How we acted on patient safety issues you reported

The seventh review and response report, including National Patient Safety Alerts

March 2020

Contents

Why publish this report?

Reporting all patient safety incidents, whether they result in harm or not, is fundamental to improving patient safety. The national action we take as a result of what we learn from incident reports is vital in protecting patients across the NHS from harm.

Year-on-year reporting to the National Reporting and Learning System (NRLS) continues to grow and we now receive over two million incident reports each year. This report explains how we reviewed reports in the period April to September 2019 and describes the action we took whether directly or working with partners. It also includes a summary of the National Patient Safety Alerts we issued between April 2019 and March 2020. You can find previous review and response reports on our website.

Our review and response work relies on staff, patients and members of the public taking the time to report incidents – this publication is a way to thank you for your efforts. By showing the difference you make, we hope you find this report both informative and inspirational; and that it encourages you and your colleagues to continue to report all incidents so that together we can improve patient safety and protect our patients from harm.

Based on the benefits estimates within the NHS Patient Safety Strategy, each year of review and response, including National Patient Safety Alerts, will save 80 lives and prevent 240 disabilities in each following year, with associated financial savings of £6.8 million annually.

How we review and respond

Most patient safety challenges, such as reducing diagnostic error, preventing self-harm, avoiding falls or managing long-term anticoagulation, are well recognised. These 'giants' of patient safety have complex causes and no simple solutions. They are the focus of wide, long-term programmes, including initiatives led by NHS Improvement and other organisations, and through partnerships. Such initiatives are described in the NHS Patient Safety Strategy under the 'Improvement' aim and include the National Patient Safety Improvement Programme, the Maternal and Neonatal Health Safety Improvement Programme, the Mental Health Safety Improvement Programme and the Medication Safety Improvement Programme, as well as wider initiatives such as work to tackle healthcare-associated infection and antimicrobial resistance. The information we routinely collect through the NRLS and other sources informs this work, as outlined in the NHS Patient Safety Strategy, but a national system can also identify new or under-recognised patient safety issues that may not be obvious at local level. When we identify these issues, we work with frontline staff, patients, professional bodies and partner organisations to decide if we can influence or support others to act or, if we need to, issue a National Patient Safety Alert that sets out actions organisations can take to reduce the risk. You can watch a short video on how we do this.

A national system can also develop or promote new resources or new interventions that help the NHS improve a known safety issue. When new resources would help prevent death or disability we issue a National Patient Safety Alert setting out actions organisations should take to ensure the resources are used to improve safety. When a specific technical change or safer procedure has been developed and tested, we may also issue a National Patient Safety Alert requiring their implementation.

As a member of the National Patient Safety Alerting Committee (NaPSAC), we have developed and improved our processes for issuing National Patient Safety Alerts and are the first organisation to be accredited to issue these. The standards set for National Patient Safety Alerts ensure that the safety-critical and mandatory actions they require organisations to take are clear, feasible and effective. National Patient

Safety Alerts are issued in a new template that stands out from other communications, so that providers know which safety actions they must comply with.

Information review

Our role starts with the clinicians in our patient safety team reviewing information from a range of sources to identify new or emerging issues that may need national action. We call this our 'review and response' function.

In the period April to September 2019 our clinical teams reviewed

11,300

Incidents that have been reported with an outcome of death or severe harm or meet other thresholds for clinical review (including additional review of incident reports that were updated with extra information)

4,202

Selected categories of Serious Incident reported to StEIS (new or under-recognised review)*

240

Potential and confirmed Never Events reported to StEIS*

48

Incidents reported to the NRLS by patients or the public (we review all these even if not reporting harm)

6

Regulation 28 letters (letters from coroners where they have identified a need for action to prevent further deaths)

When exploring a patient safety issue we also analyse several thousand lower harm NRLS reports as part of the focused reviews we explain below.

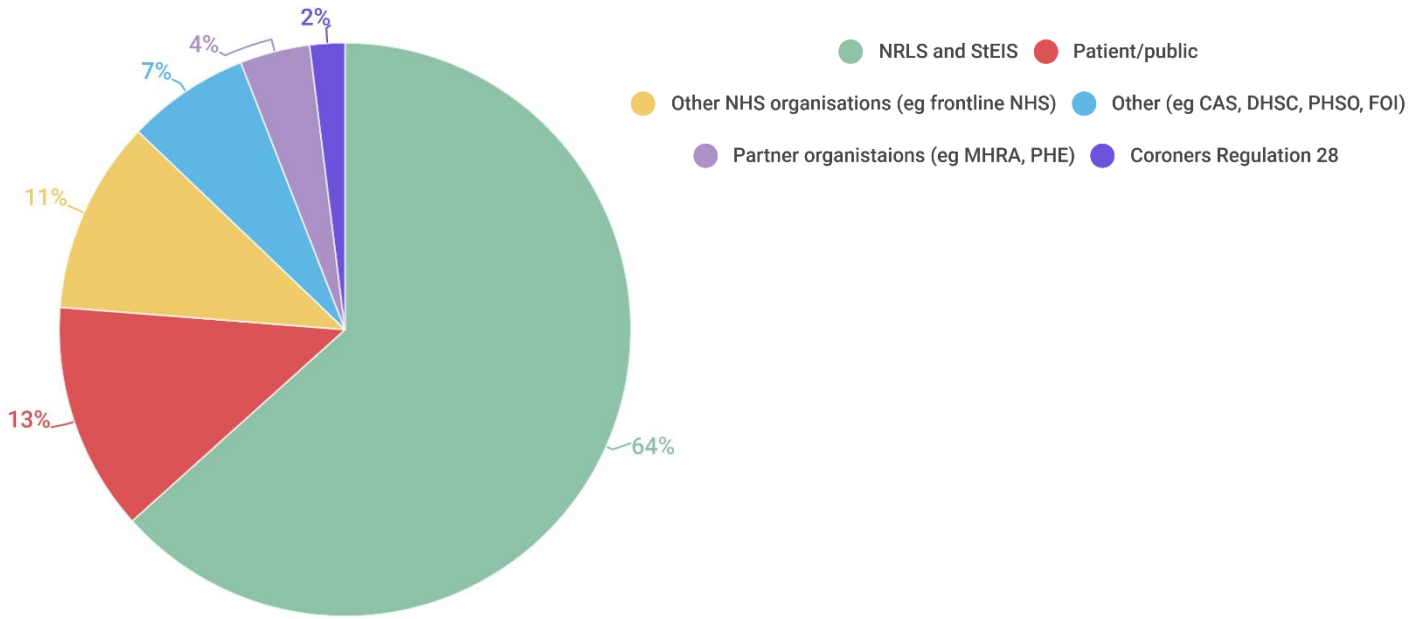
* View our StEIS, Serious Incident framework and Never Event webpages for further information.

This function is supported by registered nurses with experience in patient safety and surgical, medical, community, paediatric, neonatal and mental healthcare, a midwife, pharmacists, a pharmacy technician and a physiotherapist, many of whom work on wider patient safety policy and projects as well as review and response.

Additionally, we use the skills and experience of expert patient safety advisors who combine working one day a week with us with clinical, educational or leadership roles as paramedics or in the care home, mental health or learning disability sectors. Administrative support for our response function helps us track and record the multiple issues we need to act on. We also access internal human factors and behavioural insights expertise to inform our work, and support team members to develop their expertise in patient safety and human factors through postgraduate courses.

Where our review suggests there could be a new or under-recognised issue that requires national action we explore further. Although our process is often triggered by a single patient safety **incident**, from that point onwards we work to understand the patient safety **issue**. We do this by looking to identify any wider pattern in similar incidents reported previously, including no harm 'near miss' incidents – and we focus on what could go wrong in future. Figure 1 shows the sources of the 55 issues between April and September 2019 that our clinical teams took forward for potential national action.

Figure 1: Sources of issues we took forward for potential national action



Should we issue an Alert?

Our process starts with looking for new and under-recognised risks: not all of these will require an Alert. To identify if an Alert or other action is needed, we:

1. Check whose **remit** an issue falls under, as some aspects of patient safety are handled by other national organisations and we can pass these to them for action.

2. Look for up-to-date detail about the issue in the NRLS, research studies and other published material, and seek advice from specialists and frontline staff to help identify the **likelihood of this happening again** and the potential for harm, including the **risk of death or disability**.

3. Consider if the patient safety issue can be addressed **at source** – for example, by the manufacturer of a device – and if it can, whether this will happen rapidly enough for no other action to be required.

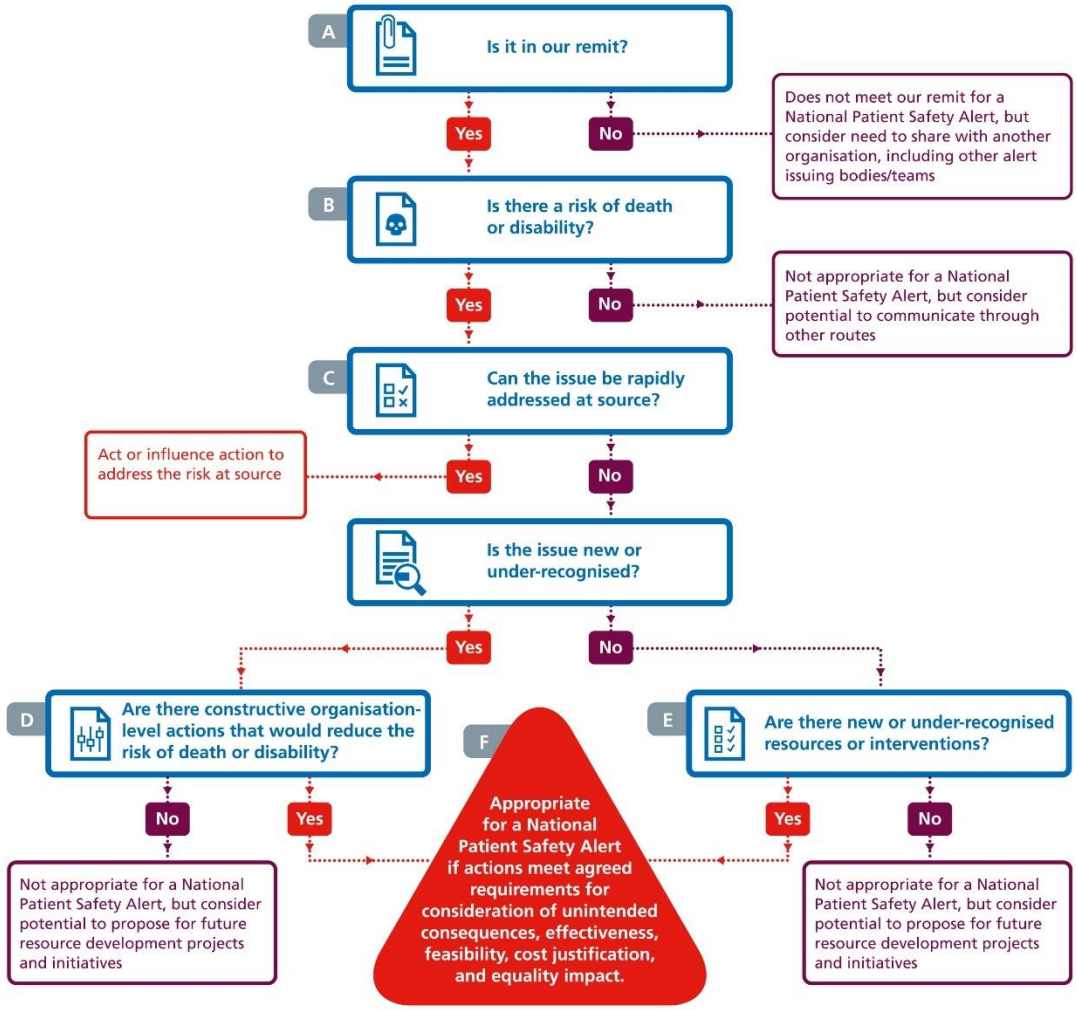
4. Talk to experts, patients and their families, and frontline staff to identify if the patient safety issue is **new or under-recognised**; these groups may have different perspectives.

5. If it is **new or under-recognised**, explore whether organisations can do something more **constructive** than simply raising awareness and warning people to be vigilant against error, and the options for these actions (including interim actions while more robust barriers to error are developed).

6. If the patient safety issue is **well known**, including if it was the subject of an earlier Alert, we recognise that substantial efforts will already have been made to address it, and further improvements will need more support than can be provided by a National Patient Safety Alert alone. We will consider if there are **new or under-recognised resources or interventions**. You can read more about the standards we set for these in Boxes 1 and 2 below.

7. Consider if a National Patient Safety Alert is **the best route**; if actions only require changes in practice by a professional specialty, rather than wider action by healthcare teams or organisations, they may be more effectively communicated by a professional society, such as a royal college.

Figure 2: Does the patient safety issue, resources or intervention meet the criteria for an NHS England and NHS Improvement National Patient Safety Alert?



A. NHS England and NHS Improvement's National Patient Safety Alert remit is defined as "when systemic actions can be taken to prevent or reduce errors of omission or commission by healthcare staff".

B. Agreed by NaPSAC as "more likely than not one or more potentially avoidable deaths or disability in healthcare per 50 million population in the following year".

C. An example of addressing an issue at source is manufacturers of medical equipment or IT systems changing their design in such a way that it eliminates the risk of error.

D. To be constructive, actions must do more than raise awareness or warn people to be vigilant against error. They require healthcare organisations to take systemic action, not actions that are more effectively delivered by professional organisations such as royal colleges.

E. 'Resources and interventions' can include new technology or new networks or collaboratives, as well as more traditional resource sets. To support an Alert, they must do more than describe correct care and additionally help to systemically reduce the risk of error.

F. As defined by NaPSAC; see https://improvement.nhs.uk/resources/national-patient-safety-alerting-committee/

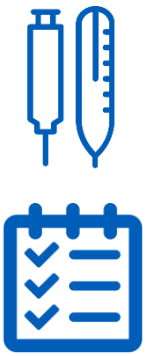
Box 1: Resources linked to Alerts

Alerts can be used to make healthcare providers aware of any substantial new resources that will help improve patient safety. They require healthcare providers to plan implementation in a way that ensures sustainable improvement. Resources could include new networks or collaboratives as well as more traditional materials. These may have been developed in response to a patient safety issue that is already well-known through publications or national initiatives, or because it has been the subject of a previous Alert.

Requirements for resources	Why is this important?
 New, or include some new or under-recognised content	Alerts asking for adoption of resources have greatest impact when part of an overall plan to support uptake and implementation of new resources.
 Published by one or more national[1] bodies, professional or patient organisations or networks, bearing their logo and hosted on their website	This ensures resources are developed by specialists and will be updated or removed when evidence or best practice changes. Local resources can be shared through less formal routes.
 Substantial, in relation to the patient safety issue	This question asks whether the resource or resource set addresses a substantial part of the patient safety issue. Resources that only address a narrow aspect can be shared through less formal routes.
 Practical and helpful	Publications that deepen our understanding of a problem have value, but in isolation they are not resources and can be disseminated through other routes.
 Focused on patient safety improvement	Public health messages and other aspects of quality, such as clinical effectiveness guidelines from the National Institute for Health and Care Excellence (NICE) and materials to improve patient experience, have their own communication routes.

[1] By national, we mean an English or UK-wide organisation. International resources are generally promoted through other routes as national differences in service provision and regulation usually mean adaptation is needed rather than direct adoption. We do sometimes highlight international resources that are clearly relevant and ready to use in England.

Box 2: Interventions linked to Alerts



An intervention to reduce harm could be: introducing new technology, removing older technology or requiring a procedure to be done in a different way. If an Alert requires adoption of a single, specific intervention, we need to be confident it has been developed and tested to the point where it can be universally adopted. Interventions also include improvements to patient safety through standardisation; all healthcare providers practising in the same way, including the processes or equipment they use.

Who advises us?

Insight to help us understand each patient safety issue and develop the required actions in our Alerts mainly comes from frontline staff, patients, professional bodies and partner organisations on our National Patient Safety Response Advisory Panel. This panel is made up of:

20%

Patient and public voice

40%

Frontline staff from providers and commissioners in all healthcare sectors

40%

Key national and professional stakeholders

These representatives encompass a range of roles in NHS acute, mental health, ambulance and community services, and clinical commissioning groups (CCGs), as well as the following organisations:

- Care Quality Commission (CQC)
- Healthcare Improvement Scotland*
- Royal College of Obstetricians and Gynaecologists (RCOG)

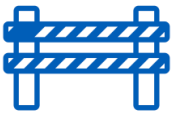
- Health and Social Care in Northern Ireland*
- Healthcare Safety Investigation Branch*
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Mothers Instinct
- National Association for Safety and Health in Care Services
- NHS Wales*
- NHS Wales Delivery Unit*
- Royal College of Emergency Medicine (RCEM)
- Royal College of General Practitioners (RCGP)
- Royal College of Midwives (RCM)
- Royal College of Nursing (RCN)
- Royal College of Ophthalmologists (RCOphth)
- Royal College of Paediatrics and Child Health (RCPCH)
- Royal College of Pathologists (RCPath)
- Royal College of Physicians (RCP)
- Royal College of Psychiatrists (RCPsych)
- Royal College of Radiologists (RCR)
- Royal College of Surgeons (RCS)
- Royal Pharmaceutical Society (RPS)
- Safer Anaesthesia Liaison Group (SALG)
- The Patients Association

*Denotes organisations that are observers to support alignment with their own work.

What criteria do we set for our Alert actions?

There is a balance to be struck between issuing an Alert as soon as possible and waiting until we can provide the best possible resources and interventions, and therefore we will consider the best actions available at that point in time. For any patient safety issue, we have the option to issue a further National Patient Safety Alert for a patient safety issue if new resources and/or new interventions become available that provide more effective barriers to error.

We work within NaPSAC criteria when developing the actions required by our Alerts. We ask the following questions to comply with these criteria:

Are the actions required…	Why is this important?
 Assessed for potential unintended consequences?	In a complex healthcare system any action intended to improve safety can potentially have unintended harmful consequences (eg separate storage of a drug to reduce selection error could delay access to it in emergencies). Proactive risk assessment methods, testing or piloting may be appropriate depending on the actions required. For significant changes in practice, evidence of safe implementation may be needed from several healthcare providers.
 Feasible?	We need to consider the feasibility at national level (eg not rely on purchase of equipment that is unavailable at the scale needed). The feasibility for all care sectors and types of healthcare provider that the Alert is directed at may be confirmed by the National Patient Safety Response Advisory Panel but may also need to be confirmed with testing/piloting, or through previous implementation by a number of healthcare providers.
 Based on understanding of the likely effectiveness of the actions?	Alerts cannot always identify 'strong' barriers that eliminate the problem, but we assess whether the actions in an Alert provide strong, medium or weak barriers. We also consider their suitability to the nature of the issue (eg checklists have a role in reducing slips and lapses, while education and senior review can better address knowledge-based errors).
 Cost[2] of implementing the actions proportionate to the reduction in harm they can be expected to achieve?	Calculating the scale and cost of current harm and the impact of the Alert actions is not straightforward for most patient safety issues, but we work within the principles used by NICE – cost per year of quality-adjusted life – to direct finite NHS resources at the patient safety issues where they are likely to

[2] Note we only calculate the cost of introducing new actions (eg replacing airflowmeters with powered nebulisers), not the cost of consistently delivering an established requirement (eg ensuring girls and women taking valproate have a pregnancy prevention plan). We do not formally calculate cost/benefit when the cost is minimal, but we always ask our National Patient Safety Response Advisory Panel to confirm our assessment of minimal cost.

have greatest impact. For some issues, the potential to reduce costs of litigation may also need to be factored in.

Have considered the equality impact of the actions?

Actions should be mindful of the needs of disadvantaged groups. For example, actions to standardise a drug supply to reduce error should not disadvantage patients who need an easier-to-swallow preparation, and patient safety information needs to be provided in formats accessible to people with learning disabilities.

Acceptable without wider public consultation?

For actions where our National Patient Safety Response Advisory Panel is concerned about adverse impacts or costs, or does not agree which of two or more current approaches to adopt as standard, a wider public consultation may be needed.

Finally, we use the National Patient Safety Response Advisory Panel and the expertise of our communications team to confirm the Alert actions are written in a way that is SMART (specific, measurable, achievable, realistic and timely).

Interested in finding out more?

If you would like to know more about why we have designed our national clinical review and response process as we have, read this journal article which links our process to the underpinning patient safety theories.

What action did we take?

National Patient Safety Alerts

Our National Patient Safety Alerts are issued through the Central Alerting System (CAS) to a wide range of healthcare organisations, including trusts, general practices and community pharmacies. Trusts have to declare compliance via CAS once they complete all the required actions in an Alert. We publish monthly data on trusts that have not declared they have done so by the designated deadline. Compliance with National Patient Safety Alerts is a focus of CQC inspections and CQC takes regulatory action where implementation is not appropriate. Private healthcare and social care providers may also find Alerts useful and they can subscribe to receive them from CAS.[3]

Between April and September 2019, we issued one Patient Safety Alert, the last Alert before we were formally accredited to issue the new National Patient Safety Alerts. Ahead of this accreditation we were already working to meet the standards the new Alerts would require.


Classification: Official

NHS Improvement

Patient Safety Alert

Assessment and management of babies who are accidentally dropped in hospital

9 May 2019

Alert reference number: NHSPSA/RS/2019/002

Resource Alert

Actions

Who: All organisations providing NHS-funded inpatient hospital care for babies aged under one year, including on labour wards, postnatal wards, midwifery-led units, paediatric and neonatal units, and mother and baby units in mental health trusts

When: To commence immediately and be completed by 8 November 2019

Sharing resources and examples of work

Patient Safety improvement.nhs.uk/resources/patient-safety-alerts

See page 2 for resources, references and advice on who this alert should be directed to

Contact us: patientsafety.enquiries@nhs.net

Assessment and management of babies who are accidentally dropped in hospital

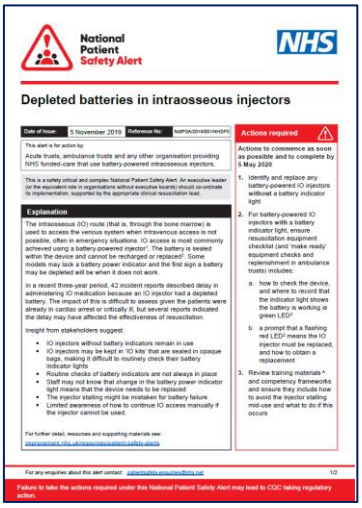
Issued 9 May 2019

Resource Alert

This Alert provides a resource to support organisations in developing or updating their local guide on how to act when a baby is accidentally dropped in hospital.

[3] To subscribe to CAS alerts, contact the CAS helpdesk by emailing safetyalerts@mhra.gov.uk

Between October 2019 and March 2020, we issued three National Patient Safety Alerts:


National Patient Safety Alert

NHS

Depleted batteries in intraosseous injectors

Date of issue: 5 November 2019 Reference No: NatPSA/2019/010/NHSPS

This alert is for action by:

Acute trusts, ambulance trusts and any other organisation providing NHS funded-care that use battery-powered intraosseous injectors.

This is a safety critical and complex National Patient Safety Alert. An executive leader (or the equivalent role in organisations without executive boards) should co-ordinate its implementation, supported by the appropriate clinical resuscitation lead.

Explanation

The intraosseous (IO) route (that is, through the bone marrow) is used to access the venous system when intravenous access is not possible, often in emergency situations. IO access is most commonly achieved using a battery-powered injector[1]. The battery is sealed within the device and cannot be recharged or replaced[2]. Some models may lack a battery power indicator and the first sign a battery may be depleted will be when it does not work.

In a recent three-year period, 42 incident reports described delay in administering IO medication because an IO injector had a depleted battery. The impact of this is difficult to assess given the patients were already in cardiac arrest or critically ill, but several reports indicated the delay may have affected the effectiveness of resuscitation.

Insight from stakeholders suggest:

- IO injectors without battery indicators remain in use
- IO injectors may be kept in 'IO kits' that are sealed in opaque bags, making it difficult to routinely check their battery indicator lights
- Routine checks of battery indicators are not always in place
- Staff may not know that change in the battery power indicator light means that the device needs to be replaced
- The injector stalling might be mistaken for battery failure
- Limited awareness of how to continue IO access manually if the injector cannot be used.

For further detail, resources and supporting materials see: improvement.nhs.uk/resources/patient-safety-alerts

Actions required

Actions to commence as soon as possible and to complete by 5 May 2020

1. Identify and replace any battery-powered IO injectors without a battery indicator light
2. For battery-powered IO injectors with a battery indicator light, ensure resuscitation equipment checklist (and 'make ready' equipment checks and replenishment in ambulance trusts) includes:
   a. how to check the device, and where to record that the indicator light shows the battery is working ie green LED[3]
   b. a prompt that a flashing red LED[3] means the IO injector must be replaced, and how to obtain a replacement
3. Review training materials * and competency frameworks and ensure they include how to avoid the injector stalling mid-use and what to do if this occurs

For any enquiries about this alert contact: patientsafety.enquiries@nhs.net 1/2

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action.

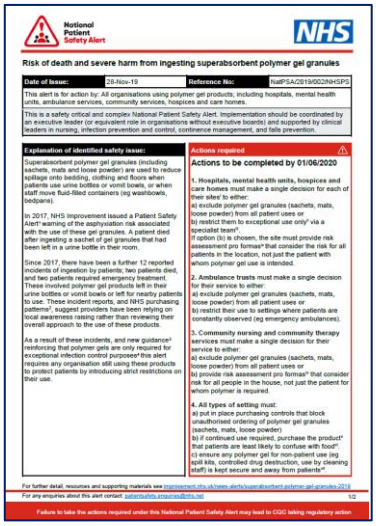
Depleted batteries in intraosseous injectors

Issued 5 November 2019

The intraosseous (IO) route (that is, through the bone marrow) is used to access the venous system when intravenous access is not possible to administer medicines or fluids, often in emergency situations, including cardiopulmonary resuscitation. IO access is most commonly achieved using a battery-powered injector. The battery is sealed within the device and cannot be recharged or replaced.

For devices without a battery power indicator, the first sign the battery is depleted may be when the device does not work.

This Alert asks providers to replace any IO devices that do not have a battery power indicator light with ones that show how much power is remaining, and to regularly check IO devices with power indicators to ensure sufficient battery power remains for the device to be usable when required.


National Patient Safety Alert

NHS

Risk of death and severe harm from ingesting superabsorbent polymer gel granules

Date of issue: 28-Nov-19 Reference No: NatPSA/2019/002/NHSPS

This alert is for action by: All organisations using polymer gel products; including hospitals, mental health units, ambulance services, community services, hospices and care homes.

This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by an executive leader (or equivalent role in organisations without executive boards) and supported by clinical leaders in nursing, infection prevention and control, continence management, and falls prevention.

Explanation of identified safety issue:

Superabsorbent polymer gel granules (including sachets, mats and loose powder) are used to reduce spillage onto bedding, clothing and floors when patients use urine bottles or vomit bowls, or when staff move fluid-filled containers (eg washbowls, bedpans).

In 2017, NHS Improvement issued a Patient Safety Alert[1] warning of the asphyxiation risk associated with the use of these gel granules. A patient died after ingesting a sachet of gel granules that had been left in a urine bottle in their room.

Since 2017, there have been a further 12 reported incidents of ingestion by patients, two patients died, and two patients required emergency treatment. These involved polymer gel products left in their urine bottles or vomit bowls or left for nearby patients to use. These incident reports, and NHS purchasing patterns[2], suggest providers have been relying on local awareness raising rather than reviewing their overall approach to the use of these products.

As a result of these incidents, and new guidance[3] reinforcing that polymer gels are only required for exceptional infection control purposes[4] this alert requires any organisation still using these products to protect patients by introducing strict restrictions on their use.

Actions required

Actions to be completed by 01/06/2020

1. Hospitals, mental health units, hospices and care homes must make a single decision for each of their sites[5] to either:
a) exclude polymer gel granules (sachets, mats, loose powder) from all patient uses or
b) restrict them to exceptional use only[4] via a specialist team[6].
If option (b) is chosen, the site must provide risk assessment pro formas[7] that consider the risk for all patients in the location, not just the patient with whom polymer gel use is intended.

2. Ambulance trusts must make a single decision for their service to either:
a) exclude polymer gel granules (sachets, mats, loose powder) from all patient uses or
b) restrict their use to settings where patients are constantly observed (eg emergency ambulances).

3. Community nursing and community therapy services must make a single decision for their service to either:
a) exclude polymer gel granules (sachets, mats, loose powder) from all patient uses or
b) provide risk assessment pro formas[7] that consider risk for all people in the house, not just the patient for whom polymer is required.

4. All types of setting must:
a) put in place purchasing controls that block unauthorised ordering of polymer gel granules (sachets, mats, loose powder)
b) if continued use required, purchase the product[4] that patients are least likely to confuse with food[8].
c) ensure any polymer gel for non-patient use (eg spill kits, controlled drug destruction, use by cleaning staff) is kept secure and away from patients[4].

For further detail, resources and supporting materials see improvement.nhs.uk/news-alerts/superabsorbent-polymer-gel-granules-2019

For any enquiries about this alert contact: patientsafety.enquiries@nhs.net 1/2

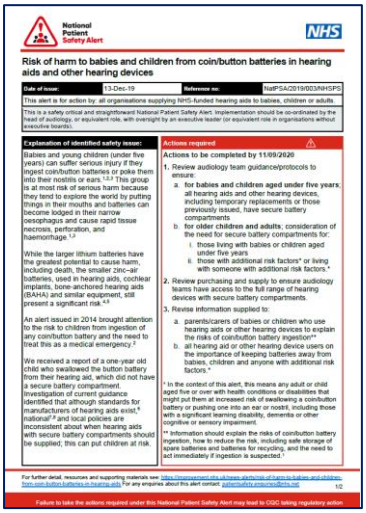
Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action.

Risk of death and severe harm from ingesting superabsorbent polymer gel granules

Issued 28 November 2019

Superabsorbent polymer gel granules are used to reduce spillage onto bedding and clothing when patients use urine bottles or vomit bowls, or when staff move fluid-filled containers (eg washbowls and bedpans). If a person puts the gel granules into their mouth, they will expand on contact with saliva, risking airway obstruction.

This Alert requires any organisation still using these products to protect patients by strictly restricting their use.



National Patient Safety Alert

NHS

Risk of harm to babies and children from coin/button batteries in hearing aids and other hearing devices

Date of issue: 13-Dec-19 | Reference no: NaPSA/2019/003/NHSPS

This alert is for action by: all organisations supplying NHS-funded hearing aids to babies, children or adults.

This is a safety critical and straightforward National Patient Safety Alert. Implementation should be co-ordinated by the head of audiology, or equivalent role, with oversight by an executive leader (or equivalent role in organisations without executive boards).

Explanation of identified safety issue:

Babies and young children (under five years) can suffer serious injury if they ingest coin/button batteries or poke them into their nostrils or ears.[1,2,3] This group is at most risk of serious harm because they tend to explore the world by putting things in their mouths and batteries can become lodged in their narrow oesophagus and cause rapid tissue necrosis, perforation, and haemorrhage.[1,3]

While the larger lithium batteries have the greatest potential to cause harm, including death, the smaller zinc–air batteries, used in hearing aids, cochlear implants, bone-anchored hearing aids (BAHA) and similar equipment, still present a significant risk.[4,5]

An alert issued in 2014 brought attention to the risk to children from ingestion of any coin/button battery and the need to treat this as a medical emergency.[2]

We received a report of a one-year old child who swallowed the button battery from their hearing aid, which did not have a secure battery compartment. Investigation of current guidance identified that although standards for manufacturers of hearing aids exist,[6] national[7,8] and local policies are inconsistent about when hearing aids with secure battery compartments should be supplied; this can put children at risk.

Actions required

Actions to be completed by 11/09/2020

1. Review audiology team guidance/protocols to ensure:
   a. for babies and children aged under five years: all hearing aids and other hearing devices, including temporary replacements or those previously issued, have secure battery compartments
   b. for older children and adults: consideration of the need for secure battery compartments for:
      i. those living with babies or children aged under five years
      ii. those with additional risk factors* or living with someone with additional risk factors.*
2. Review purchasing and supply to ensure audiology teams have access to the full range of hearing devices with secure battery compartments.
3. Revise information supplied to:
   a. parents/carers of babies or children who use hearing aids or other hearing devices to explain the risks of coin/button battery ingestion**
   b. all hearing aid or other hearing device users on the importance of keeping batteries away from babies, children and anyone with additional risk factors.*

* In the context of this alert, this means any adult or child aged five or over with health conditions or disabilities that might put them at increased risk of swallowing a coin/button battery or pushing one into an ear or nostril, including those with a significant learning disability, dementia or other cognitive or sensory impairment.

** Information should explain the risks of coin/button battery ingestion, how to reduce the risk, including safe storage of spare batteries and batteries for recycling, and the need to act immediately if ingestion is suspected.[1]

For further detail, resources and supporting materials see: https://improvement.nhs.uk/news-alert/risk-of-harm-to-babies-and-children-from-coin-button-batteries-in-hearing-aids/ For any enquiries about this alert contact: patientsafety.enquiries@nhs.net

1/2

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Risk of harm to babies and children from coin/button batteries in hearing aids and other hearing devices

Issued 13 December 2019

Babies and young children (under five years) can suffer serious injury if they ingest coin/button batteries or poke them into their nostrils or ears. While the larger lithium batteries have the greatest potential to cause harm, including death, the smaller zinc–air batteries, used in hearing aids, cochlear implants, bone-anchored hearing aids (BAHA) and similar equipment, still present a significant risk.

This Alert requires all organisations supplying NHS-funded hearing aids to ensure those issued to babies and children under five years of age have secure battery compartments. They are also required to consider this need for others who live with young children or babies, and for people with additional risk factors, such as a significant learning disability, dementia or other cognitive or sensory impairment.

National Patient Safety Alert

Ligature and ligature point risk assessment tools and policies

Issued 5 March 2020

In keeping with guidance around publishing information of this nature, this alert is not available in the public domain and can only be accessed through the Central Alerting System website by registered users. Amongst other actions, it requires review local policies, guidance or tools for ligature risk assessment to ensure they are up to date and reflect all Estates and Facilities Alerts related to ligature risk, and the most current version of CQC's Brief Inspectors' Guide to Ligature Points.

We share our Alerts with the devolved nations of Scotland, Wales and Northern Ireland and they choose whether to use or adapt the learning in their own countries.

Scotland issued the following Alerts published in the period covered by this report:

- Assessment and management of babies who are accidently dropped in hospital (NHS/PSA/RE/2019/002) (issued to NHS Scotland on 23 May 2019).

Wales issued the following publication based on Alerts published in the period covered by this report:

- Assessment and management of babies who are accidently dropped in hospital (NHS/PSA/RE/2019/002) (issued as PSN050 on 24 July 2019)
- Risk of death and severe harm from ingesting superabsorbent polymer gel granules (NatPSA/2019/002/NHSPS) (issued as PSN052 on 11 February 2020)
- Risk of harm to babies and children from coin/button batteries in hearing aids and other hearing devices (NatPSA/2019/003/NHSPS) (issued as PSN000 on 5 February 2020)

Northern Ireland issued the following publication based on Alerts published in the period covered by this report:

- Assessment and management of babies who are accidently dropped in hospital (NHS/PSA/RE/2019/002) (issued as HSC (SQSD) 11/19 on 23 May 2019).
- Depleted batteries in intraosseous injectors (NatPSA/2019/001/NHSPS) (issued as HSC (SQSD) 33/19 on 28 November 2019)
- Risk of death and severe harm from ingesting superabsorbent polymer gel granules (NatPSA/2019/002/NHSPS) (issued as HSC (SQSD) 34/19 on 18 December 2019)

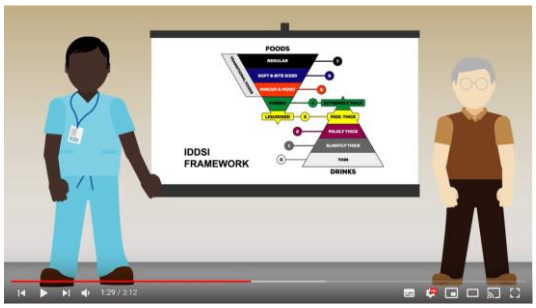
- Risk of harm to babies and children from coin/button batteries in hearing aids and other hearing devices (NatPSA/2019/003/NHSPS) (issued as HSC (SQSD) 35/19 on 21 January 2020)

‘Ask why’ and patient story videos

Our Alerts ask for co-ordinated action at an organisational level, as that is the most effective way of addressing patient safety issues. If an Alert requires specific changes, we may produce an ‘ask why’ video around the time the Alert actions need to be completed. These videos encourage staff to ‘ask why’ if changes have not been made in their workplace.

We also produce patient story videos as a powerful way to make staff aware of the personal impact on patinets who have been harmed by the risks we highlight in our Alerts.

We promote our videos via social media and offer them to organisations to use in their own training. They are available on our YouTube channel



In May 2019 we released an ‘ask why’ video to support our Resources to support safer modification of food and drink Alert. This can be viewed on the Alert’s resources webpage and YouTube.

Issues where we advised or influenced others on action

Below we give examples of the actions we took through routes other than Alerts in the period covered by this report.

Access to interventional acute stroke services

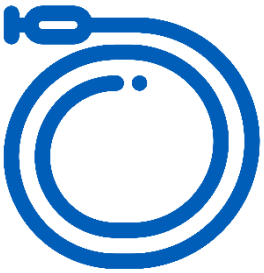
Disability can be significantly reduced if thrombolysis and thrombectomy are provided soon after the first signs of a stroke.

We identified two incidents where patients did not receive either of these treatments because of difficulty determining if they could benefit from acute interventional stroke services and therefore which hospital or unit they should be taken to. Incident reports indicate:

- ambulance and hospital staff find it difficult to quickly decide where a patient should be taken because service provision is complex and units vary in their clinical inclusion and exclusion criteria
- defined catchment areas in commissioning or contractual agreements add to the complexity.

We raised issues about access to thrombolysis with the National Clinical Director for Stroke and the leads for the Sentinel Stroke National Audit programme (SSNAP). The Getting it Right First Time (GIRFT) stroke programme will continue to work with providers to reduce variation.

We also shared our thrombectomy findings with NHS England's Specialised Commissioning Team who had published 'Clinical commissioning policy: Mechanical thrombectomy for acute ischaemic stroke' in March 2018 to assist in the development of services.



Replacing a displaced percutaneous endoscopic gastrostomy (PEG) tube

A patient attended an emergency department (ED) with a displaced PEG tube. A clinician replaced it about six hours after it had come out and the patient was sent home. The patient died the next day, and their death was found to relate to PEG tube misplacement into the abdominal space rather than the stomach.

We advised the British Association for Parenteral and Enteral Nutrition (BAPEN) and the National Nurses Nutrition Group that no national guidelines exist for replacing PEG tubes and they agreed to develop such guidance. This will include:

- the competence and experience a clinician replacing the tube is expected to have
- clear information that pH does not confirm correct placement as gastric contents will leak into the abdominal cavity if the new PEG tube is not in the stomach
- specific safety netting advice for patients, their carers and families to take home with them after tube replacement.

Once developed, this guidance will help clinicians determine that a replaced PEG tube is correctly sited and safe to use.

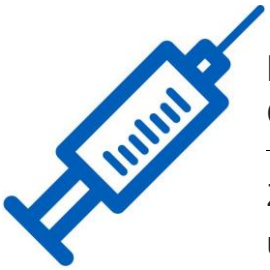
Look-alike selection error involving muscle relaxants

Muscle relaxants are used to paralyse an anaesthetised patient. Where two different medicines are similar in appearance it is possible that the wrong one can be chosen and administered, so-called look-alike selection errors.

We reviewed an incident where a patient was inadvertently given a muscle relaxant (vecuronium) instead of an antibiotic (vancomycin). The patient experienced muscle paralysis while conscious, and while emergency intervention prevented the paralysis leading to

respiratory and cardiac arrest this isa terrifying experience for those that encounter it – similar to 'Kathryn's story'.

We asked for this incident to be included in a Safe Anaesthesia Liaison Group (SALG) Patient Safety Update to raise awareness among anaesthetists and other clinicians of this risk. In response to similar concerns, muscle relaxant packaging in other countries such as Australia is now distinct and carries prominent warning labels. We informed MHRA of our concerns, providing examples of similar incidents, and asked them to review requirements for labelling of muscle relaxants. Labelling design does not eliminate the risk of mis-selection, but can reduce the risk and protect patients from severe harm.



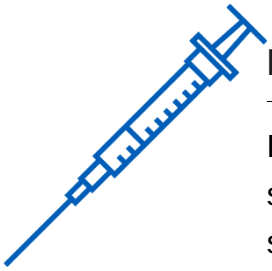
Risk of confusion between zuclopenthixol acetate and decanoate injections

Zuclopenthixol acetate injection has a rapid onset of action and is used in the initial treatment of acute psychoses, including mania. It is not intended for long-term use and should only be prescribed in a hospital setting.

Zuclopenthixol decanoate injection acts for longer and is used in the maintenance treatment of schizophrenia and paranoid psychoses.

Specialist mental health practitioners made us aware of the risk of the acetate and decanoate preparations being confused: giving the acetate preparation in error may lead to severe over-sedation of the patient. Review of the NRLS for a 12-month period identified five incidents describing this confusion.

We shared this risk with NHSX who have included it in their ongoing work with primary care prescribing/dispensing software suppliers. We also shared with Open Prescribing who haved developed a new kind of alert that flags inappropriate prescribing.



Prescribing and administration of dexmedetomidine

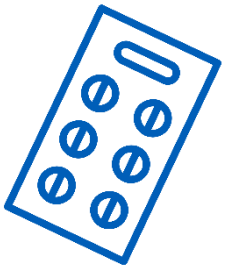
Dexmedetomidine is used to sedate patients in intensive care settings or to support conscious sedation during some diagnostic or surgical procedures. It should only be administered by healthcare professionals skilled in the management of patients requiring intensive care.

We became aware of a patient being unintentionally overdosed with dexmedetomidine administered through an infusion pump.

A review of the NRLS identified 102 incidents related to the use of dexmedetomidine. Identified concerns included: use outside ITUs (in both adults and children), rate of administration, administration as a bolus rather than an infusion, preparation errors and suboptimal sedation.

In response to sharing our concerns:

- The co-ordinator of The Injectable Medicines Guide agreed to ensure the rate of administration was clear on the monograph for dexmedetomidine.
- The Royal College of Paediatrics and Child Health's Neonatal Paediatric Pharmacists Group Medicines Committee confirmed that dexmedetomidine is among the drugs being considered in its current review of the use of sedatives in children.
- SALG members agreed to ask the Royal College of Anaesthetists to consider these concerns as part of a wider review of the use of sedation outside theatres and critical care.



Monitoring of patients following ingestion of a toxic dose of prolonged-release medication

National guidance recommends patients who ingest a toxic dose of a prolonged-release preparation of a certain type of medication are observed for at least 24 hours after ingestion. Reported incidents suggest that this recommendation may not be well-recognised. In

one incident, a patient was assessed in an emergency department before being transferred to another care setting without suitable monitoring. The patient had a cardiac arrest and later died.

We liaised with the Clinical Standards Group of the National Poisons Information Service, who host Toxbase (a clinical toxicology database). They revised the content and format of their monograph for this medication to highlight the importance of extended observation, which should result in reduced harm by ensuring safer observation of patients who ingest a toxic dose.

Air embolism following central venous catheter removal

During CVC removal, air can be drawn in if the entry point is not rapidly covered with an occlusive dressing. This risks sudden and potentially fatal obstruction of the circulation..

We identified a report where a patient suddenly deteriorated following central venous catheter removal and needed cardiopulmonary resuscitation. This was thought to have occurred because the dressing used to cover the removal site was not an air-tight ‘occlusive’ dressing. The dressings used for many other purposes in healthcare are typically watertight but air-permeable.

The Renal Association, British Renal Society and Intensive Care Society are developing national guidelines on central venous catheter removal and we asked them to include advice on the type of dressing to be used.

Potential for air embolus from vented caps on three-way taps

We identified an incident describing the possibility of air being drawn in through a three-way tap with vented caps; these caps are vented (contain holes) to facilitate sterilisation during manufacture.

The risk of vented caps causing an air embolus was highlighted by MHRA in 2013 via a Medical Devices Alert.

The incident was discussed at a meeting with SALG, attended by the MHRA, following which SALG determined that not all frontline staff knew to replace the vented cap with a non-vented one. Subsequently, MHRA worked with manufacturers to remove the vented caps entirely.

Reviewing 'scout films' to support radiological diagnosis

A 'scout film' is a preliminary film taken of a body region before definitive imaging, such as of the chest before a CT scan. It helps determine the area for definitive imaging. Unlike definitive images, scout films are not routinely reviewed by a radiologist.

We identified a report where diagnosis of a serious condition was delayed because, although visible on the scout film, it could not be seen on the area that was definitively imaged and reported on.

We asked the Royal College of Radiologists (RCR) whether scout films should be routinely interpreted. RCR advised that interpretation of scout films is complex but agreed to improve awareness of the issue among members via its regular newsletter Radiology Event and Learning. In addition, they committed to review whether the development of national guidance on scout view interpretation will improve patient care.

Retained valve from an intrauterine balloon

We identified an incident where a woman found a retained valve from an intrauterine balloon in her vagina, three months after having a caesarean section. Intrauterine balloons are used to control severe haemorrhage following delivery. If used during or following a ceasarean section, the balloon's valve should be temporarily removed to allow it to be passed through a woman's relatively

closed cervix. The valve is then replaced and used for subsequent inflation/deflation of the balloon.

We raised concerns with MHRA about how balloon manufacturers highlight the risks of different application techniques, particularly around removal, safe keeping and replacement of the valve during different stages of the procedure, and asked that they are included in the next review of the instructions for use.

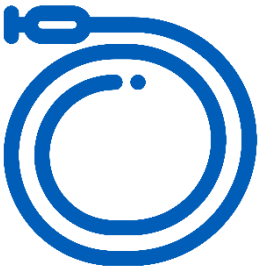
This will help protect staff from unintentionally leaving a valve behind and patients from a valve being retained; causing pain and infection.

Linking point of care devices to the correct patient

We reviewed an incident where the results of a point of care (POC) glucose test appeared in the wrong patient's electronic patient record (EPR). When introducing these POC devices the organisation had not activated the optional prompt which reminds staff to input or confirm a patient's identification before every use. In this case staff did not input the new patient's identification and results were automatically transferred to the EPR of the patient on whom the device had previously been used. Out of range results which required clinical intervention were not followed up.

Although the incident referred to a specific device, this error could occur with any POC device configured to transmit data to the EPR.

We shared this concern with NHS Digital, National Association of Medical Device Educators and Trainers (NAMDET) and the Royal College of Pathologists to highlight the importance of specification, installation and implementation of POC systems to ensure reliable connectivity with existing infrastructure. This will ensure potentially vital POC results appear in the correct patient record.



Cassettes administering medication for Parkinson's disease

Several organisations contacted us about a bespoke cassette for delivering anti-parkinsonian medication that could not be connected to the ISO 80369-3 ENFit™ feeding tube that has been adopted by the NHS.

The ISO standard was implemented to prevent wrong route connections and ensure that enteral products (those intended to be given via the gastrointestinal tract) cannot be given intravenously and vice versa. This is a vital safety standard.

We are concerned, because the cassette is not compatible with ENFit, that patients dependent on this medication could be harmed and that staff will look for workarounds, use special connectors or revert to the older connectors.

Following discussions with the manufacturer and MHRA, work has begun to make the medication cassette ENFit™ compatible, which will ensure patients who rely on this treatment can continue to recieve it, and eliminate the risk of wrong-route injection.

Automatically generated ECG results contributing to diagnostic error

We received a report of a patient who had experienced central chest pain for three days and despite automated electrocardiograph (ECG) analysis being classified as normal, abnormalities in the ECG report were identified post mortem.

We were concerned that use of the term 'normal', rather than more neutral language such as 'no abnormalities detected', displayed in automated analysis of ECG recordings could influence clinical decision-making. Experts in ECG interpretative algorithms advised us that the internationally agreed and accepted term for an automated ECG interpretation that detects no specific abnormality is 'normal' and therefore we were unlikely to be able to influence change. However, they confirmed that they continually work to ensure basic and specialist medical training emphasises the need for human ECG interpretation: an ECG trace is significant only when interpreted in conjunction with a patient's other clinical findings. They also highlighted referral pathways which help focus clinicians, especially those in primary care, on symptoms as well as automated ECG reports.

ECG results requiring demographics to support algorithm

Experts in ECG algorithm software told us that the importance of inputting patient age and sex when performing an ECG recording with automated interpretation was not always recognised. Although the displayed ECG waveform is unaffected, the automated interpretation will typically default to that for a 50-year old male. This default could mean an automated report interprets an ECG as 'normal' when had the correct age and sex been inputted a condition requiring medical intervention may have been indicated.

When age and sex are unknown, automated software should indicate 'without knowing patient's sex/age'. Some hospitals use bar code scanning systems linked to ECG machines which can input

age and sex automatically. ECG interpretation by a clinician incorporates other factors including patient history, symptoms, disease profile. Automated interpretation of the ECG recording however, only reflects cardiac rhythm at that moment in time.

We shared this insight with NAMDET and asked MHRA to raise with manufacturers the need to convey this to users. This should reduce the risk of cardiac anomalies being missed.

Specialist paediatric medicines started in secondary care

Over the last 18 months we identified several similar incidents involving children with exceptional clinical needs who required unusual doses or concentrations of medicines that are typically only given in specialist secondary care settings, eg a special formulation of morphine sulfate solution, an unusual dose of dalteparin and confusion over the number of clonidine patches to be administered. When these patients were discharged home and back under the care of their GP, prescribing and dispensing errors occurred because the primary care staff assumed a more familiar dose or concentration should be provided. The exceptional needs of these children had not always been clearly communicated.

We raised this issue with the RCPCH / NPPG Medicines Committee, who are seeking further information to identify how to improve medication safety at the point of transfer of care. We also proposed that the Academic Health Science Networks considered this issue as part of their ongoing work on Transfer of Care Around Medicines.

Flushing after small volume intravenous infusions

The risk of harm due to under dosing when the administration of small volume infusions is not followed by a flush, was raised with the national patient safety team.

We agreed to co-ordinate action on this issue, culminating in the National Infusion and Vascular Access Society (NIVAS) publishing the first national guidance on best practice in April 2019: Intravenous infusion drug administration: flushing guidance. This is now included in The Royal Marsden Manual of Clinical Nursing Procedures, and NIVAS plans to update it in early 2020.This guidance will enable patients to receive optimum benefit from infused medicines.

Incorrect calibration of radioisotopes

Radioisotopes are routinely used for diagnostic and therapeutic purposes and are prepared in pharmacy or nuclear medicine departments. We identified an incident where several patients were injected with a higher than normal dose of a radioisotope, due to the calibrator being on the incorrect setting, and we sought advice from a chief radiopharmacist, the UK Radiopharmacy Group (UKRG), and the British Nuclear Medicine Society (BNMS).

As a result, this incident was highlighted to nuclear medicine and radiopharmacy staff via the BNMS newsletter. This emphasised the recommendation in the BNMS/UKRG Safe drawing up of radiopharmaceuticals in nuclear medicine departments guidance that doses are independently checked at the time they are drawn up.

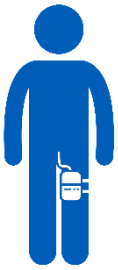
Cervix wrongly biopsied during colonoscopy

Colonoscopy is an examination used to detect changes or abnormalities in the large intestine (colon) and rectum. A long, flexible tube (colonoscope) is inserted into the rectum and a camera at the tip of the tube allows the doctor to view the inside of the entire colon and take a biopsy if required.

Following a review of the NRLS, we identified five incidents where biopsies of the cervix were taken rather than of the colon. This is a seemingly impossible error, but whether due to distorted anatomy,

efforts to protect a patient's dignity reducing the operator's field of vison, or interpreting what was seen in light of what is expected to be seen (confirmation bias), these patients had an unnecessary procedure and delayed diagnosis.

We took this issue to the British Society of Gastroenterology who recommended to their members that the perineum is always visually inspected after rectal intubation to check the correct orifice has been used, before proceeding with the examination and taking any biopsies.



Novel procedure for bladder drainage

We became aware of the novel use of gastrostomy buttons placed durring a surgical procedure to facilitate intermittent bladder drainage in patients who would otherwise require a long-term indwelling catheter.

This raised the concern that if a patient has a gastrostomy button in their bladder as well as one for feeding, feed could mistakenly be administered into the bladder instead the gastro-intestinal tract.

We took this issue to the British Association of Urological Surgeons (BAUS) who advised that a study is underway to evaluate the use of gastrostomy buttons for bladder drainage. We have asked BAUS to consider developing interim guidance.

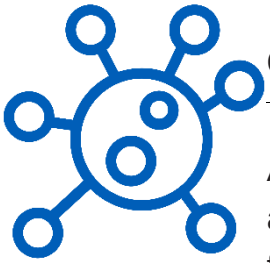
Complications from retained cervical sutures

Cervical cerclage sutures are placed around the cervix to reduce a pregnant woman's risk of premature labour. They are usually removed between 36 and 37 weeks' gestation, or at the onset of labour if this is earlier than 36 weeks.

Following a report detailing complications from a retained suture, we searched the NRLS and found nine similar cases of wholly or partially retained sutures, potentially exposing these women to

infection, difficulties in labour and other complications. In two of the reports sutures were retained following caesarean section.

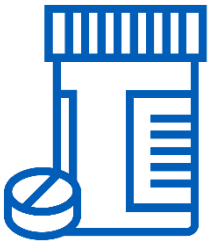
We successfully influenced the National Institute for Health and Care Excellence (NICE) to update the 2019 version of their Preterm labour and birth guidance to include the need to plan for cerclage suture removal. They did this in collaboration with the Royal College of Obstetricians and Gynaecologists.



Observation after allergy testing

An incident described an inpatient who experienced anaphylaxis and required resuscitation and intubation following an allergy test for penicillin . The reaction occurred after the allergy team had left the ward. This highlighted the apparent lack of a defined observation period after an allergy test. We established that no guideline states how long a person should be observed for after being tested for an allergy to a medicine or food.

We asked the Standards of Care Committee at the British Society for Allergy and Clinical Immunology that future guidelines for specialists in allergy testing specify the time period for observation following testing and state that this applies to all clinical settings where allergy testing is undertaken. We also asked that guidelines include information for patients and carers on any further monitoring at home and the signs and symptoms of anaphylaxis that may require urgent medical intervention.



Confusion as a sign of cerebral bleed in patients taking warfarin

We reviewed an incident that suggested those taking warfarin and their relatives/carers may not recognise that ‘confusion’ is a symptom of a cerebral bleed. Early recognition of cerebral bleeding is particularly vital in those taking warfarin as reversal of

anticoagulation and urgent medical treatment will be needed to reduce their risk of disability or death.

We identified that the patient information leaflets (PILs) for warfarin did not list ‘confusion’ as a sign of a cerebral bleed. We informed MHRA of this and they committed to work with pharmaceutical companies to include this information on warfarin PILs.

Accidents associated with doorstops in hospital

We reviewed an incident in which a patient tripped on a doorstop in a hospital toilet and fractured their clavicle. We found seven other incidents involving different types of doorstops positioned on floors, skirting or walls in the NRLS. Patients had either tripped on doorstops or been knocked over by a swing door while trying to pick up or kick away the doorstop.

We raised this issue with our Estates and Facilities team. They issued an Estates and Facilities Alert in October 2019 stating that organisations should include doorstops as part of their overall multidisciplinary risk assessmentof the hospital environment .

An update: Safety netting for children leaving an emergency department following a first suspected afebrile seizure

(previous report April to September 2018)

We became aware of a child who died from sudden unexplained death in epilepsy (SUDEP). This prompted us to review the advice available to parents whose child has a seizure for the first time.

When a child attends an ED following a suspected afebrile seizure (a seizure with no associated fever) they may be referred to a specialist for further assessment, which is likely to include consideration of epilepsy. As this appointment may be up to two

weeks away, the family needs clear ‘safety netting’ information when their child is discharged from the ED.

The Royal College of Emergency Medicine’s (RCEM) standards for assessment had included giving the child and family a leaflet highlighting activities that may put their child at risk, such as swimming, bathing and cycling. However, little detail was given on what the leaflet needs to cover and the information in these leaflets used to vary across the country.

We contacted colleagues in the RCEM and RCPCH, and the RCPCH Epilepsy Programme Board agreed to lead work with relevant partners. They have now developed and published a safety netting information leaflet for this situation. This gives parents clear, consistent and comprehensive advice to help them keep their child safe.

An update: Death after ingestion of cleaning products in hospital

(previous report April to September 2018)

A patient died after they drank cleaning fluids that had been put in a water jug. We found 18 other incidents where patients had swallowed cleaning products in healthcare settings. We worked with our Estates and Facilities team and they issued an Estates and Facilities Alert via CAS in February 2019.

Learning from investigations suggested that Control of Substances Hazardous to Health (CoSHH) training and notices should consider the needs of staff with low literacy or whose first language is not English. We shared this insight with the Health and Safety Executive and they produced a new poster in April 2019 which now which adopted a pictorial style conveys risks using pictures (CoSHH Safe Handling of Chemicals).

New or under-recognised ligatures, ligature points or other means of self-harm

Publishing detailed information on methods of self-harm is unsafe as it can give people ideas about how to harm themselves. Prevention of self-harm ultimately relies on improving the therapeutic environment, not focusing on environmental safety alone. However, to help improve environmental risk assessments in mental health units, we routinely notify mental health directors of nursing via the National Mental Health Nurse Directors Forum of new or under-recognised methods of self-harm or methods of concealing items for self-harm.

If we identify novel methods of self-harm in the community where there may be potential to restrict public access to the method used, we notify the appropriate public body.

Issues shared with NHS Digital

We routinely share patient safety incidents relating to IT systems with NHS Digital. Where appropriate, these concerns are then investigated by NHS Digital and with the system suppliers and trusts concerned.

In the period covered by this report we shared 16 patient safety incidents with NHS Digital including those relating to:

- delayed transfer of clinical messages, discharge letters and pathology results to GP systems
- systems that did not support timely follow-up of cancer patients.

Partnership learning from specialist review of NRLS data

We regularly share data with a number of clinical and professional networks that review incidents and use their findings to support safety improvements in their specialty.

These include:

- the **Royal College of Emergency Medicine**, which shares its findings in safety flashes
- the **Safer Anaesthesia Liaison Group**, which shares its findings in quarterly patient safety updates and uses them to inform wider guideline development
- **Public Health England**, which shares its findings in Safer Radiotherapy reports
- the **MHRA**, which uses NRLS data to inform its regulatory functions for medication and medical device safety
- the **Renal Association**, which shares its findings in patient safety updates
- the **Health Safety Investigations Branch** (HSIB), which uses NRLS and Serious Incident data to provide wider context to their specific investigations.

We also share NRLS data with organisations and researchers who are looking into a specific patient safety topic. Between April and September 2019, we fulfilled 23 external requests for such data. Examples include:

- incidents relating to prison healthcare to inform a research project at Cardiff university on avoidable harm in prison healthcare in England
- incidents relating to medication errors in young people shared with Southampton University to inform their investigation of the prevalence and type of paediatric medication errors in hospital and community settings.

Journal articles including review of NRLS data

One output from the support we provide to university researchers, royal colleges and other professional bodies or individuals is publications based on NRLS data. In the

period covered by this report, topics covered in journal publications featuring NRLS data included (see Appendix 1 for references):

- review of diagnostic errors
- retained vaginal swabs
- incidents in the last days of life
- Cortrak-guided tube misplacements
- text mining analysis of medication administration incident reports
- staffing and medication administration errors
- incidents related to clozapine
- children in the community dependent on long-term ventilation
- children in the community receiving enteral feeding.

Acting through our MSO and MDSO networks

NHS Improvement and MHRA jointly support the Medication Safety Officer (MSO) and Medical Devices Safety Officer (MDSO) networks. These were established following Patient Safety Alerts issued in March 2014 asking providers to identify an MSO and MDSO in their organisation. All NHS trusts now have MSOs and MDSOs, and an increasing proportion of CCGs and private providers of NHS-funded care have also created MSO and MDSO roles.

The MDSO network

NHS England and NHS Improvement and MHRA support the MDSO network through:

- **MDSO handbook** – supports newly appointed MDSOs and signposts the responsibilities of the post
- **MDSO forum** – encourages MDSO members to develop new themes, raise concerns and communicate with each other
- **MDSO web events** – held monthly; with invaluable support from the MDSO editorial board, these provide a platform for sharing resources and gaining specialist feedback.

The web events involve speakers from a variety of backgrounds (frontline MDSOs, NHS England and NHS Improvement, MHRA and specialists from healthcare,

procurement and industry), sharing relevant safety-related information, providing updates on the most recent MHRA Medical Device Alerts and our Patient Safety Alerts, and highlighting medical device safety issues identified through review of NRLS incident reports.

In addition to regular updates on recent Alerts relevant to MDSOs, specific web event topics have included:

- **April 2019:** Focus on device end of life. Presentations on the policy for recycling of walking aids at Hertfordshire Community NHS Trust. MHRA case study on the reuse of walking aids. Social media networking. Responsible end of life equipment management from Hilditch.
- **May 2019:** Focus on pulse oximetry. What's on the Health Education learning portal and how to use it for ESR. Manufacturer feedback following the Patient Safety Alert (PSA) Risk of harm from inappropriate placement of pulse oximeter probes. Frontline feedback on the oximeter probe PSA from the Medical Devices and Incidents Manager (MDSO) at St George's, London. Critical care network presentation on the standardisation of equipment and their training passport.
- **June 2019:** Focus on device maintenance. Organisational review of maintenance by service and how it has improved through review of compliance database. Assessment examples for medical device training (risk, league table, accredited, refresher) and medical device audit (colour-coded audit, safety walkabout).
- **July 2019:** How the Long Term Plan and Patient Safety strategy are relevant to MDSOs. Presentation from Health Tech Connect supporting the development and adoption of health technologies. Community care and managing devices using the Premises Assurance Model (PAM) toolkit, from Cambridge community services. Social media feedback
- **September 2019:** Presentation on the CQC thematic review of Never Events and its publication: Opening the door to change. Medical device CQC inspection experience from United Lincolnshire Hospitals Trust and Kent Community Health NHS Foundation Trust.

Want to find out more about MDSOs?

MDSOs are generally nominated by their organisation. If you are interested, do talk to your manager. To register and to receive forum login details, please send an email to safetyalerts@mhra.gov.uk

Since the role of the MDSO varies from organisation to organisation, you can find out who your MDSO is by contacting your risk manager, clinical governance team or by emailing safetyalerts@mhra.gov.uk

The MSO network

The MSO network is a collaboration between the NHS England and NHS Improvement patient safety team, MHRA and Specialist Pharmacy Service (SPS). Through email and the discussion forum hosted by MHRA, we routinely provide details of all recent Patient Safety Alerts, focusing on how MSOs can support effective implementation. We also use this network to share advice and guidance issued through routes other than Alerts.

The network is supported by a one-hour web event each month; these are recorded and made available to all MSOs. Alongside MSOs in England, guests from the devolved nations (Northern Ireland, Wales and Scotland), America, Canada and Australia are invited.

In addition to the monthly observatory report provided by the United Kingdom Medicines information (UKMi) service and updates on recent Alerts relevant to MSOs, web events have covered the following specific topics:

- **April 2019:** Medication incidents with insulin and sodium chloride, MHRA pregnancy testing and contraception during treatment with medicines of teratogenic potential, an update on anticoagulant safety and the LASA survey.
- **May 2019:** Medication incidents with Stalevo, MHRA presentation on dependence and addiction with opioids, the standardisation of oral liquids to improve safety and definitions of medication error.
- **June 2019:** Healthcare Safety Investigation Branch Report (HSIB) describing the inadvertent administration of an oral liquid medicine into a vein, safe administration of medicines at Wirral University Teaching Hospital, medication safety training in the HEE South Region and safety issue of cassettes used to administer medication for Parkinson's Diseaseand the WHO technical report on high risk medicines
- **July 2019:** updates for the Medicines Safety Programme, England deprescribing network and the Yellow Card system; a reminder of the insulin Never Event definition; highlighting the Patient Safety Strategy and the WHO technical report on polypharmacy.

- **August 2019:** speaking up – a team-based approach to patient safety, managing and communicating medicines shortages, a new approach to QA assessments of generic medicines and a call for information on dexmedetomidine, short-bowel syndrome, and the third in the series of WHO technical reports (transitions of care).
- **September 2019:** Serious Incident learning, the KidzMed Project Part 1: Pill heroes and MHRA biosimilars and biological medicines – the reporting of adverse drug reactions.

The MSO network is maturing and developing into special interest groups, including community pharmacy MSOs, ambulance MSOs and regional MSO groups.

Want to find out more about MSOs?

A handbook explaining the role of MSOs is available.

The role of the MSO varies from organisation to organisation and may be allocated to more than one person. MSOs are nominated by their organisation and can be registered and receive forum login details via safetyalerts@mhra.gov.uk. If you are unsure who the MSO is in your organisation, your chief pharmacist or superintendent pharmacist will be able to tell you.

Inspired to report?

For staff working in most NHS organisations, including NHS trusts and foundation trusts, the most effective way to report to the NRLS is via your own local reporting system. Reporting to your local system means local action may be taken, and your report will also be anonymously shared with the NRLS through a weekly or monthly upload of data. You can learn more about the NRLS on our website.

If you belong to a small organisation such as a community pharmacy or GP surgery, you can report directly to the NRLS using our eForms.

Patients and the public can report to us via the public reporting portal. Please note we do not investigate individual reports but we do review public concerns and use this information to improve safety.

If you are aware of a new or under-recognised issue that you believe we should be acting on, we can be contacted via patientsafety.enquiries@nhs.net.

Interested in finding out more about our wider work?

Researchers or healthcare professionals who would like to use NRLS data for learning should contact NHSI.NRLSDataRequest@nhs.net.

This report only describes some aspects of our work; those focused on clinical review, our response to new or under-recognised risks to patient safety and our alerting system. You can find out more about the wider aspects of our work in the NHS patient safety strategy, which describes how the NHS will continuously improve patient safety, building on the foundations of a safer culture and safer systems.

Please also see our webpages for a broader understanding of all the ways we work to improve patient safety.

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Appendix 1: Journal publications including review of NRLS data

Cooper A, Carson-Stevens A, Siriwardena N, Edwards A (2019) Learning from diagnostic error when primary care services are located in or alongside emergency departments: a theory generating mixed-methods study. British Journal of General Practice 69 (Suppl 1): p.bjgp19X703277.

Gundry R, Frost J (2019) Learning from 'Never Events' – working towards targeted, evidence-based safety standards for the prevention of retained vaginal foreign objects in obstetrics and gynaecology. BJOG 126: 120.

Dinnen T, Williams H, Yardley S, et al (2019) Patient safety incidents in advance care planning for serious illness: a mixed-methods analysis. BMJ Supportive & Palliative Care [Epub ahead of print].

Taylor SJ, Allan K, Clemente R (2019) Undetected Cortrak tube misplacements in the United Kingdom 2010–17: An audit of trace interpretation. Intensive and Critical Care Nursing 55: 102766.

Härkänen M, Paananen J, Murrells T, Rafferty AM, Franklin BD (2019) Identifying risks areas related to medication administrations-text mining analysis using free-text descriptions of incident reports. BMC Health Services Research 19(1): 791.

Härkänen M, Vehviläinen-Julkunen K, Murrells T, et al (2020) The contribution of staffing to medication administration errors: a text mining analysis of incident report data. Journal of Nursing Scholarship 52(1): 113–123.

Dabba K, Elswood M, Ameer A, Gerrett D, Maidment I (2019) A mixed methods analysis of clozapine errors reported to the National Reporting and Learning System. Pharmacoepidemiology and Drug Safety 28(5): 657–664.

Nawaz RF, Page B, Harrop E, Vincent CA (2019) Analysis of paediatric long-term ventilation incidents in the community. Archives of Disease in Childhood [Epub ahead of print].

Page B, Nawaz R, Haden S, Vincent C, Lee AC (2019) Paediatric enteral feeding at home: an analysis of patient safety incidents. Archives of Disease in Childhood 104 (12): 1174-1180.

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This publication can be made available in a number of other formats on request.

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