HSIB

HEALTHCARE SAFETY INVESTIGATION BRANCH

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## SUMMARY REPORT

# INADVERTENT ADMINISTRATION OF AN ORAL LIQUID MEDICINE INTO A VEIN

I2017/009

Independent report by the
**Healthcare Safety Investigation Branch**

April 2019 Edition


HSIB
HEALTHCARE SAFETY
INVESTIGATION BRANCH

# PROVIDING FEEDBACK AND COMMENT ON HSIB REPORTS

At HSIB we welcome feedback on our investigation reports. The best way to share your views and comments is to email us at **enquiries@hsib.org.uk**

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Please email us at **enquiries@hsib.org.uk**. We aim to provide a response to all correspondence within five working days.



# 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 though:

- 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[1], 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'[2] 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'[3] 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.

[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.

[4] A Luer lock syringe allows fixation by screw fitting to administer intravenous medication.

16 There has been no national assessment of the effectiveness of the Patient Safety Alerts regarding the introduction of oral syringes.

17 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.

18 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.

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

20 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.

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

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

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

24 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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# FURTHER INFORMATION

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

If you would like to request an investigation then please read our **guidance** before submitting a safety awareness form.

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

## CONTACT US

If you would like a response to a query or concern please contact us via email using **enquiries@hsib.org.uk**. We monitor this inbox during normal office hours - Monday to Fridays (not bank holidays) from 0900hrs to 1700hrs. We aim to respond to enquiries within five working days.

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