, cluttered clinical rooms. A system is required to support identification of medicines easily, especially those used in emergencies. As some medicines have to be refrigerated, and some are CDs, and some are neither oral nor IV, separating drugs by route of administration would be impractical.

5.1.3.13 Storage of oral, liquid and injectable medicines in different locations could provide an additional cue to distinguish between the different forms and act as an additional safety barrier for the process of selecting the right medicines. In the reference case, the fact that the oral and intravenous forms of midazolam were stored together is linked to other studies on ‘look-alike’ and ‘sound-alike’ medicines (Ciociano & Bagnasco, 2013). The limited storage space observed in clinical areas makes implementation of recommendations regarding segregated storage difficult and sometimes unachievable in practice.

For ease of understanding, the following analysis is broken down into the relevant component parts of the process for medicines storage, prescribing, and administration.

- **Storage**

5.1.3.10 In the reference event, the oral midazolam and the IV midazolam were stored on the same shelf in the CD cupboard.
5.1.3.14 The location of specific syringes is available in a haphazard way. There is a requirement, given the mobile workforce (as nurses and doctors work in many trusts), for consistency and common approaches to storage to help mitigate staff not being familiar with syringes and their use. The investigation team is aware that cost and/or unavailability may be a prohibitive factor for some trusts; however, safety has to be a priority.

5.1.3.15 Recently reviewed professional guidance on the safe and secure handling of medicines (Royal Pharmaceutical Society, 2018) includes supplementary guidance as appendices. The guidance predominantly applies to areas not under the direct supervision of a pharmacy professional, for example hospital wards and other clinical areas.

• Prescribing

5.1.3.16 The prescribing of midazolam is complex. The dose is ‘once-only’ but administration requires titration\(^{12}\); there is no simple way of specifying it or specifying rescue doses\(^{13}\) of flumazenil. In effect, the prescription is for a dose sufficient to produce conscious sedation, administered by slow IV up to a maximum of 10 mg (Accord Healthcare Limited, 2018).

5.1.3.17 In the reference event, the prescription for midazolam could have been written analogously to the prescription for flumazenil. If written ‘As needed’ some clarification as to the purpose of the administration could have been given, but it is not the natural place to write single-use medicines. The prescribing doctor did write ‘micrograms’ in full on the drug chart, which is in accordance with prescribing guidance.

5.1.3.18 While no conclusions have been drawn from the prescription, it is possible that had the midazolam been written more fully to represent the actual dose based on the patient’s weight, this may have been a visual prompt to the nurse during checking that the midazolam was for intravenous use.

5.1.3.19 The behaviour of the doctors in training in this case is consistent with the findings of the Royal College of Physicians’ report (Royal College of Physicians, 2017) which states that ‘junior doctors are responsible for two thirds of all hospital prescriptions. Prescribing is a significant part of their role, but despite this, induction processes and postgraduate teaching around safe prescribing can be variable. Moreover, there is lack of a concerted effort to address the safety culture around safe prescribing, with junior doctors often being unaware of their mistakes and not always receiving the feedback that they need to learn and to continuously improve’.

5.1.3.20 Within the report of the SLWG on reducing medication-related harm, the Prescribing Safety Assessment (see 5.1.2.26) was considered a positive innovation with a suggestion it should build on appropriate training in pharmacology and therapeutics.

5.1.3.21 Prescribing safety assessments are not a complete solution for safe prescribing and there needs to be an ongoing focus on prescribing safety for all prescribers. The Single Competency Framework for Prescribers (Royal Pharmaceutical Society, 2016a) has already been adopted officially by the NMC. The Royal College of Physicians states that junior doctors should be signposted to the competency framework and the Health and Care Professions Council has consulted on adopting the competency framework.

5.1.3.22 The investigation team identified inconsistencies in training and competency assessments. Training competency standards (including prescribing standards) should be the same for all healthcare staff involved in the same or similar tasks in relation to the handling of medicines and competencies that are demonstrated.

5.1.3.23 A dashboard of prescribing indicators has been developed by NHS Digital and NHS Business Services Authority (Health and Social Care Information Centre & NHS Business Services Authority, 2018). In addition, the Medicines Safety Programme Board has identified learning from prescribing as one of its safety actions (Cattell, 2018). Consequently, no further recommendations have been made by the investigation team in lieu of ongoing work and the roll-out of the Medicines Safety Programme in April 2019.

\(^{12}\) Titration is the process of determining the medication dose that reduces symptoms to the greatest possible degree while avoiding possible side effects. In this case when the doctor “titrates” a dose of midazolam, they are adjusting how much medicine is safe to administer to adequately sedate the patient.

\(^{13}\) Flumazenil reverses the effects of benzodiazepines and would be given as a rescue dose if the patient was overly sedated.
5.1.3.24 The environment for prescribing medication was observed in some areas as sub-optimal. Studies have been undertaken internationally and have made reference to learning from the aviation sterile cockpit rule (Kyle et al, 2010). The Federal Aviation Administration in 1981 enacted policies that prohibit non-essential tasks and communications by aircraft personnel during flight operations below 10,000 feet, where the activities of take-off and landing are complex and must occur within a short period (Pape, 2003).

5.1.3.25 The Institute for Safe Medication Practices recommended a ‘No Interruption Zone’ (NIZ) based on this. Embracing the sterile cockpit concept minimises distractions during critical periods and various quality improvement projects have seen the NIZ adapted to the hospital setting (Kyle et al, 2010).

5.1.3.26 The use of a dedicated area where prescribers cannot be interrupted, except in an emergency, was trialled in a paediatric intensive care unit and led to a significant reduction in prescribing error rate (Booth et al, 2012). It was out of the scope of the investigation to review this in detail.

• Preparation

5.1.3.27 In the reference event, the elective renal biopsy was carried out on a day-case ward. The nurses were familiar with preparing oral midazolam (for sedation for dental procedures), however the nurse preparing the midazolam in the reference event had never prepared midazolam in IV form. The oral midazolam stored was midazolam (Amsed®) 2.5 mg/ml oral liquid (100 ml), which is supplied by Oxford Health NHS Foundation Trust. There can be variation in the licensing of different medicines containing the same drug and Amsed® is classed as a ‘special’. It is out of the scope of the investigation to examine the use of ‘specials’, however Appendix D gives some background information about this class of medication.

5.1.3.28 The medication was prescribed by an ST1-3 doctor in training for intravenous administration. In the reference case, the intravenous midazolam is supplied in an ampoule and the oral midazolam is supplied in a bottle. Both preparations are clear but oral is more viscous. In the reference case, the IV midazolam concentration was 1 mg per ml and therefore 10 mg equated to 10 ml, whereas with the oral midazolam, 10 mg was 4 ml.

5.1.3.29 The prescribing doctor and nurse prepared and checked the medication together. This consistency with the checking process did not warn the nurse that the doctor had prescribed the medication intravenously. This one checking procedure did not alert the doctor that the nurse had prepared the oral medication. The prescribing doctor did not challenge the nurse when given oral midazolam in the purple syringe. Neither doctor appeared to have understood the meaning of the purple syringe or the procedures for dispensing oral and IV medicines; therefore, they did not detect the multiple cues available.

5.1.3.30 The investigation team spoke to undergraduate and postgraduate doctors who commented that they were unfamiliar with oral ‘purple’ syringes and are unaware of the rationale for their introduction.

5.1.3.31 Safety features designed to prevent wrong route administration failed consecutively (see section 7.2 of the human factors report, Appendix A).

5.1.3.32 The checks were not independent, and both checkers had knowledge gaps. As all human action is vulnerable to human error, particularly where there is a risk of staff becoming overloaded, processes that rely solely on one staff member checking the actions of another or referring to written policies are not strong barriers (NHS Improvement, 2018a).

5.1.3.33 A human factors expert concluded that the behaviour of the nurse may have been due to the operation of informal norms taking precedence over policy. The nurse was familiar with oral midazolam and in her personal experience midazolam was only prescribed in oral form on the day-case ward. Her assumption that the prescription was for oral midazolam would make it less likely that she would check the prescription form in detail, and only check the parts of the form relevant to the prescription.
5.1.3.34 The nurse recalled checking the form in its entirety using the five rights. However, a human factors expert stated that it is entirely likely that she had not seen that the request was for IV midazolam because she was not expecting to do so (see Appendix A). This is an example of the cognitive bias that can influence human judgement without those affected being aware of it, that is, it can occur unconsciously (Balcetis & Dunning, 2006). People are prone to see what they expect to see, not detecting contradictory information until it becomes overwhelming. This is also known as confirmation bias.

5.1.3.35 The human factors expert also explained the cognitive bias of goal-orientated motivated reasoning, which is often associated with time-pressured scenarios. Researchers have found if there is a motivation to achieve a given goal then - like confirmation bias - only feedback supportive of goal attainment is detected and contradictory feedback is not detected. Norman’s human action cycle in goal performance (Norman, 1981) would suggest that in the reference case it is not about whether the staff involved considered the cues; they may not even have perceived them.

5.1.3.36 In the reference case and in the observations conducted, two-person checking was not independent. Multiple processes were being performed at the same time. The failure of the checking process in the reference event and in the observations witnessed, combined with the undefined roles and relationships between personnel, are considered important contributors to the wrong route error.

5.1.3.37 Nationally, the standard of checking medications was observed to be inconsistent. The value of second checks as a process to reduce medication errors continues to be disputed because of the variability in, and paucity of, rigorous conclusive research evidence of its effectiveness (Armitage, 2008). Given the plan to develop a national template for medicines related policies as described in 5.1.3.8, there is an opportunity to define a process on how and when to complete an independent two-person check.

5.1.3.38 While there are physical barriers, for example oral syringes that make connection to an IV cannula impossible, there are knowledge gaps in terms of their existence and when they are used. The national findings identified the limited availability of oral syringes as a further issue. The Care Quality Commission (CQC), in Regulation 12: Safe care and treatment (Care Quality Commission, 2018a), states: ‘Providers must make sure that the premises and any equipment used is safe and where applicable, available in sufficient quantities. Medicines and medicine consumables must be supplied in sufficient quantities, managed safely and administered appropriately to make sure people are safe’. CQC can take enforcement action for a breach of this regulation, or a breach of part of the regulation, if a failure to meet the regulation results in avoidable harm to a person using the service or if a person using the service is exposed to significant risk of harm.

5.1.3.39 The investigation team had a conversation with the CQC Head of Medicines Optimisation. As part of the CQC hospital well-led inspection, the trust chief pharmacist is interviewed about medicines safety, the governance arrangements supporting the safe and effective use of medicines, monitoring and responding to safety alerts, and incident reporting, investigation and sharing of learning. It would be unrealistic to make a recommendation about specific medicines consumables because of the significant numbers of safety alerts from the many bodies that have previously issued them, often without completely clear SMART14 actions and some alerts being superseded since their initial introduction.

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14 SMART is a best practice framework for setting goals. A SMART goal should be specific, measurable, achievable, realistic and time-bound.
HSIB MAKES THE FOLLOWING SAFETY OBSERVATION

Observation:
Availability of oral/enteral syringes in all clinical areas (in accordance with the requirements contained in the National Patient Safety Agency’s Patient Safety Alert 19) is inconsistent. A national audit tool may be helpful to organisations.

- Administration

5.1.3.40 The HSIB investigation team identified that not all relevant guidance for administration of medicines was known or understood by healthcare professionals.

5.1.3.41 All NMC registrants must practise in line with the requirements of the NMC Code (Nursing and Midwifery Council, 2015). This states at section 18 that they must advise on, prescribe, supply, dispense or administer medicines within the limits of their training and competence, the law, NMC guidance and other relevant policies, guidance and regulations.

5.1.3.42 The GMC’s guidance Good practice in prescribing and managing medicines and devices (General Medical Council, 2013) states: ‘You must keep up to date with, and follow, the law, our guidance and other regulations relevant to your work’.

5.1.3.43 The guidance also states: ‘You should take account of the clinical guidelines published by: NICE, […] medical royal colleges and other authoritative sources of specialty specific clinical guidelines’.

5.1.3.44 In the reference event the administering doctor gave the midazolam. This was a departure from policy as the administering doctor was not involved in the preparation or checking process. The local investigation concluded that the Trust’s Injectable Medicines Policy was not followed. The policy states: ‘It is not acceptable for a registered practitioner to administer an injectable medicine that has been prepared by anyone else, unless they have been present throughout the whole of the preparation process. The administrator should be the first or second checker not just an observer’.

5.1.3.45 The administering doctor stated that she expected the syringe to contain IV midazolam because that is what she asked for. These expectations remained unchanged despite multiple cues to the contrary and that the purple syringe cannot be filled from an ampoule and has the word ‘enteral’ written on it.

5.1.3.46 The preparation, verification and administration of all medicines relies on all users reading the label carefully and accurately and being able to assimilate and act on the information presented (Medicines and Healthcare products Regulatory Agency, 2001). The syringes, which included one for a saline flush and one for the midazolam, were not labelled once prepared and therefore the administering doctor had to rely on a verbal reassurance that the syringe contained IV midazolam. The administering doctor did not question why the syringe had no label.

5.1.3.47 Not being a part of the preparation process resulted in a belief that the correct medication had been drawn up in the wrong syringe; verbal reassurance that it was IV midazolam in the syringe provided the administering doctor with further confirmation of this.

5.1.3.48 There were three medical staff with the child including one member of staff who had prescribed the midazolam and been involved in the checking process. No-one questioned the administering doctor when she administered the midazolam despite her not being present for any of the checking procedure. A human factors expert suggested this may be a knowledge-based mistake and may be exacerbated by a lack of teamwork and effective communication (see Appendix A).

5.1.3.49 The investigation team did consider the medical hierarchy (Sydor et al, 2013), (Walton, 2006) and whether the hierarchical gradient contributed to individuals not speaking up – a consultant, the administering doctor (ST6-8) and the prescribing doctor (ST1-3) – however the analysis did not suggest this was a factor, rather it was more related to a lack of teamwork and effective communication, which is detailed later in the report.
5.1.3.50 The nurse who was involved in the preparation for administration was not in the procedure room when the medication was administered. The NMC standards for medicines management in use at the time of the reference event (Nursing and Midwifery Council, 2007) explicitly stated in standard 8, ‘you must be certain of the identity of the patient to whom the medicine is administered’.

5.1.3.51 In addition, the guidance stated, ‘you must be aware of the patient’s plan of care, care plan or pathway’. The nurse was aware the child was having an elective renal biopsy but was not aware of what this involved. The NMC also stated, ‘Where you may be required to prepare substances for injection by a doctor, for example, in an emergency situation, you should ensure that the person administering the medication has undertaken the appropriate checks as indicated above’ (Nursing and Midwifery Council, 2007). As the nurse was not present in the room, it was not possible for her to confirm that the person administering the medication had done the appropriate checks. The nurse confirmed to the investigation team that had she been in the room, she would have immediately stopped the intravenous administration of the medication as she believed that the medication was prescribed for the purpose of oral administration.

5.1.3.52 The GMC’s Outcomes for graduates 2018 emphasises the prescribing stage as a required competency (see section 5.1.2.28). However, doctors are involved with – and are sometimes not prepared for – the administration of medicines.

5.1.3.53 It was concluded that neither the prescribing doctor or the administering doctor understood the significance of the purple syringe. This was thought to be related to the fact that medical staff are rarely expected to administer oral medicines and have not received the necessary training. In human factors this would be classified as a mistake, rather than a violation, where violation is a deliberate act breaking a recognised rule.

5.1.3.54 Professional practice guidance on the safe and secure handling of medicines has recently been updated and published (Royal Pharmaceutical Society, 2018).

5.1.3.55 During the analysis stage of the investigation, it was confirmed that the Royal Pharmaceutical Society and the Royal College of Nursing were co-producing guidance on the administration of medicines for use by all health care professionals. The guidance was developed in response to the announcement of the withdrawal of the Medicines Management Standard by the Nursing and Midwifery Council. The new guidance has since been published (Royal Pharmaceutical Society & Royal College of Nursing, 2019) and has been endorsed by the Royal College of Midwives and the Association of Pharmacy Technicians. The document is hosted on the Royal Pharmaceutical Society website, and the Nursing and Midwifery Council and Royal College of Nursing websites. It is accessible by all healthcare professionals including physicians and general practitioners.

Safety Action:
The Royal Pharmaceutical Society has produced and published professional guidance on the administration of medicines for use by all healthcare professionals.

5.1.3.56 The investigation team suggested that the Royal Pharmaceutical Society work collaboratively with the professional bodies and other royal colleges, including the Royal College of General Practitioners and Royal College of Physicians, to review the professional guidance on the administration of medicines for use by all health care professionals. The Royal Pharmaceutical Society has requested endorsement from the Royal College of Physicians and the Royal College of General Practitioners subject to their endorsement processes.

5.1.3.57 While not the case at the reference site, the HSIB investigation team identified that the five rights principles were sometimes being used as a performance tool during local investigations, resulting in a focus on individual performance. The human factors analysis (see Appendix A) focuses on the systemic factors that influence individual performance rather than the performance itself.
5.1.3.58 Midazolam comes in IV, oral and other forms. Both IV and oral forms are colourless liquids, and both are referred to as ‘midazolam’. The similarity in these forms introduces a clear latent hazard which requires constraints to be put in place to minimise the risk of a safety occurrence. Packaging of the two forms provides the first constraint in place designed to prevent exposure to the hazard. The IV form is stored in ampoules and the oral form in bottles. This physical coding separates the two forms and is easily understood. However, the safety barrier provided by the different packaging is undermined by dispensing both forms of midazolam into syringes, effectively ‘joining them up again’ at a conceptual level.

5.1.3.59 Although protective incompatibility is built into the syringes it is incomplete. It is unlikely that the purple syringe could be filled from an ampoule, whereas the IV syringe can be filled from a bottle (this appears to have happened in other safety occurrences). Similarly, the purple syringe cannot be connected to a cannula but the IV syringe could be used to introduce medication orally (although is unlikely to cause significant harm).

5.1.3.60 Many solutions for injection are presented as clear liquids. Therefore, the appearance of the contents of the syringe does not necessarily trigger the thought that the medication at hand is only for administration via the enteral route. However, some medications intended for intravenous administration are presented as white emulsions, for example propofol. In methadone, Physeptone® for oral administration is coloured green. The IV preparation is a clear, colourless solution (Martindale Pharma, 2017a, 2017b).

5.1.3.61 The electronic Medicines Compendium (eMC) (The electronic Medicines Compendium, 1999), which launched in 1999, contains up-to-date, easily accessible information about medicines licensed for use in the UK. In the eMC there are examples of coloured oral solutions (Rosemont Pharmaceuticals Limited, 2016), (Wockhardt UK Ltd, 2018). The reasons for colour may be related to formulation, ingredients and stability, and not specifically as a safety intervention; it was out of the scope of the investigation to explore this further.

5.1.3.62 Subject matter experts did suggest that the colouring of oral medications to make them distinguishable from other medications may have a justifiable role in improving safety and minimising wrong route errors. Colourings are inactive substances that may be used in oral formulations of medicines and may help in distinguishing different forms of medicine. The investigation team received mixed responses to use of colour and were cautioned that the use of any specific colouring agent in oral medication preparation should be discussed and justified in terms of allergenic potential and the risk of toxicological implications. The justification should address both the necessity to colour the preparation and the selection of a particular colouring agent.

5.1.3.63 During a conversation with a pharmacist at a CQC Never Events thematic review meeting, when a proposal was made in favour of colouring medication, she stated that “putting something into a medication that had no function in treatment was fundamentally an unsound idea” and questioned its validity as a recommendation.

5.1.3.64 Unlike other inactive substances in medications, the use of colouring agents in medicinal products is governed by a specific directive (Directive 2009/35/EC) of the European Parliament and of the Council of 23 April 2009 (Official Journal of the European Union, 2009) on the colouring matters which may be added to medicine.

5.1.3.65 The human factors expert advised that, when procured, oral and intravenous versions of the same medicines should not have the same appearance; rather, distinctive physical cues should differentiate them. The investigation team was unable to gather enough evidence to make a recommendation for the colouring of liquid oral medications to make them distinguishable from other medications. However, it did conclude that colouring of high-risk and/or oral liquid medications commonly associated with inadvertent medication administration may have a justifiable role in improving safety and minimising wrong route errors.
5.1.3.66 In 2017 the Medicines and Healthcare products Regulatory Agency (MHRA) published guidance on applying human factors to medical devices (Medicines and Healthcare products Regulatory Agency, 2017). This guidance is primarily aimed at manufacturers of all device classes and developers of medical devices and drug-device combination products, and the notified bodies responsible for assuring the quality of those devices. It applies to the design of future products and changes in user interfaces of existing products, rather than those already approved for the UK and EU market. The investigation has been advised that the MHRA plans to evaluate how this guidance has been received through a number of activities during 2019, including a survey of the intended audience for the guidance document.

5.1.3.67 An overall observation from analysis of the process for medicines safety is that the structure and culture of the NHS make it difficult to share best practice. It appears hard to communicate, implement or monitor the effects of systemic improvement. This is despite the enthusiasm and commitment of the healthcare professionals and national bodies the investigation consulted.

5.1.3.68 The SLWG made recommendations for a programme of work to tackle medication error and improve medication safety. This included the establishment of a Medicines Safety Programme Board. The programme appears to cover four high-level domains – patients, medicines, healthcare professionals and systems and practice – each with a series of medicines safety programme actions (Cattell, 2018). This is a whole-system approach and includes NHS England, NHS Improvement, NHS Digital, Health Education England, regional office engagement with Sustainability and Transformation Plans, Integrated Care Services, clinical commissioning groups (CCGs), and providers and is nationally co-ordinated with royal colleges, professional bodies, academia, Academic Health Science Networks and regulators.

In light of these actions being taken, the investigation has therefore not made a recommendation about system-wide leadership and notes the following safety action.

**Safety Action:**
NHS Improvement is working towards a formal launch of the National Medicines Safety Programme in April 2019.

**Observation:**
Colouring of high-risk and/or oral liquid medications (such as midazolam) may have a justifiable role in improving safety as it will offer a signal to differentiate oral from parenteral preparations.

**THE FOLLOWING SAFETY OBSERVATION IS BASED ON THE OVERALL FINDINGS OF THIS SECTION**

**Observation:**
It would be beneficial if potential interventions designed to reduce wrong route administration medication errors were subjected to human factors testing, review, evaluation and modification prior to being introduced at scale; this includes standards, processes, and the design of medication and administration devices.

5.2 Safety culture and priorities

The NHS Improvement patient safety alerts (PSAs) are designed to address systemic issues affecting healthcare organisations. The following sections describe the main patient safety alerts and other factors that are relevant to the investigation, looking at their impact at the reference event Trust and nationally.

5.2.1 National Patient Safety Alert 19 – Promoting safer measurement and administration of liquid medicines via oral and other enteral routes

5.2.1.1 In 2007, the National Patient Safety Agency (NPSA) issued advice to healthcare organisations promoting safer measurement and administration of liquid medicines via oral and other enteral routes (Patient Safety Alert (PSA)19) (National Patient Safety Agency, 2007b). This provided guidance on actions that would, if implemented, reduce the chances of oral liquid medication being given via the wrong route.

5.2.1.2 One of the suggestions/recommendations of PSA 19 was to adopt connectors compliant to safety standard EN1615 (British Standards
The archived alerts have been collated and are available via the Specialist Pharmacy Service website:

5.2.1.3 Oral/enteral syringes have ENFit connectors with female tips and were introduced so that oral liquid medicines might be measured accurately and administered to patients via the correct route and could not be connected to an intravenous line. Oral/enteral syringes are generally recognised by a purple coloured plunger or syringe barrel to help differentiate them from intravenous syringes (Figure 6).

5.2.1.4 Intravenous syringes should not be used to prepare or administer oral medicines due to the risk of oral medications being administered intravenously. After filling an intravenous syringe with an oral or enteral medication, it takes only a momentary mental lapse to connect it to an IV line and inject it (Hurst, 2016).

5.2.1.5 In January 2018, NHS Improvement released a document, Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list 2018 (NHS Improvement, 2018b). This did not set out new requirements but summarised past requirements from NPSA that could no longer be accessed via the archived NPSA website15. Within the report an ISO standard is documented for enteral equipment (ENFit).

5.2.2 National situation

5.2.2.1 HSIB investigators identified variability and inconsistency in implementation of PSA 19. The review of other incidents of inadvertent administration of oral liquid into a vein suggests that the actions contained in the alert are not consistently applied.

5.2.2.2 The HSIB investigation team was informed that in 2007, PSA 19 was received and sent via email to the Heads of Nursing and to Pharmacy staff with a request for divisions to cascade.

5.2.2.3 The Trust had readily available access to enteral/oral syringes.

5.2.2.4 Various syringes were available in the drawers within the side room where the reference procedure was performed.

5.2.2.5 Storage of enteral syringes is variable. In one of the sites visited oral/enteral syringes were mixed with the IV Luer lock plastic syringes (Figure 12).

5.2.3.2 One of the PSA 19 actions states, ‘make sure stocks of oral/enteral syringes are available in all clinical areas that may need to measure and administer oral liquid medicines in a syringe’. There is however no nationally designed audit for organisations to measure against.

5.2.3.3 The investigation looked at why IV syringes were used in wrong route incidents and one of the common reasons is that there were no oral/enteral syringes available within the immediate vicinity, as referred to in paragraph 5.1.3.38 and the subsequent safety observation.

5.2.3.4 In the reference case, the manufacturer’s visual labelling cues (the purple plunger and the word enteral on the barrel) were not recognised by the doctors. Following a literature review, it was evident that colour-coding, labelling, and tagging or imprinting (for example ‘feeding only’, ‘medication only’) on the device, are not sufficient to mitigate the risk of enteral misconnection (Department of Health, 2004).

5.2.3.7 When IV syringes have been used, there appears to be no consistent way of labelling syringes; pre-printed labels for infusion bags do have spaces for relevant information (although they may not be completed). Labels can obscure the contents of a syringe, introducing second order risks.

5.2.3.8 Findings from the CQC Never Events Thematic review (Care Quality Commission, 2018b) field work linked closely with the HSIB’s national investigation findings. Specifically:

- The level and rigour of the monitoring and auditing of implementation of PSAs is varied but generally poor.

- Governance responsibilities for monitoring and overseeing implementation are variable and often lacking.

5.2.3.9 National and international standards have been written with a focus on building in protective incompatibility to minimise the risk of wrong route error incidents. The British Standards Institute (BSI) is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level. The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees.

5.2.3.10 The design of oral/enteral syringes is driven by the same BSI and ISO processes used in other industries and influenced by several key concepts used in systems engineering. BSI and ISO documents and standards were viewed as part of the investigation (British Standards Institute, 2000b), (British Standards Institute, 2008), (British Standards Institute, 2011), (British Standards Institute, 2018), (Ibenthal, et al., 2017), (International Organization for Standardization, 2017), (International Organization for Standardization, 2016), (Food and Drug Administration, 2009). Some of these documents set out the requirements for the design and testing of the devices. A guideline for the implementation of medical products using small bore connectors specified in the ISO 83069 series was produced in April 2017 (ISO/TC 210 - IEC/SC62D/ Joint Working Group 4 Small bore connectors, 2017).

5.2.3.11 British Standard (BS) EN 15546-1:2008 - Small bore connectors for liquids and gases in healthcare applications. General requirements (British Standards Institute, 2008), provides a framework to assess non-interchangeability of small bore connectors based on their inherent design and dimensions. Some of the process issues associated with the introduction of protective incompatibility are discussed. New connectors are subject to a design review and the document touches on how these reviews should be conducted.

5.2.3.12 The Food and Drug Administration (FDA) collaborated with ISO to develop the ISO 80369-3 standard for enteral applications and, in February 2015, officially recognised the standard and issued specific guidance to manufacturers on ensuring adoption (Food and Drug Administration, 2015).

5.2.3.13 ISO 80369-3:2016 (Internal Organization for Standardization, 2016) specifies the dimensions and requirements for the design and functional performance of small bore enteral connectors, to be used in devices such as enteral feeding sets. This part of ISO 80369 was developed because of several incidents, with catastrophic consequences, resulting from firstly, the administration of inappropriate medication into the alimentary canal and secondly, from enteral solutions being administered via incorrect routes, including intravenously and into the airway. The 80369-3 standard only defines the interfaces of the connectors and the tests that establish their efficacy. The investigation has been informed that ISO is currently working on a device standard that covers the devices that include these connectors.

5.2.3.14 ISO 80369-1:2010 (British Standards Institute, 2011) was replaced in November 2018 by BS EN ISO 80369-1:2018 (British Standards Institute, 2018). This document provides the methodology to assess non-interconnectable characteristics of small-bore connectors based on their inherent design and dimensions to reduce the risk of misconnections between medical devices or between accessories for different
applications. The document does not, however, specify requirements for the medical devices or accessories that use these small bore connectors.

5.2.3.15 The protective incompatibility works well if the users understand why it is there and its significance. Evidence suggests however that the protective incompatibility does not stop staff decanting medicines into inappropriate delivery devices.

5.2.4 Analysis

5.2.4.1 The colour purple has been used in the UK and Europe as an identifier for all devices associated with administering of feed and medication and fluids via the enteral route for more than 10 years. This is not limited to syringes, but includes the administration sets, connections on feeding tubes, labelling of infusion pumps designed for enteral applications and so on. This standardisation has occurred across the range of enteral device manufacturers but has not been a requirement set out in either design standards or regulatory requirements.

5.2.4.2 The Global Enteral Device Supplier Association (GEDSA) was formed by leading enteral device manufacturers to help introduce international standards in medical device tubing connectors. The aim of the organisation was/is to facilitate a stronger flow of communication to raise awareness and encourage adoption of the adaptors via the ‘stay connected’ campaign (Global Enteral Device Supplier Association, 2019).

5.2.4.3 Examination of BS and ISO standards reveals a systematic approach to the design of medical device connectors and associated devices. The approach is formalised and includes verification and validation of design solutions by independent authorities. However, it was not possible to establish if there is a consistent implementation strategy for new products which might, for example, include training needs analysis or hazard identification exercises. Also, the investigation team could not find evidence of any human factors activities to support the introduction of purple syringes at a local level. Training needs analyses and hazard identification exercises are commonly used in high-risk industries to support the integration of new systems or devices, for example in new military systems.

5.2.4.4 No evidence was found of a systematic process for introducing the oral/enteral syringes at ward level. The PSA 19 (National Patient Safety Agency, 2007a) was a list of recommendations to trusts and as discussed above, was inconsistently implemented. It was out of the scope of the investigation to assess this at a more granular level, however it is considered important.

5.2.4.5 Safer ‘non-standardised’ small bore (non-Luer) connectors are now being introduced across the NHS to minimise the risk of wrong route errors when administrating medication via oral/enteral and neuraxial routes.

5.2.4.6 The medical device regulations require that risks of harm are mitigated as far as possible through inherent safe design and construction and that any residual risks are mitigated, firstly via protective systems and then by labelling and instructions or declaration that the remaining risk cannot be mitigated but the benefit of use outweighs the residual risk. MHRA considers that the adoption of the ENFit connectors for enteral/oral syringes and other devices for this application is an appropriately strong mitigation against wrong route administration (personal communication, 8 February 2019).

5.2.4.7 The investigation team was advised that the Parenteral and Enteral Nutrition Group (PENG) (PENG, 2018) will be responsible for hazard identification and risk assessment when implementing new devices. Specific concerns have been raised regarding neonatal and paediatric patients who may be at a higher risk of medication error due to the design of the ENFit system (Bledsoe et al, 2016), (Institute for Safe Medication Practices, 2015a). ‘When a medication intended for oral administration has been drawn into an ENFit syringe via a bottle adapter or ENFit straw, if the dose is given orally and not connected to a feeding tube, the patient will not receive the full amount of liquid, and thus an incomplete dose. This is because fluid will remain in the dead space after delivering the medication into
the patient .... When infants, small children, or others are receiving very small volumes of liquid orally, we recommend using oral syringes for oral doses.’ (Institute for Safe Medication Practices, 2015b). The device used to administer an oral liquid is critical in ensuring that the dose administered is accurate.

5.2.4.8 As well as an under-dose risk, there is also a comment on the potential for small groups receiving overdoses of up to 0.179ml in Annex A, A.2 of ISO 80369-3 (International Organization for Standardization, 2016). One attempt to overcome this risk has been the introduction of a ‘low dose tip’ (Global Enteral Device Supplier Association, 2016).

5.2.4.9 The origins of the purpose of the syringe is steeped in history (Exchange Supplies, 2018). They appear to have been adapted to meet different requirements, more recently to administer medicines by mouth or into tubes. While it is often efficient when a solution that meets one requirement is adapted to meet another, in the case of medications new hazards (second order risks) are introduced because medicines can be put into the wrong syringe. Steps to minimise the risk have been made (the oral syringes have purple plungers, a different diameter and protective incompatibility to prevent them being connected to needles and cannulae) but the protection is incomplete and does not appear to be sufficiently well-understood.

5.2.4.10 A human factors expert shared his view that “it is risky to dispense oral medication using syringes. It simply creates a link between oral and IV that should not be there and means that staff have to learn to distinguish between the two kinds of syringes”. Conversations indicate that some experts agree with this sentiment, however other experts, some of the same professional group, have very different views due to the requirement for oral medication to be accurately measured in doses that may require administration in very small doses, for example to neonates, and much larger volumes in adults. This highlights two different functions for syringes:

- to give liquids by different routes
- to measure volumes accurately and ensure that the correct volume is administered (taking into account any equipment dead space).

5.2.4.11 A debate about the relative risks and benefits of administering oral medicines using less accurate instruments against the risks of wrong route administration would be indicated although is outside of the scope of this investigation.

5.2.4.12 From the evidence reviewed, procedures for dispensing oral and IV medications and the use of syringes with clear and purple plungers are understood by nurses. Qualitative feedback from undergraduate and postgraduate medical staff suggests they are not familiar with administration of oral medicines or the different syringe types. This may be because doctors rarely administer oral/enteral medication, unlike intravenous medication where both doctors and nurses will administer.

5.2.4.13 It is noted that colour coding is not intended to be the primary defence; it is only a secondary cue to support physical incompatibility. In the reference event, the cue was not recognised.

5.2.4.14 Knowledge-based errors are errors in thinking, in this case due to a lack of understanding of the equipment used in a sequence of actions or of the processes or policies underlying its use. In this case, understanding the significance of the purple plunger in the oral syringe. Such an error explains why the doctors did not read the word ‘ENTERAL’ printed on the side of the syringe (reading anything written on the syringe was not part of the ‘a-priori’ action sequence (see human factors report, Appendix A). This line of reasoning suggests that having syringes with the word ‘ENTERAL’ printed on them will be of limited effectiveness in preventing knowledge-based errors. In summary, if you are not looking for it, you probably will not see it.

5.2.4.15 ISO draft technical report (ISO/TC 210/ JWG 4 N 406) (International Organization for Standardization, n.d.) sets out the colour coding of devices for administering medicines and refers to the colour purple in

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16 Relating to or denoting reasoning or knowledge which proceeds from theoretical deduction rather than from observation or experience.
- ‘a priori assumptions about human nature’
Europe (orange in America) as the colour to be used for the enteral devices. This report is a general proposal and the HSIB investigation team was advised that this was written with a view for discussing the subject in greater detail and with specific outcomes. As part of an ISO project, a draft is (usually) proposed to give a context of what is intended; there are usually significant changes through the working time of such documents.

5.2.4.16 The HSIB investigation team was unable to determine the rationale for the colours or any evidence of trials to assess their effectiveness and comprehension. The SLWG findings acknowledged that the UK is making good progress in the area of labelling and packaging, however recognised that the issue of colour and name differentiation in medication and its packaging could be problematic.

5.2.4.17 In the reference event, the nurse thought the prescription for midazolam was oral and used the syringe appropriate for oral administration. The Institute for Safer Medicines Practice has in the past recommended that ‘to improve safety, dispense, when possible, oral liquid medications from the pharmacy in the most ready-to-use forms. For oral solutions that are not available from manufacturers as unit-dose liquids, have pharmacy dispense these medications in oral syringes. Requiring medication to be dispensed from the pharmacy in labeled, patient-specific doses helps to reduce the manipulations that may occur on the patient care units’ (Institute for Safe Medication Practices, 2009).

5.2.4.18 The investigation team did not identify any reports or other evidence of quality improvement measures taken to introduce the PSA 19 actions. While the investigation is aware that older circulated patient safety alerts have been reviewed by the national bodies, the investigation was unable to find any evidence to suggest any evaluation of the impact of the original alert. In the reference case and in other similar incidents nationally, there was no evidence as to how organisations ensure new staff are made aware of applicable safety alerts.

5.2.4.19 The investigation team has established through observation and conversations that workarounds happen, despite the existence of safety alerts that promote standardisation.

5.2.4.20 The investigation team was informed that the Secretary of State for Health and Social Care has asked the NHS Director of Patient Safety to lead the development of systems for ensuring the NHS can clearly recognise alerts requiring action to protect patients from the most serious risks, regardless of which safety body issues them. The work is being taken forward through a new National Patient Safety Alert Committee (NaPSAC) which will agree common standards, thresholds, and formats for National Patient Safety Alerts issued by bodies including the Chief Medical Officer, Department for Health and Social Care Supply Disruption, the MHRA, NHS Digital, NHS England, NHS Improvement Estates & Facilities, NHS Improvement Patient Safety, and Public Health England. NaPSAC will also provide advice to CQC on inspecting compliance with these alerts.

**HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATION**

**Recommendation 2019/028:**
It is recommended that NHS Improvement, through the National Patient Safety Alert Committee, set standards for all issuers of patient safety alerts which make clear that alert issuers should assess for unintended consequences of the actions in the alert, the effectiveness of barriers created by these actions, and provide appropriate advice for providers on implementation, include ongoing monitoring.

5.2.4.21 A systems approach to medication safety should consider how hazards are controlled at all stages, from procurement to administration, by the application of appropriate constraints.

**HSIB MAKES THE FOLLOWING SAFETY RECOMMENDATION**

**Recommendation 2019/029:**
It is recommended that NHS Improvement support the development of necessary knowledge, skills and capacity for the effective operationalisation of hazard identification and risk analysis at a national, regional and local level, as an integral part of the National Patient Safety Strategy.
5.3 National Standards for Invasive Procedures

In 2015, NHS England published the National Safety Standards for Invasive Procedures (NatSSIPs) (NHS England, 2015). The aim of the NatSSIPs is to reduce the number of patient safety incidents related to invasive procedures in which surgical Never Events could occur.

The document directs NHS providers to review current clinical practice and ensure the NatSSIPs are embedded into local processes by developing their own local safety standards for invasive procedures in collaboration with staff, patients and the public. It was intended that local safety standards should be created by multi-professional clinical teams to standardise key elements of procedural care across all clinical environments where invasive procedures occur. The standards demanded that local safety standards set out minimum standards considered necessary for the delivery of safe care during invasive procedures, to include details on the number and skill-mix of staff to patients undergoing invasive procedures, as well as underpinning aspects of education and training.

5.3.1 Reference case

5.3.1.1 The Trust local investigation stated that prior to the safety guidance in 2015, the Trust had already commenced a risk assessment of all procedures undertaken outside theatre settings as part of its Never Events action plan. The risk assessment of renal biopsy is detailed in Table 3.

5.3.1.2 Following the receipt of the safety alert in 2015, all areas of the Trust commenced the development of local safety standards for their highest risk procedures. The risk assessment at the time concluded there was no possibility of a Never Event for renal biopsy.

5.3.1.3 The HSIB investigation team established that there was not a local safety standard for elective renal biopsy. In addition, there was not a standard operating procedure that may have been referred to as a local safety standard.

5.3.1.4 There was not an agreed standard for staffing the elective renal biopsy list addressing skill-mix of staff and education and training competencies.

5.3.1.5 One of the doctors recalled at interview asking for a nurse to be present in the room, however the nurses were too busy and there were “three in the room”.

5.3.1.6 One of the doctors described the case as “an opportunistic elective procedure”. She described that “it is not like a theatre environment whereby you do three biopsies back to back with the same team. This is ad hoc along with the usual business of the day...”.

5.3.1.7 One of the doctors described the day-case ward as “chaotic” and recalled being sent in and out of the room to get things. It took “two to three goes” to get the medicine prepared.

5.3.1.8 The investigation identified that a key staff member normally present for all renal biopsy procedures was working in another area of the Trust on the day of the incident. The usual skill-mix for undertaking renal biopsies

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**TABLE 3**

<table>
<thead>
<tr>
<th>WHAT IS FORMAT OF PATIENT ID CHECK</th>
<th>SAFETY CHECKLISTS IN PLACE Y/N</th>
<th>IF NO CHECKLIST IN PLACE RATIONALE</th>
<th>WHAT OTHER SAFETY MEASURES ARE IN PLACE TO PREVENT HARM</th>
<th>RISK ASSESSMENT OF POTENTIAL FOR NEVER EVENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name band/ Verbal</td>
<td>N</td>
<td>Policy in place</td>
<td>Aseptic</td>
<td>0 - NO POSSIBILITY 1 - POSSIBLE BUT UNLIKELY 2 - POSSIBLE</td>
</tr>
</tbody>
</table>

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at the reference site was reported as two doctors and the practice nurse educator. The elements of the role normally undertaken by the practice nurse educator were undertaken by a Specialty Trainee (ST1-3) doctor in training.

5.3.1.9 The consultant described that he was confident in the knowledge and experience of the two doctors and that both had performed renal biopsies previously. He did not consider cancelling the procedure in the absence of the clinical practice educator as he had worked with both doctors doing renal biopsies in the preceding days.

5.3.1.10 The investigation team noted that the consultant said very little during the procedure. The consultant described his role in preparing and positioning the patient. He also recalled saying to the doctors, “Are you good to go?” (meaning is the sedation ready). He described how he could tell by the mannerisms of the staff to “hold on a second”. The consultant described how he assumed the cannula wasn’t working and stated: “I let them get on working out what was going on […] I don’t want to interrupt too much”. He was unaware of the specific actions of other team members.

5.3.1.11 When reflecting on the events, the consultant did question his own behaviour, stating: “I maybe put them under pressure a bit … without saying hurry up, just my actions of being busy doing things”.

5.3.1.12 There was no standardisation and supervision of process. The practice nurse educator role has defaulted to one that oversees the process; however, in his absence nobody assumed this role.

5.3.1.13 The prescribing doctor, the administering doctor and the consultant all confirmed they were familiar with renal biopsy procedures. The administering doctor did comment that there was no specific process for training in renal biopsy, stating it is more a case of “let’s just do one”.

Safety Action:
The reference event site has acted upon the requirement for a Local Safety Standard for Invasive Procedures (LocSSIP): ‘…a Local Safety Standard (LocSSIP) should be developed for all invasive procedures including renal biopsies and any other procedures that include sedation. Including minimum staffing/skillmix required’.

5.3.2 National findings

5.3.2.1 The HSIB investigation team attended another Trust to observe an elective renal biopsy. This Trust also did not have a local safety standard although suggested one would be written. Contact with a further Trust confirmed it also did not have a local safety standard for its renal biopsy cases.

5.3.2.2 There are examples of local safety standards for invasive procedures on the NHS Improvement website.

5.3.2.3 A NatSSIPs implementation survey (March 2018) was carried out between February 2018 to March 2018 as part of the CQC Expert Advisory Group review of Never Events (NHS Improvement, 2018c). The report did not draw conclusions or make any judgements. It stated that the biggest reported barrier to implementation of national and local safety standards is lack of time, which scored a ‘reasonable’ or ‘significant’ impact for 69.6% of the 125 organisations that responded.

5.3.2.4 Staff culture was reportedly another significant barrier to the implementation of safety standards. Included in this category were issues around prioritisation, applicability to the working environment and a resistance to change. In addition, safety standards were considered to be too bureaucratic, time consuming and “another thing to do”.

5.3.3 Analysis

5.3.3.1 The HSIB investigation team considered the conditions that existed before the reference event occurred that contributed to the pre-existing deviation from national and local practice. As there was not a local safety standard or similar standard operating procedures, the child’s care did not adhere to an established set of minimum safety standards.

5.3.3.2 A local safety standard should have helped define and then provide the team with an understanding of the purpose and the work that must be performed by the team to
achieve it. When developing a local safety standard, the team composition would have been considered.

5.3.3.3 A reconstruction of events and a simulation were undertaken, and it was apparent from the simulation that there is a significant amount of communication between team members when the correct procedures are followed. From the reconstruction of events and the evidence reviewed, this interaction appeared to be lacking on the day the incident took place. Effective teamwork (Salas et al, 2009) depends on a knowledge of the skills and actions of other team members, and knowing what to expect of each other, not just sharing a common goal.

5.3.3.4 The practice nurse educator described having a responsibility for supporting the medical team in preparing the necessary equipment and specifically supporting the medical staff in preparing the medication for renal biopsy procedures, whether performed on the day-case ward or on the in-patient unit.

5.3.3.5 It was evident to the investigation team through interview and observation that the practice nurse educator works to an established pattern of working with the team which is known, but not formally recorded. In the reference event it appears therefore that patient safety was over-reliant on the practice nurse educator’s presence and therefore the clinical team can be described as ‘brittle’ rather than resilient (Alliger et al, 2015). In his absence, five safety constraints designed to prevent wrong route administration failed consecutively due to knowledge gaps, lack of adherence to standard procedures, lack of local safety standards for renal biopsy and the operation of local norms.

5.3.3.6 One of the characteristics of effective teamwork is that team members share a common goal, have shared understanding of key elements needed to reach the goal (a shared mental model of the overall process) and know what to expect from fellow team members. Additionally, effective teamwork depends on a knowledge of the skills and actions of other team members, not just sharing a common goal, as reflected in research comparing error rates between familiar and unfamiliar teams (ElBardissi et al, 2008). ‘High performing teams are those that have been trained to have, and have demonstrated proficiency in, specialized knowledge, skills and attitudes that support teamwork.’ (Salas et al, 2009)

5.3.3.7 The investigation team has identified through conversations and observation that the implementation of local safety standards is inconsistent, particularly where invasive procedures are carried out outside the operating theatre.

5.3.3.8 The investigation considered that the variability in implementing the recommendations contained in the patient safety alerts is suggestive of a wider cultural issue regarding patient safety priorities. It was outside of the scope of the investigation to look at patient safety culture, however the report Opening the door to change (Care Quality Commission, 2018b) looks at NHS safety culture and the need for transformation. One of the conclusions of the themed work by the CQC is that ‘staff are struggling to cope with large volumes of safety guidance, they have little time and space to implement guidance effectively, and the systems and processes around them are not always supportive’.

5.3.3.9 The findings of its fieldwork analysis are consistent with what the HSIB investigation team saw and heard, and the reference case provides insights into the safety culture in operation at the time.

5.3.3.10 A safety recommendation has therefore not been made given the recommendations made following the work by the CQC Never Events Expert Advisory Group (Care Quality Commission, 2018b).

5.3.3.11 The reference event site organisation and HSIB collaborated to reconstruct the wrong route medicines administration incident. This was then followed by a simulation of the updated current process. It is anticipated that using actual serious adverse event stories, like this one, will be one way to help shape the safety of healthcare in the future. By embracing the fundamental premise that we are human and we all make mistakes and that what happened in this scenario could happen
to any healthcare professional involved in prescribing, preparing and administering medication, there is an opportunity to educate the current and future workforce.

5.3.3.12 The video of the reconstruction, which is accompanied by a teaching aid, will be used to support learning for improvement.

**Safety Action:**

HSIB, supported by a teaching hospital, has produced a reconstruction of events and a simulation of what happened during the reference event along with a supplementary teaching aid to increase awareness of this type of error.

### 5.4 Safe sedation for children and young people under 19

5.4.1 In 2010, NICE published guidance on using sedation for diagnostic and therapeutic procedures for children and young people under 19 years old (National Institute for Health and Care Excellence, 2010). This guideline covers the assessment, preparation, training and monitoring needed when using sedation in people aged under 19 years.

5.4.2 A renal biopsy is an interventional diagnostic procedure and may well be painful and/or distressing for the individual concerned. A general anaesthetic or sedation can be used safely for renal biopsy. Many paediatric renal units use sedation. Often an urgent report is needed, and sedation gives much greater flexibility to getting an urgent report. The aims of sedation during diagnostic or therapeutic procedures include reducing fear and anxiety, augmenting pain control and minimising movement during the procedure.

5.4.3 Midazolam should be administered only by experienced physicians in a setting fully equipped for the monitoring and support of respiratory and cardiovascular function and by persons specifically trained in the recognition and management of expected adverse events including respiratory and cardiac resuscitation.

5.4.4 Severe cardiorespiratory adverse events have been reported. These have included respiratory depression, apnoea, respiratory arrest and/or cardiac arrest. Such life-threatening incidents are more likely to occur when the medication is given too rapidly or when a high dosage is administered.

### 5.4.2 Reference case

5.4.2.1 The procedure was performed in a side room on a day-case ward. The side room is at the end of a bay and the only access to the side room is through the bay. The resuscitation trolley should have been located directly outside the room when the renal biopsy was performed, however it was located close to the nurses' station.

5.4.2.2 The only procedure undertaken on the day-case ward that requires intravenous sedation is renal biopsy and this occurs on average on the day-case ward around 100 times per year. The majority at the reference site are performed as in-patients on the in-patient ward.

5.4.2.3 The reference event site had a local policy for sedation in adults, however it did not have guidelines on safe sedation in children and young people under the age of 19.

5.4.2.4 The reference event site does have an integrated care pathway for children requiring admission undergoing a procedure requiring sedation. This is a five-page document and page one of this document gives instructions for completion.

5.4.2.5 The integrated care pathway was only partially completed by the senior nursing assistant and there was no medical assessment recorded.

5.4.2.6 The reference event site investigation did confirm that the administering doctor had the required evidence of training and competency, which included completion of a theoretical training course covering the principles of sedation practice and a record of practical experience of sedation techniques as recommended in the NICE guidance.

### 5.4.3 National investigation

5.4.3.1 The HSIB investigation team identified that no medications have a UK marketing authorisation specifically for sedation in young people under 19.
5.4.4 Analysis

5.4.4.1 HSIB investigators considered the conditions which existed before the reference incident occurred that contributed toward pre-existing deviation from national and local practice. As there was no guideline for safe sedation in children or the necessary emergency equipment within the immediate area, the child's care did not follow an established set of minimum safety standards.

5.4.4.2 The evidence suggests that due to the absence of a completed integrated pathway, the existing local standards were not followed.

Safety Action:
The reference event site has developed a safe sedation guideline for under 19s and reviewed the integrated care pathway for children undergoing a procedure requiring sedation.

5.4.4.3 The HSIB investigation findings highlight that local implementation of safety standards to improve patient safety are weak and suggestive of a culture whereby safety priorities are negotiable. This is exacerbated by competing priorities in implementing safety standards.

5.4.4.4 The HSIB investigation team identified that renal biopsies are performed in different environments dependent on the hospital; this could be as an out-patient on a day-case ward, in a radiology department or in a theatre. Some are performed by nephrologists and some by interventional radiologists. HSIB investigators discussed the reference case with the President of the British Association for Paediatric Nephrology (BAPN) regarding environments for elective renal biopsies in children. The BAPN President is also a Vice-President of the Renal Association, which is the umbrella organisation including both paediatric and adult nephrologists. There is no established standard for where such interventional procedures should be performed and there is a risk that recommendations made on this issue could have unintended adverse consequences on the number of elective procedures being performed. It was considered out of the scope of the investigation to explore this area further.

5.5 Workload and shift patterns

5.5.1 The NHS is consistently reporting pressures in the system and that there are ongoing operational demands for providing safe care (Robertson et al, 2017). The HSIB investigation team gathered information on workload to understand if this contributed to the reference event.

5.5.2 Reference case

5.5.2.1 During interview the investigation team was informed that in the weeks and months leading up to the incident, there was a known staffing problem, particularly in the renal service.

5.5.2.2 At the time of the incident the renal team was reported as being 2.5 whole time equivalent (WTE) doctors down on the established number of staff required. The consultant opined that the unit had been “chronically understaffed since the grid trainee17 had gone on maternity leave leaving gaps in the rota”. The investigation team was informed that it was difficult to fill the workforce requirements for the entire service and therefore consultants were having to take on the role of junior doctors during some weeks.

5.5.2.3 The prescribing doctor advised that in the weeks prior to the incident, he had completed two five-day weeks working at least 52.5 hours per week and had already completed two 12-hour shifts on the week of the occurrence. The prescribing doctor described feeling tired with minimal opportunity for rest breaks.

5.5.2.4 The prescribing doctor described himself as being the only doctor in the previous weeks doing the ward rounds and he was relieved and “felt really good” that another doctor was doing the ward round with him on the day of the incident.

5.5.2.5 The prescribing doctor had also experienced two stressful life events in the days leading up to the incident.

5.5.2.6 The consultant described how one of the doctors involved had made a minor error prior to the incident and was a nervous character who lacked confidence. However, he had no concerns about their professional capability.

17 A grid trainee in this scenario is a doctor training to be a nephrologist (a kidney specialist).
5.5.2.7 The prescribing doctor described the ward as being very busy on the day of the incident and recalled having to wait for a nurse to become available to assist with preparing the required medication.

5.5.2.8 The nursing staff recalled the ward being busy but "no busier than normal". The nurse staffing levels should have been four registered nurses and two health care support workers for the shift. However, on the day of the incident, one of the registered nurses became sick at short notice so only three nurses were on the ward.

5.5.2.9 The impact of the incident on all staff involved was recognised by the investigation team and the impact on the team preparing the medication was significant.

5.5.3 National findings

5.5.3.1 Similar incidents of inadvertent oral liquid medication into a vein refer to staff shortages. In some cases, student nurses and newly qualified nurses have been involved in Never Events and have not been trained or been competency assessed in all aspects of medicines safety. Staffing shortages and busy environments were repeatedly cited as contributory factors to errors occurring.

5.5.3.2 The British Medical Association undertook a survey in 2018 which reported that three quarters of doctors believe that the drive to meet financial targets is overriding patient safety (British Medical Association, 2018).

5.5.3.3 There are reports about the impact of stress on healthcare staff resulting in staff leaving the professions and suicide of staff (British Medical Association, 2019).

5.5.4 Analysis

5.5.4.1 NHS Digital produces a monthly report showing the number of NHS Hospital and Community Health Service (HCHS) staff groups working in trusts and CCGs in England (excluding primary care staff). Data is available as headcount and full-time equivalents (NHS Digital, 2018). The data are described as 'an accurate summary of the validated data extracted from the NHS's HR and Payroll system'.

5.5.4.2 The investigation contacted NHS Digital to establish the headcount and full time equivalent (FTE) of medical staff working in renal medicine at the reference site. This was a bespoke report and presented the information by grade to enable the identification of the different types of doctor for a two-year period from March 2016 as at the last day in each specified month. The report indicated that staffing had remained consistent.

5.5.4.3 The investigation could not correlate the feedback from staff (that is, that the renal team was 2.5 WTE medical staff short) and the data supplied by NHS Digital. However, the NHS Digital data does not account for sickness, maternity leave and annual leave.

5.5.4.4 Long working hours and stress can increase error (Harrington, 2001). For example, checking processes are at risk if ability, skills and vigilance are compromised. In this incident, the tired member of staff was one of those prescribing, preparing and checking the medication so had a particularly critical role.

5.5.4.5 A human factors expert stated that while it is not possible to make retrospective inferences about the mental condition of the prescribing doctor at the time of the occurrence, the individual’s compliant behaviour can be seen through the lens of selected items from the General Health Questionnaire (Goldberg, 1978). Staff suffering depression are more likely to report:

- difficulties being able to concentrate on what they are doing
- feeling that they are not playing a useful part in things
- losing self-confidence
- thinking of themselves as being worthless.

5.5.4.6 The human factors expert also commented that it seems likely that, in this state of mind, the propensity to challenge or question instructions from more senior colleagues would be reduced and compliance more likely.

5.5.4.7 Although beyond the scope of this report, there is a wealth of evidence that staff wellbeing is associated with patient safety.
outcomes (Hall et al, 2016) and that staff involved in errors and complaints have significant risks of moderate/severe depression, anxiety and suicidal ideation (Bourne et al, 2015). Similar findings have been reported in other high-risk industries (Day et al, 2012).

5.6 Training

Health Education England (HEE) is responsible for ensuring that there are high-quality learning environments for all healthcare learners. HEE’s Quality Strategy 2016 – 2020 (Health Education England, 2016a), and an associated multi-professional HEE Quality Framework, set out the expectations for quality within the work-based learning environment (Health Education England, 2016b).

5.6.1 Reference case

5.6.1.1 Nursing staff all reported up-to-date mandatory and role-specific training had been completed. This was confirmed by the leadership team.

5.6.1.2 The doctors in training have a training post for two years. The prescribing doctor was on a quarterly rotation programme. He had joined the Trust in June and had missed the routine doctors’ induction which is in February and August. The investigation team was informed that the administering doctor had moved to the specialty due to staffing shortages.

5.6.1.3 The investigation was advised that the induction for doctors in training had moved from a central induction to a local induction. As part of the local induction, doctors in training are given a book which provides guidance on common clinical conditions and interventions in renal medicine, including renal biopsy.

5.6.1.4 Training in medicines process is not task focused, it is profession focused, with different professional groups receiving different levels of training. Nurses shared how they undergo a competency training and assessment prior to being signed off as competent to administer medication. This was not the same for medics who described that most of their medicines training is accessed online and via “on the job” learning. The investigation team identified unequal training standards.

5.6.1.5 The Medication Safety Officer role (MSO) was established in 2014 to improve medication error incident reporting and learning and to serve as an essential component for the identification and implementation of local and national medication safety initiatives (NHS England, 2014). The MSO role did not appear to be well defined at the reference event site and it was unclear if the expectations of the role were being met.

5.6.2 National findings

5.6.2.1 The reference event findings were not isolated, and the investigation team heard from a range of healthcare staff that shared inconsistencies in training and competency.

5.6.2.2 When doctors rotate outside of the usual February and August intakes, induction training is ad hoc.

5.6.2.3 The investigation team was informed by staff at the reference site and other trusts that there is inconsistency in doctors’ training overall. The standard of evidence required to complete the junior doctors’ e-portfolio was also reported to be inconsistent and “lacked robustness”.

5.6.2.4 The investigation team has reviewed recommendations made in similar Serious Incident investigation reports. Contained therein are recommendations that staff require ‘more training’. While education and training are important, if healthcare safety is to improve a paradigm shift is needed to cultivate system-focused interventions (Royal Academy of Engineering, 2017) and design errors out. The introduction of PSA 19 anticipated doing exactly that, however the reference event and other reports of incidents of the inadvertent administration of an oral drug into a vein all have the ‘human in the room’ and this, combined with inconsistency in training and policy, means the alert has not eliminated the error.

5.6.2.5 Every doctor in training in England has access to SCRIPT eLearning modules. SCRIPT is a Health Education England (HEE)
resource to improve prescribing competency and the safer use of medicines (Health Education England, 2018a). The programme comprises 47 web-based eLearning modules relating to prescribing and therapeutics across a wide range of subject areas. Two of the modules relate specifically to the reference incident: ‘Dosing and Calculation’ and ‘Medication Errors’. The Medication Errors module discusses the use of oral syringes and provides examples of near misses and Never Events in relation to such wrong route errors. An example screen shot can be seen in Figure 16.

5.6.2.6 The modules are mandated in many regions across England and Wales, and the HEE resource is designed to standardise postgraduate education in relation to therapeutics. Currently the decision about how the learning is integrated into training is made at regional level, which may lead to inconsistency. A data capture from August 2016 to February 2019 shows the number of medical students and doctors in training that had completed the two relevant modules that link specifically to the reference case.

Trainee doctors:
- Medication Errors: 8,115 trainees completed the learning
- Dosing and Calculation: 5,200 trainees completed the learning.

Medical students:
- Medication Errors: 1,257 students completed the learning
- Dosing and Calculation: 2,674 students completed the learning.

5.6.2.7 The investigation identified inconsistencies in role definition at a national level when defining the role of a Medication Safety Officer. There is variation in the time allocated to the role and the banding of the individual. There appear to be no minimum standards for resourcing the role. In one Trust, for example, there is a dedicated team of staff working in medicines safety and able to fulfil the elements of the MSO role. However, in other organisations the role appears to be an add-on to the day job of a relatively junior pharmacist. There is therefore inequity in ability to fulfil the requirements of the role.
5.6.3 Analysis

5.6.3.1 There appears to be a lack of induction for trainees when they rotate between departments and hospitals every three months. The reference event site had come up with bespoke solutions to create training for the skills needed, but this led to inconsistencies compared to a doctor rotating in February and August. There was an emphasis on self-directed learning and e-learning.

5.6.3.2 There is variation in medicines process and safety training between the professional groups, despite all requiring an understanding of individual roles. The NHS report Building a Safer NHS, published in 2004 (Department of Health, 2004), recommended joint teaching at relevant stages within schools of medicine, nursing and pharmacy which would help to foster an understanding of the contributions different professions make to medication processes. The investigation team was informed that while this has started in some areas, it is variable and limited.

5.6.3.3 More recently in Supporting junior doctors in safe prescribing (Royal College of Physicians, 2017), there was an emphasis on the importance of multi-professional working, teams, and reporting and learning, with some examples of good practice; it did not directly address the area of preparation, administration or monitoring.

5.6.3.4 WHO reported that ‘Health care professionals sometimes prescribe and administer medicines in ways and circumstances that increase the risk of harm to patients’ (World Health Organization, 2017).

5.6.3.5 It was reported in the CQC report Opening the door to change (Care Quality Commission, 2018b), that ‘people we spoke with and the existing literature talked about the benefits of multidisciplinary training rather than training in individual clinical groups. Working and training as a multidisciplinary team is important for many reasons, not least because it can help to break down hierarchies’.

5.6.3.6 HEE and the professional regulators (including the General Medical Council, the Nursing and Midwifery Council, the General Pharmaceutical Council and the Health and Care Professions Council) have committed to work together to create opportunities to enable and empower interprofessional learning.

5.6.3.7 The General Medical Council is developing plans to establish a Medical Licensing Assessment (General Medical Council, 2019) to build on its existing assurance work to set a common threshold for safe practice. The new assessment will start in 2022. There may be an opportunity within the Medical Licensing Assessment to mandate as part of the Clinical Practical Skills Assessment stations coverage of some important therapeutic practical skills, for example the practical aspects of medication administration.

5.6.3.8 Recognising that training is people focused and at the bottom of the hierarchy of effectiveness (patientsafe, 2017), there is an opportunity for improved interprofessional education and training in medicines safety. This has been considered as part of the Medicines Safety Programme actions under domain 3 Healthcare Professionals, in which one of the actions is, ‘professional regulators must ensure adequate training in safe and effective medicines use is embedded in undergraduate training, and professional leadership bodies’ (Cattell, 2018).

5.6.3.9 Given the remit and anticipated launch of the Medicines Safety Programme actions in April 2019, no further recommendations have been made regarding undergraduate training.

5.6.3.10 The investigation team heard support for a requirement that interprofessional learning should be further developed during postgraduate training. Describing that such training, practice, and ongoing learning should cover the practical skills needed to use medicines safely, providing awareness of the established safety design systems and alerts that are intended to reduce error for all professions.

5.6.3.11 Within the report Supporting junior doctors in safe prescribing (Royal College of Physicians, 2017) the importance of multi-professional working, teams, and reporting and learning was emphasised. This supported the investigation findings...
in which the investigation heard from people who shared their thoughts that joint induction training of new staff in safe medication practices should be encouraged. It may be appropriate at the end of this induction period to assess competence in the skills required by each discipline to practise safely. Knowledge and skills relating to medication safety should be regularly updated through formal programmes of continuing professional development.

5.6.3.12 The Royal College of Physicians has a joint working group on medicines safety with the Royal Pharmaceutical Society, British Pharmacological Society, Royal College of General Practitioners, Royal College of Nursing, Royal College of Midwifery and NHS Improvement to ensure input from across the entire healthcare system.

5.6.3.13 Completion of SCRIPT modules is inconsistent, with each region mandating different modules depending on whether they have received Serious Incident reports or consider these high-risk areas. To improve consistency across England, it is considered appropriate that HEE should mandate more of the modules.

HSIB MAKES THE FOLLOWING SAFETY OBSERVATIONS

**Observation:**
SCRIPT is an eLearning programme to improve safety and competency among healthcare professionals around prescribing, therapeutics and medicines management. It would be beneficial to roll out SCRIPT as a mandatory requirement for all prescribers.

5.6.3.14 The level of seniority and time dedicated to the MSO role is not defined and the role has been implemented inconsistently (see 5.6.2.7). MSOs are usually pharmacists, but medication errors are usually made by doctors or nurses. The investigation was unable to discover if the impact of the MSO role had been evaluated.

HSIB MAKE THE FOLLOWING SAFETY RECOMMENDATION

**Recommendation 2019/030:**
It is recommended that the Royal College of Physicians, in collaboration with the Royal Pharmaceutical Society, British Pharmacological Society, Royal College of General Practitioners, Royal College of Paediatrics and Child Health, NHS Improvement, the professional bodies for the professions regulated by the Health and Care Professions Council, Royal College of Nursing and Royal College of Midwives, provide leadership in recommending the postgraduate learning needs and activities to standardise professional development in medicines safety processes.

**Recommendation 2019/031:**
It is recommended that NHS Improvement undertake a formal evaluation of banding, time and resource given to the Medication Safety Officer role across England and publish its findings and mandate minimum resources and standards.
6 ACTIONS RESULTING FROM THE LOCAL SERIOUS INCIDENT INVESTIGATION

6.1 The local Trust’s internal investigation into the reference event identified lessons learned which were subsequently put in to a detailed action plan.

The lessons learned included:

- A local safety standard should be developed for all invasive procedures including renal biopsies and any other procedures that include sedation. This should include the minimum staffing/skill-mix required.

- The risk assessments of procedures undertaken in a non-theatre setting should be reviewed.

- All staff administering medicines must be present throughout the preparation process. The administrator should be the first or second checker, not an observer.

- Compliance with NICE Clinical Guideline [CG112], Sedation in under 19s: using sedation for diagnostic and therapeutic procedures, should be assessed and improved as required.

- A policy and procedure for administration of safe intravenous sedation in children should be developed and implemented.

- The Medicines Policy regarding preparing, checking and administration of medication should be reinforced with staff and level of compliance with policy should be assessed.

- Awareness of barriers to prevent wrong route administration of medication, including Trust policies, should be increased via education so that staff are aware of ‘red flags’ that may highlight the need to consider the potential for an error.

- The ‘5 Rights’ checking process (right patient, right medication, right dose, right route, right time) should be reiterated to staff and general awareness of safe medicines procedures raised including use of purple syringes.

- The provision of emergency equipment in the immediate vicinity while undertaking intravenous sedation should be included as a requirement as part of the safe sedation in children policy.

- The processes in relation to ensuring the completion of aseptic non-touch technique (ANTT) training should be strengthened.

- The ward nursing staff should be trained in supporting renal biopsy procedures.
7 SUMMARY OF HSIB FINDINGS, SAFETY RECOMMENDATIONS AND OBSERVATIONS

7.1 The HSIB’s national investigation has reviewed the wider remit of wrong route medication and conducted an examination of the process of medicines storage, prescribing, preparation and administration.

7.2 The investigation has identified challenges with the medicines process. Monitoring and evaluation of previous intentions to improve medicines safety appears inconsistent and limited, resulting in a plethora of papers and reports referring to a lack of, and a need for, system-wide improvements. Some initiatives to prevent medication error, not specifically wrong route error, focus on the end user.

7.3 Figure 1 showed Reason’s model of accident causation as applied to medication errors in hospitals. The findings of the investigation are in accordance with the model.

7.4 Monitoring and evaluation of national patient safety actions, for example patient safety alerts and design and procurement of new equipment, is limited and where implemented is inconsistent, making it difficult to track progress and plan for continual learning for improvement.

7.5 Despite the national initiatives previously implemented, the repeated incidents of wrong route error of oral medication into a vein would suggest that there are opportunities for improvement. The case has highlighted an opportunity for wider system learning in relation to safe medications practice.

7.6 National investigation findings

1. Human factors can hinder the correct prescribing, preparation, verification and administration of medicines.

2. Administration of medicine via the wrong route is defined as a Never Event in the NHS, however, consistent human interactions are required to prevent it.

3. Using purple oral/enteral syringes doesn’t always prevent wrong route administration of medication.

4. Decanting medication from an oral/enteral syringe into an IV syringe is not an isolated event.

5. Some safeguards are in place on wards to reduce the risk of wrong route administration of medication, but these may fail due to local anomalies, such as staff shortages and lack of training.

6. Medication administration is complex with cognitive demands made on staff during critical stages. For example, interruptions, distractions and multi-tasking in the medicine administration process are common.

7. There is no national standard for second-person checking of medication preparation and administration.

8. There appears to be a lack of understanding about the use of oral/enteral syringes among doctors.

9. There appears to be a lack of understanding about the purpose of the colour coding of syringes among doctors.

10. The training of medical students and qualified doctors in the preparation and administration of oral and IV medicines is variable, with no formal mandatory standard drug administration training for doctors in hospitals.

11. While the national Prescribing Safety Assessment is now a mandatory requirement for medical students to graduate, it does not cover practical competencies such as the manipulation and administration of medicines.

12. IV syringes are used when oral/enteral syringes are not available.

13. IV syringes have been used when oral/enteral syringes are available.

14. Practice varies between healthcare facilities in how medicines and syringes are stored.

15. There is significant variation in how existing safety standards are implemented and continually monitored.
There has been no national assessment of the effectiveness of the patient safety alerts regarding the introduction of oral syringes.

There is variation in the time available and grade/experience of individuals designated as Medication Safety Officers. There has been no national assessment of the effectiveness of Medication Safety Officer roles.

Implementation strategies to support the integration of new systems and devices, for example training needs analysis and hazard identification exercises, are not systematically used and consistently applied.

The practice of labelling of syringes with the contents of the medicine is inconsistent.

Many organisations, including NHS Improvement, Health Education England, royal colleges and professional regulators, play a substantial role in medicines safety. However the current system is confused and complex with a lack of clarity of the roles of these organisations and their responsibilities for system-wide implementation of safety standards and the dissemination of messages concerning safety. This is despite the enthusiasm and commitment of the healthcare professionals and national bodies the investigation team consulted.

Interventions to improve medicines safety are challenging as they attempt to address complex interrelated human factors.

Recommendations identified in previous publications on improving medicines safety, dating back over a decade, appear to be challenging to implement and remain outstanding.

Guidance and standards on prescribing, preparation, checking and administration of medicines are fragmented and divided between a range of professional and NHS regulatory bodies.

Local medication policies and guidelines do not follow a consistent core framework linking the various strands of medicines use within the NHS.

7.7 Safety Recommendations

Recommendation 2019/028:
It is recommended that NHS Improvement, through the National Patient Safety Alert Committee, set standards for all issuers of patient safety alerts which make clear that alert issuers should assess for unintended consequences of the actions in the alert, the effectiveness of barriers created by these actions, and provide appropriate advice for providers on implementation, include ongoing monitoring.

Recommendation 2019/029:
It is recommended that NHS Improvement support the development of necessary knowledge, skills and capacity for the effective operationalisation of hazard identification and risk analysis at a national, regional and local level, as an integral part of the National Patient Safety Strategy.

Recommendation 2019/030:
It is recommended that the Royal College of Physicians, in collaboration with the Royal Pharmaceutical Society, British Pharmacological Society, Royal College of General Practitioners, Royal College of Paediatrics and Child Health, NHS Improvement, the professional bodies for the professions regulated by the Health and Care Professions Council, Royal College of Nursing and Royal College of Midwives, provide leadership in recommending the postgraduate learning needs and activities to standardise professional development in medicines safety processes.

Recommendation 2019/031:
It is recommended that NHS Improvement undertake a formal evaluation of banding, time and resource given to the Medication Safety Officer role across England and publish its findings and mandate minimum resources and standards.

7.8 Safety Observations

Observation:
It is recommended that staff with a responsibility for medicines safety, for example Medicines Management and Chief Pharmacists, Clinical Governance Leads, Heads of Medicines Optimisation and Medication Safety Officers are familiar with the contents of the existing National Institute for Health and Care Excellence clinical guidance on medicines optimisation and can demonstrate how they have implemented
the quality standard on medicines optimisation [QS120] and quality statement 3, ‘Learning from medicines-related patient safety incidents’.

**Observation:**
It would be beneficial to define a national standard for independent two-person checking when preparing high-risk medication for administration to minimise medication errors associated with high-risk medications.

**Observation:**
Availability of oral/enteral syringes in all clinical areas (in accordance with the requirements contained in the National Patient Safety Agency’s Patient Safety Alert 19) is inconsistent. A national audit tool may be helpful to organisations.

**Observation:**
Colouring of high-risk and/or oral liquid medications (such as midazolam) may have a justifiable role in improving safety as it will offer a signal to differentiate oral from parenteral preparations.

**Observation:**
It would be beneficial if potential interventions designed to reduce wrong route administration medication errors were subjected to human factors testing, review, evaluation and modification prior to being introduced at scale; this includes standards, processes, and the design of medication and administration devices.

**Observation:**
SCRIPT is an eLearning programme to improve safety and competency among healthcare professionals around prescribing, therapeutics and medicines management. It would be beneficial to roll out SCRIPT as a mandatory requirement for all prescribers.

**Observation:**
There is an opportunity with the new General Medical Council Medical Licensing Assessment to mandate additional therapeutic practical skills for example, the practical aspects of medicines administration, as part of the Clinical Practical Skills Assessment.

### 7.9 Safety Actions carried out and/or in progress

**Safety action:**
The Trust where the reference event occurred removed an inaccurate notice affixed to the inside of a controlled drugs cupboard and reviewed its storage arrangements.

**Safety action:**
In January 2019 the Specialist Pharmacy Service published its Medicines Governance Do Once Programme, which includes a plan to develop national templates for medicines-related policies for adaptation and adoption within NHS organisations and other publicly funded commissioned services.

**Safety action:**
The Royal Pharmaceutical Society has produced and published professional guidance on the administration of medicines for use by all healthcare professionals.

**Safety action:**
NHS Improvement is working towards a formal launch of the National Medicines Safety Programme in April 2019.

**Safety action:**
The reference event site has acted upon the requirement for a Local Safety Standard for Invasive Procedures (LocSSIP): ‘...a Local Safety Standard (LocSSIP) should be developed for all invasive procedures including renal biopsies and any other procedures that include sedation. Including minimum staffing/skillmix required’.

**Safety action:**
HSIB, supported by a teaching hospital, has produced a reconstruction of events and a simulation of what happened during the reference event along with a supplementary teaching aid to increase awareness of this type of error.

**Safety action:**
The reference event site has developed a safe sedation guideline for under 19s and reviewed the integrated care pathway for children undergoing a procedure requiring sedation.
By: Dr RS Bridger, Ph.D, Fellow CIEHF

Specialist Field: Human Factors
On behalf of: Knowledge Sharing Events
On the Instructions of: HSIB
Subject Matter: Medication Error

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1 Qualifications and Professional Expertise

1.1 I am a Fellow of the Chartered Institute of Ergonomics and Human Factors, qualified to Ph.D level and with over 35 years’ experience in the field. I have recently provided HF support to:

1.1.1 A Service Inquiry into an incident involving HMS AMBUSH in 2016.

1.1.2 A Fleet Commander’s Safety Investigation into the electrocution of an Engineer while deployed in the Mid-Atlantic whilst serving as a panel member in 2017.

1.1.3 A Fleet Commander’s Safety Investigation into a hard landing of a WILDCAT helicopter on a ship at sea as HF Advisor.

1.1.4 I received training as an Expert Witness at Gray’s Inn in 2007 and have received instructions from Government Legal (formerly the Treasury Solicitors’ Office) on five occasions since 2009.

1.2 I am the author of over 250 articles in peer-reviewed journals, official reports and conference proceedings. I am sole author of the textbook, ‘Introduction to Human Factors and Ergonomics’ now in its fourth edition and published by CRC Press.

1.3 For further information about my qualifications and experience, please visit my website www.rsbridger.com

2 Instructions Received and Evidence Reviewed

2.1 I am instructed to act as a Human Factors expert in the investigation of an incident on 2 Aug 17. I have reviewed the local Trust Serious Incident Investigation Report Level 2. In addition I have reviewed the following documents related to the case:

1 National Safety Standards for Invasive Procedures. 7 Sept 15.

2 Practical guide to reducing medication errors. Towards zero tolerance.

3 Safe Medication practice – what can we learn from root cause analysis and related methods. 20 Oct 16.


6 Medication Errors. Commonwealth Fund International Health Policy Survey.

7 Medication without harm. WHO Global Patient Safety Challenge.

8 Provisional publication of never events date 27 Feb 17 NHS improvement. Stats on never events.

9 NMC PB-STMM-A5-0410. Standards for Registrants.

10 Promoting safer measurement and administration of oral liquid medicines March 2007.

2.2 I have attended a preliminary meeting at the HSIB offices in Farnborough on 15 Jan 18 and have reviewed recordings of interviews with:

The ST6-8 (Specialist Trainee)
The Consultant Nephrologist
The ST1-3 (Speciality Trainee)
Nurse A, The Dispensing Nurse on Ward
The Clinical Practice Educator
2.3 I attended a reconstruction of the actual events and a simulation of what should happen on 23 Mar 18.

2.4 My report is based on the evidence I have reviewed and makes reference to research on human factors in safety where this supports the analysis and any recommendations that HSIB may wish to make.

2.5 I have not been able to review other sources of information relevant to the case. These include: any safety precautions when medicines are purchased including consideration of Human Factors; findings of any human factors activities trials of purple syringes and any HF activities undertaken to assess risk prior to their introduction (e.g. Human Factors Integration; training needs analyses; records of user consultation; feedback).

3 Terminology

3.1 In this report, I use the following terms:

3.1.1 System Safety: The application of controls to eliminate hazard or their effects during system design and operation (‘safe to operate’ and ‘operated safely’)

3.1.2 A Safety Constraint (Leveson, 2011) is any constraint that specifies a specific safeguard. Safety involves controlling what happens next during system operation. Safety constraints limit what can happen next.

3.1.3 A Latent Hazard is defined as a hazard of which staff are not aware. Latent hazards are akin to dormant viruses that only become apparent when activated by other factors. The oral and IV forms of midazolam do not conform to HF principles and might be regarded as a latent error in the process of procuring medicines.

3.1.4 Performance Shaping Factors (PSFs) (Croskerry & Cosby, 2009): Those influences that enhance or degrade human performance. Internal PSFs are influences that the individual brings to the situation such as mood, fitness, stress level, etc. External PSFs are influences in the situation or environment that affect the individual such as temperature, noise, work practices, etc. Particular combinations of PSFs can cause a latent hazard to activate leading to a safety occurrence when safety constraints are defeated.

4 Brief Narrative of Events

4.1 This report should be regarded as supplementary to the HSIB final report, therefore only a brief outline of the events is presented.

4.2 Patient A was admitted for an elective renal biopsy with conscious sedation. This is to ensure the child is as comfortable and pain free as possible during the procedure, without the requirement for a general anaesthetic. Midazolam was the medication used. The ST6-8 requested IV midazolam which the ST1-3 obtained. The ST1-3 obtained flumazenil (the antidote to midazolam) from an adjacent ward. Returning to the ward where the procedure was taking place, and after a delay of approximately 15 minutes, the ST1-3 found a nurse to obtain and prepare the midazolam. The Nurse who dispensed the midazolam was accustomed only to dispensing oral midazolam. She prepared the medication in a purple syringe for oral administration in front of the ST1-3. The ST1-3 took the medication to the side room where the procedure was being performed. The nurse did not accompany the ST1-3 to the side room. The ST1-3 handed the medication to the ST6-8 to administer, in breach of policy as she had not been involved in any part of the prescribing, preparation or checking process. The ST6-8 attempted to inject the contents of the purple syringe into the patient’s cannula but the attempt failed because the purple syringe is designed such that it cannot be connected to a cannula. She then instructed the ST1-3 to decant the contents of the syringe. The nurse who had been involved in
the preparation of the medication queried why the midazolam was in an IV syringe and escalated to a colleague that the oral midazolam she had recently dispensed had been given intravenously.

5 Systems Analysis: Summary of Human Factors and Risk Management

5.1 The Human Factors Analysis outlined below considers the contributory human factors in relation to the incident.

5.2 Midazolam is procured in IV and oral forms. Both are colourless liquids and both are referred to as ‘midazolam’. This is a Latent Hazard introduced on delivery. Safety constraints are put in place to minimise the risk of a safety occurrence caused by the hazard.

5.3 Packaging of the two forms is the first safety constraint in place to prevent exposure to the hazard. The IV form is stored in ampoules and the oral form in bottles. This physical coding separates the two forms and is easily understood.

5.4 This constraint is subsequently undermined by dispensing both forms of midazolam into syringes, effectively ‘joining them up again’ at a conceptual level. Although protective incompatibility is built into the syringes it is incomplete. It is unlikely that the purple syringe could be filled from an ampoule, whereas the IV syringe can be filled from a bottle (this appears to have occurred in other safety occurrences). Similarly, the purple syringe cannot be connected to a cannula but the IV syringe could be used to introduce medication orally. The syringes have different diameters preventing the interchange of plungers either deliberately or by mistake.

5.5 The incident occurred due to the failure of 5 successive safety constraints:

5.5.1 The dispensing nurse provided oral midazolam because she was accustomed only to use oral midazolam on her ward, despite the correct route information being given on the prescription record. This was a lapse of attention under the operation of a local norm.

5.5.2 The ST1-3 did not challenge the dispensing nurse when given oral midazolam in the purple syringe. At interview, he explained that he lacked the knowledge to do so. He appears not have understood the meaning of the purple syringe thus defeating the safety constraint.

5.5.3 The team in the room where the procedure was being performed did not question the ST6-8 when she administered the midazolam despite her being absent for any of the checking procedure. This was contrary to policy and may be a knowledge-based mistake exacerbated most likely by a lack of teamwork and effective communication.

5.5.4 The ST6-8 proceeded to connect the purple syringe to the cannula but was defeated by the protective incompatibility.

5.5.5 She then asked for the midazolam to be decanted into an IV syringe, therefore defeating the protection. If it is assumed that neither the ST1-3 or the ST6-8 understood the significance of the purple syringe this is a mistake, rather than a violation.

5.6 The incident occurred after the 5 safety constraints were defeated. If all of these safety constraints were independent of each other and each had a failure probability of 1/100 then the probability of them all failing would be 1/1010 or one in ten billion. Between 1 April 2016 and 30 November 2017, there were 61 reported wrong route medication errors. This suggests the safety constraints described above are vulnerable to the same PSFs in wards. Like dominos lined up close together, when one fails, they all fail.

5.7 From a systems perspective, then, safety can be improved by changing the work environment to minimise the effect of these factors or by introducing new safety constraints that are not susceptible to the same PSFs – for example, safety measures that do not depend on teamwork and a shared understanding of the process.
6 Human Factors Analysis of the Incident

6.1 Key human factors lessons have been identified and these centre on the failure of multiple successive safety constraints, put in place to control a latent hazard arising from the form and packaging of medication. These safety constraints failed when individual and organisational factors combined to degrade system performance.

7 Intra-Venous Administration of Oral midazolam

7.1 The ST6-8 was given a syringe with a purple plunger containing the oral form of midazolam. She proceeded to connect the syringe to the cannula in order to inject the contents into a vein. These syringes have protective incompatibility – they cannot be connected to a cannula. When this action was negated by the protective incompatibility, she asked the ST1-3 to decant the midazolam into an IV syringe. When this had been done, she connected the IV syringe to the cannula and proceeded to inject oral midazolam into the vein, (approximately 1.5 ml or 3.5 mg). However, due to the viscosity of the oral form of midazolam, she encountered resistance. Upon leakage of the contents, she sensed that the medication was incorrect. Her next action was to flush the cannula with saline and requested the ST1-3 to check with the nurse if it was IV midazolam.

7.2 Norman’s Human Action Cycle in Goal Attainment (Norman, 1981) can be used to analyse these actions.

7.2.1 Goal formation: the goal was to inject a sedative prior to a kidney biopsy.

7.2.2 The tasks required to attain the goal were to obtain IV midazolam and inject it into the patient.

7.2.3 The action sequence was initiated. Feedback was received from each action to indicate that the actions were unsuccessful but this feedback was not detected by the ST6-8.

7.2.4 On detecting that the medication was not as intended, the action sequence ceased.

7.3 There are three mechanisms by which people detect their own errors (Sellen, 1994). Action-based detection occurs when the person detects incorrect actions as they are being performed. This requires that the person attends to feedback from the task and understands what the feedback means. Process-based detection occurs when events in the real world ‘short-circuit’ the action sequence (as did the protective incompatibility in the purple syringe). Outcome-based detection occurs when the former two processes fail and the error is made apparent by its consequences (e.g. when a teabag floats to the top of a cup of coffee that has just been poured).

7.4 In the current example, Outcome-based Detection halted the action sequence despite the presence of at least 5 earlier cues concerning: the significance of the purple syringe indicating that the contents were for oral administration only; the absence of a label on the syringe; the protective incompatibility indicating that the contents were not to be injected into the cannula; the viscosity of the oral medication when decanted and on attempting to inject it.

7.5 In order for outcome-based detection to succeed, the person must attribute any mismatches between desired and expected outcomes to their own actions and not to hardware or extraneous factors. That the ST6-8 proceeded to flush the cannula is indicative of the latter possibility, most likely due to a knowledge-based error.

7.6 Knowledge-based errors are errors in thinking, in this case due to a lack of understanding of the equipment used in an action sequence or of the processes or policies underlying its use. In this case, understanding the significance of the purple plunger in the oral syringe. Such an error explains why the ST6-8 did not read the word ‘ENTERAL’ printed on the side of the syringe (reading anything written on the syringe was not part of the ‘a-priori’ action sequence). This line of reasoning suggests that having syringes with the word ‘ENTERAL’ printed on them will be of limited effectiveness in preventing knowledge-based errors.
The ST6-8 stated at interview that she expected the syringe to contain IV because that is what she asked for. These expectations remained unchanged despite multiple cues to the contrary and that the purple syringe cannot be filled from an ampoule. This is evidence that the ST6-8 had some significant knowledge gaps about the design of oral syringes and procedures for dispensing medication and may never have filled a purple syringe herself. On examination, it appears that the only way for a purple syringe to be filled with IV medication is for the plunger to be removed and the contents of the ampoule decanted into the orifice before replacing the plunger, or from an IV syringe. Both of these are violations of correct procedure. This also suggests a lack of knowledge of the procedures for dispensing medication and the practices of other team members. This is discussed further in a following section under ‘Teamwork’.

**The ST1-3**

**8.1** The ST1-3 was sent to obtain the medication required for the procedure. Due to absences of staff and workload, there were delays and he went to the adjacent ward whereby he obtained the antidote. He was familiar with the ward and the staff on that ward. On return to the day case ward, he obtained assistance from a nurse to prepare the prescribed IV midazolam medication. The nurse and the ST1-3 checked the dose. The nurse then dispensed the required amount of oral midazolam into the purple syringe. At interview the ST1-3 stated that he did not understand the procedures for dispensing medicines to children or the meaning of the purple syringe. This may explain why she did not respond to the fact that the medication was drawn from a bottle rather than an ampoule, why the nurse did not label the syringe and why he accepted the medication in an unlabelled syringe.

**8.2** During the administration of the medicine to the patient by the ST6-8, the ST1-3 did not challenge the ST6-8’s request to decant the medication from the purple syringe into an IV syringe. Again this may reflect a lack of knowledge and/or the operation of other performance shaping factors.

**8.3** In the weeks prior to the occurrence, the ST1-3 had completed two 5-day weeks working at least 52.5 hours per week and had already completed two 12 hour shifts on the week of the occurrence. He had also experienced two stressful life events and may have been depleted and/or depressed. Whilst it is not possible to make retrospective inferences about the mental condition of the ST1-3 at the time of the occurrence, his compliant behaviour can be seen through the lens of selected items from the General Health Questionnaire (Goldberg, 1978). Staff suffering depression are more likely to report:
- Difficulties being able to concentrate on what they are doing
- Feeling that they are not playing a useful part in things
- Losing self-confidence
- Thinking of themselves as being worthless

**8.4** It seems likely that, in this state of mind, the propensity to challenge or question instructions from more senior colleagues would be reduced and compliance more likely. There may have been deeper Performance Shaping Factors in the form of ‘presenteeism’ (attending work while unwell, often related to feelings of insecurity about one’s job). Although beyond the scope of this report, there is a wealth of evidence that poor staff well-being is associated with worse patient safety (Hall et al, 2016). Similar findings have been reported in other high risk industries (Day et al, 2012).

**9.1** A number of cues were either missed or ignored. The prescription clearly stated that the route for the administration was IV, not oral but Nurse A did not detect the information. The oral midazolam was stored in a bottle from where the purple syringe was filled, whereas IV midazolam is stored in ampoules. The ST1-3 did not respond to the cue that the syringe was filled from a bottle, was not labelled, that the Nurse did not accompany him to the side room where the procedure was being
performed to check the patient wristband and that the ST6-8 who administered the medication had not been involved in any aspect of the preparation process. Further evidence of knowledge-based errors and one violation appear to have occurred (not accompanying the ST1-3 to the side room where the procedure was being performed to check the identity of the patient).

9.2 The behaviour of Nurse A may have been due to the operation of informal norms taking precedence over policy. Since midazolam, in Nurse A’s experience, was only prescribed in oral form on the day case ward, the assumption that the prescription was for oral midazolam would make it less likely that the Nurse would check the prescription form in detail, only the parts of the form relevant to the prescription of oral midazolam. This set the scene for the administration of oral midazolam by the ST6-8.

10 Communication and Teamwork

10.1 It was apparent from the simulation that there is a significant amount of communication between team members when the correct procedures are followed. From the reconstruction of events and the evidence reviewed, this interaction appeared to be lacking on the day the incident took place.

10.2 It was noteworthy during the reconstruction that the Consultant Nephrologist said very little during the procedure, appearing to be engaged almost entirely with preparing the patient for the biopsy. At interview, the Consultant stated that he regarded the ST6-8 as being sufficiently experienced to administer the sedative.

10.3 This may reflect the operation of a surgical model to the procedure, where the surgeon and anaesthetist have distinct roles and different goals. In effect, the model of teamwork may not have been appropriate to the procedure.

10.4 One of the characteristics of effective teamwork is that team members share a common goal, have shared understanding of key elements needed to reach the goal (a shared mental model of the overall process) and know what to expect from fellow team members. From the evidence reviewed, it appears that the procedures for dispensing oral and IV medications and the use of syringes with clear and purple plungers is well-understood by nurses but less-well understood by doctors as is the process by which medications are dispensed.

10.5 The ST6-8 stated at interview that she thought the purple syringe contained IV medication because that is what she asked for - indicative of a lack of understanding of the overall process. The procedure was paused whilst clarification was sought on whether the medication was intravenous. This lack of understanding is also consistent with the fact that it was the nurse who prepared the midazolam with the ST1-3 who escalated the occurrence on realising that the oral midazolam has been decanted into an IV syringe.

10.6 A final observation concerning teamwork and communication concerns cues that were either not detected or not shared with colleagues throughout the process. None of doctors in side room where the procedure occurred commented on the fact that only the ST1-3 returned to the side room with the midazolam and that he was not accompanied by the nurse who it was prepared with to check the identity of the patient. Nor did anyone consider or challenge that the ST6-8 administered the medication despite not being present for the whole of the preparation process (in breach of procedure). Neither the ST1-3 nor the consultant queried the instruction to decant the midazolam into the IV syringe. In particular, the consultant appears, in the simulation, to have been completely engaged with the patient and unaware of the difficulties experienced by his colleagues in administering the sedative.

10.7 It is noteworthy that on the day of the occurrence, the Practice Nurse Educator was absent. He is normally involved in elective renal biopsies and would undertake all of the preparation including drawing up of the midazolam (maximum dose for the child) and the antidote Flumazenil. He would then check who is going to administer the medication and all of the
medications with them, remaining and assisting with the procedure throughout. He was working on a transplant ward on the day of the procedure. Effective teamwork appears to have been over-reliant on one team member.

11 Summary and Conclusions

11.1 The root cause of the occurrence was the presence of a latent hazard due to the physical similarity of the two forms of midazolam, which cannot be differentiated at critical points in their administration when distal safety constraints fail. The PSFs that led to the occurrence are not new and have been cited before in official documents concerning invasive procedures, as listed at the beginning of this report.

11.2 Syringes were developed to meet the requirement to introduce medication into tissues beneath the skin. They appear to have been adapted to meet an additional requirement – to administer oral medicines by mouth or gastric tubes. Whilst it is often efficient when a solution that meets one requirement is adapted to meet another, in the case of medications new hazards are introduced because the oral and IV medicines can be put into the wrong syringe. Steps to minimise the risk have been made (the oral syringes have purple plungers, a different diameter and protective incompatibility to prevent them being connected to needles and cannulae) but the protection is incomplete and does not appear to be sufficiently well-understood by the doctors involved.

11.3 Given that PSFs associated with occurrences of this nature have already been identified in previous reports and the administration of medication via the wrong route continues to take place, a systems approach to patient safety with greater emphasis on the identification and removal of hazards may be of value. The main areas for consideration are:

11.3.1 Form and appearance of oral and IV medicines – remove latent hazards

11.3.2 Alternative means of administering oral medicines when these must be in liquid form

11.3.3 Appropriate training for team members to ensure understanding of safety constraints

11.3.4 Better teamwork and communications
9 APPENDIX B
PROFESSIONAL REGULATORS

Nursing and Midwifery Council (NMC)
The NMC is the regulator for nursing and midwifery professions in the UK. The NMC maintains a register of all nurses, midwives, specialist community public health nurses and nursing associates eligible to practise within the UK (England only for nursing associates). It sets and regularly reviews the standards for their education, training, conduct and performance.

All NMC registrants must practise in line with the requirements of the NMC Code (Nursing and Midwifery Council, 2015). This states at section 18 that they must advise on, prescribe, supply, dispense or administer medicines within the limits of their training and competence, the law, NMC guidance and other relevant policies, guidance and regulations.

In May 2018 the NMC published new standards of proficiency for nurses, which describe what nurses need to know and be able to do to access the NMC register (Nursing and Midwifery Council, 2018a). It also published new education and training standards for nurses, midwives and nursing associates (Nursing and Midwifery Council, 2018b). These are the standards that set out how the standards of proficiency should be taught. In addition, new standards for nurse and midwife prescribing programmes have been published. The standards came into effect on 28 January 2019 (Nursing and Midwifery Council, 2018c). The NMC’s previous prescribing standards and circulars were withdrawn for practice purposes from that date but will remain available for education and research purposes only for a transition period until September 2020.

Along with the new standards for prescribing programmes, the NMC has also adopted the Royal Pharmaceutical Society’s Competency Framework for all Prescribers (Royal Pharmaceutical Society, 2016a). This will be used not only to set the outcomes for prescribing programmes going forward but will also serve as the NMC’s core guidance on prescribing practice and set the benchmark for what safe and effective prescribing practice looks like. This became effective from 28 January 2019.

The NMC previously provided Standards for Medicines Management (Nursing and Midwifery Council, 2007). These standards were in operation at the time of the reference site incident. These standards were withdrawn in January 2019, as it is not considered to be within the NMC’s remit as a regulator to advise or provide guidance on clinical practice matters such as medicines management. Instead, the NMC now signposts registrants via its website to up-to-date guidance published by a range of organisations that produce information on medicines management issues.

This includes the Royal Pharmaceutical Society’s guidance titled Safe and Secure Handling of Medicines (Royal Pharmaceutical Society, 2018), the joint Royal Pharmaceutical Society/Royal College of Nursing Guidance on the Administration of Medicines in Healthcare Settings (Royal Pharmaceutical Society & Royal College of Nursing, 2019), and Health Education England’s Advisory Guidance on the Administration of Medicines by Nursing Associates (Health Education England, 2018b). The NMC also signposts to a variety of organisations and websites where further information on medicines can be accessed, such as the National Institute for Health and Care Excellence and the British National Formulary.

General Medical Council (GMC)
The GMC is the independent professional regulator for doctors in the UK.

The GMC has a good practice guide titled Good Practice in Managing and Prescribing Medicines and Medical Devices (General Medical Council, 2013). The GMC good practice guide sets out guidance that doctors should adhere to when administering medicines. It sets out that doctors are responsible for the prescriptions they sign and for their decisions and actions when they supply and administer medicines or instruct others to do so. Doctors must be familiar with the guidance in the British National Formulary (BNF) and British National Formulary for Children (BNFc). They must also take account of relevant clinical guidelines. Doctors should also ensure that anyone to whom they delegate responsibility for administering medicines is competent to do so.

General Pharmaceutical Council (GPhC)
The GPhC is the regulator for pharmacists, pharmacy technicians and pharmacies in Great Britain. The GPhC sets standards for pharmacy professionals and pharmacies to enter and remain on its register (General Pharmaceutical Council, 2019). It seeks
assurance that pharmacy professionals and pharmacies continue to meet its standards.

Health and Care Professions Council (HCPC)
The HCPC currently regulates the following professionals: arts therapists, biomedical scientists, chiropodists/podiatrists, clinical scientists, dietitians, hearing aid dispensers, occupational therapists, operating department practitioners, orthoptists, paramedics, physiotherapists, practitioner psychologists, prosthetists/orthotists, radiographers, social workers in England and speech and language therapists.

It keeps a register of health and care professionals who meet its standards for training, professional skills, behaviour and health. Its website explains the medicines and prescribing rights of the professionals that it registers (Health and Care Professions Council, 2018).
**APPENDIX C OTHER NON-REGULATORY PROFESSIONAL BODIES AND STANDARDS RELEVANT TO THE INVESTIGATION**

**Royal Pharmaceutical Society (RPS)**
The RPS is the professional membership body for pharmacists and pharmacy in Great Britain. The RPS provides professional standards which are developed and owned by the profession that describe good practice, systems of care or working (Royal Pharmaceutical Society, 2019).

To support all prescribers to prescribe effectively a single prescribing competency framework was published by the National Prescribing Centre/ National Institute for Health and Clinical Excellence (NICE) in 2012. Based on earlier profession-specific prescribing competency frameworks, the framework was developed because it became clear that a common set of competencies should underpin prescribing regardless of professional background. The 2012 framework is now in wide use across the UK (see ‘Uses of the framework’ – Section 3) and was due for review in 2014. NICE and Health Education England approached the RPS to manage the update of the framework on behalf of all the prescribing professions in the UK. The RPS has a competency framework for all prescribers (Royal Pharmaceutical Society, 2016a) which has been adopted officially by the Nursing and Midwifery Council. The Royal College of Physicians states that junior doctors should be signposted to the competency framework and the Health and Care Professions Council is also interested in the standards.

**British Pharmacological Society (BPS)**
The BPS is a charity with a mission to promote and advance the whole spectrum of pharmacology. It champions safe and effective prescribing and promotes activities, led by clinical pharmacologists and allied healthcare professionals, to improve patient care and safety related to medicines usage. The BPS worked with the Medical Schools Council to develop the Prescribing Safety Assessment (British Pharmacological Society, 2016). The Prescribing Safety Assessment is an online assessment of competency in the safe and effective use of medicines. All foundation doctors are required to pass the Prescribing Safety Assessment before being signed off as having successfully completed the Foundation Year 1 (FY1) year and being awarded the Foundation Year 1 Certificate of Completion (FY1CC). If the Prescribing Safety Assessment was passed more than two years before starting foundation training then it will need to be successfully retaken before completion of the FY1 year (Medical Schools’ Council Assessment & British Pharmacological Society, 2018) (applies from August 2016 FY1 entry).

The BPS has online training tools for all NHS doctors and trainees to practise their prescribing skills.

**Royal College of Nursing (RCN)**
The RCN represents nurses and nursing, promoting excellence in practice, shaping health policies (Royal College of Nursing, 2019).

**Royal College of Midwives (RCM)**
The RCM is the only professional organisation and trade union dedicated to serving midwifery and the whole midwifery team. The RCM provides workplace advice and support, professional and clinical guidance and information, and learning opportunities with a broad range of events, conferences and online resources (Royal College of Midwives, 2019).

**Royal College of Physicians (RCP)**
The RCP’s core mission is to drive improvements in health and healthcare through advocacy, education and research. The RCP raises healthcare standards by setting training curricula and exams for physicians and by developing NICE-accredited guidelines for high-quality care (Royal College of Physicians, 2019).

**UK Clinical Pharmacy Association (UKCPA)**
The UKCPA provides practitioner-led education and training for the pharmacy workforce and is accredited as a training provider by the Royal Pharmaceutical Society. The UKCPA has several specialist interest educational groups, one of which is the UKCPA Medicines Safety and Quality Group. The group has a wide remit, and focuses on areas such as managing risk, reducing errors and incident reporting. The group regularly shares its expertise through UKCPA learning events.
Institute for Safe Medication Practices (ISMP)
The ISMP is a non-profit organisation based in the USA, devoted entirely to preventing medication errors. In 2014 the ISMP produced a list of high-alert medications in acute settings. High-alert medications are medications that bear a heightened risk of causing significant patient harm when they are used in error. This list is periodically updated, and it is anticipated that hospitals use the list to determine which medications require special safeguards to reduce the risk of errors. This may include strategies such as standardising the ordering, storage, preparation and administration of these products; improving access to information about these medications; limiting access to high-alert medications; using auxiliary labels and automated alerts; and employing redundancies such as automated or independent double checks when necessary.

NHS Specialist Pharmacy Service (SPS)
The NHS SPS supports medicines optimisation across the NHS. The SPS produced an overview of NHS Procurement of Medicines and Pharmaceutical Products and Services for acute care in the United Kingdom (Specialist Pharmacy Service, 2017). The guidance provides an overview of the current arrangements for the procurement of medicines and pharmaceutical products and services in the UK. It includes an overview of arrangements for NHS England, NHS Scotland, NHS Wales and Health and Social Care Northern Ireland. In the NHS in England, medicines procurement is managed through 10 regional pharmacy purchasing groups. There is no reference made to human factors considerations in the procurement overview.

Europeans Medicines Agency (EMA)
The EMA is a decentralised agency of the European Union (EU), currently located in London. The Agency is, among other national agencies, responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU (European Medicines Agency, 2017).

The EMA, in collaboration with the EU regulatory network, was mandated to develop regulatory guidance for medication errors. This guidance is intended to support the implementation of the new legal provisions regarding the reporting, evaluation and prevention of medication errors (European Medicines Agency, 2015a). The key recommendations of the guidance include:

- The potential for medication errors should be considered at all stages of the product life cycle but particularly during product development.
- To minimise the risk of medication errors:
  - careful consideration should be given to the name and pharmaceutical design of a medicinal product (including its type of dosage form, appearance and other formulation characteristics, packaging and labelling) in order to minimise the risk of mix-ups between different products
  - the product information should inform healthcare professionals, patients and caregivers of the most appropriate use of the product
- Where medication errors result in adverse outcomes, corrective actions should be taken.

Medical Schools Council (MSC)
The MSC is the representative body for UK medical schools. The Council consists of the heads of UK medical schools and meets to shape the future of medical education in the UK (Medical Schools Council, 2018).

As well as the heads of medical schools, other groups meet under the auspices of the MSC to provide expert opinion on areas of medical education and research.

Together these groups form a body of experts which can define policy, share best practice and run national projects. Through its assessment arm, MSC Assessment, the Council is involved in delivering the Prescribing Safety Assessment.

Other
The list above includes just a few of the groups and societies that contribute to medicines safety. There are many others and the list should not be seen as exhaustive.
11 APPENDIX D LICENSING OF ‘SPECIALS’

‘Specials’ are a category of unlicensed medicines that are manufactured or procured specifically to meet the special clinical needs of an individual patient. Prescribers and pharmacists both have a responsibility to ensure that where specials are prescribed they are the most appropriate choice and patients are supported to use them effectively. The Royal Pharmaceutical Society (RPS) has published updated professional guidance for the prescribers of specials (Royal Pharmaceutical Society, 2016) which is endorsed by the Royal College of General Practitioners, the Academy of Medical Royal Colleges and the Royal College of Nursing. The guidance aims to support prescribers in all professions and in all care settings in the safe and appropriate prescribing of specials.

The supply chain encompasses manufacturing, prescribing, procuring and dispensing of specials. Pharmacists throughout the whole of the supply chain have a responsibility for procuring and supplying specials in a professional manner. RPS guidance for the procurement and supply of pharmaceutical specials (Royal Pharmaceutical Society, 2015) aims to support pharmacists and their teams to work with prescribers, patients and carers to ensure the safe and appropriate procurement and supply of specials. The RPS has also produced guidance to support pharmacists with the pharmaceutical issues to consider with crushing, opening or splitting oral dosage forms.

The use of specials presents the NHS and patients with specific challenges, particularly when patients move between care settings. The importance of ensuring that patients and prescribers are aware of the complexities and risks associated with transferring the prescribing and supply of specials across settings is also emphasised in this guidance.
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