

Patient safety review and response report April to September 2018

A summary of how we reviewed and responded to the patient safety issues you reported

26 March 2019

collaboration trust respect innovation courage compassion

We support providers to give patients safe, high quality, compassionate care within local health systems that are financially sustainable.

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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 is the fifth of its kind: it explains how we reviewed reports in the period April to September 2018 and describes the action we took as a direct result; whether by issuing a Patient Safety Alert or working with partners. 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.

Update in this edition

In this fifth report, we have updated the information on how we respond to patient safety issues, including aligning our processes to the standards being developed by the <u>National Patient Safety Alerting Committee.</u>

How we review and respond

Most patient safety challenges, such as reducing diagnostic error, preventing selfharm, 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 include the Patient Safety Collaboratives, the Maternal and Neonatal Health Safety Collaborative and the Patient Falls Improvement Collaborative. The information we routinely collect through the NRLS and other sources informs this work, as will the responses to the consultation on our proposals for a national patient safety strategy for the NHS.

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 an **alert** that sets out early 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 an **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 an **alert** requiring their implementation.

As a member of the National Patient Safety Alerting Committee (NaPSAC), we are developing and improving our processes for issuing alerts, alongside a range of other organisations and teams who also issue alerts or safety messages. The work of NaPSAC will ensure that national advice and guidance that is safety-critical and mandatory will stand out from other communications, so that providers are clear about which 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 six months covered by this report our clinical teams reviewed



9,798

Incidents reported to the NRLS with an outcome of death or severe harm (including reviewing each update of these incident reports)



4,313

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



262

Potential and confirmed Never Events reported to StEIS*



38

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



30

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 61 issues between April and September 2018 that our clinical teams 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**.
- 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 an 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 an alert is **the best route**; if actions only require changes in practice by a professional speciality, 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: Deciding if the patient safety issue, resources or intervention meet the criteria for an NHS Improvement Patient Safety Alert



- (a) NHS Improvement's 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 in England 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) '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.
- (e) To be constructive, actions must do more than raise awareness or warn people to be vigilant against error. They require healthcare organisations to take systematic action, not actions that are more effectively delivered by professional organisations such as royal colleges
- (f) As defined by NaPSAC see https://improvement.nhs.uk/resources/national-patient-safetyalerting-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.
7	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.
ι. H	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*
- Health and Social Care in Northern Ireland*
- Royal College of Obstetricians and Gynaecologists (RCOG)
- Royal College of Ophthalmologists (RCOphth)

- 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 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 delaying, to 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 subsequent 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 <u>NaPSAC</u> criteria when developing the actions required by our alerts. We ask the following questions to apply <u>NaPSAC</u> criteria:

Are the actions required...



Assessed for potential unintended consequences?

Why is this important?

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 (eq 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 via National Patient Safety Response Advisory Panel advice but may need to be confirmed with testing/piloting, or through previous implementation by a number of healthcare providers.



Cost² of implementing 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 proportionate to the reduction in harm they used by NICE – cost per year of quality-adjusted life – to can be expected to direct finite NHS resources at the patient safety issues where they are likely to have greatest impact. For some issues, the potential to reduce costs of litigation may also need to be factored in.



Have considered the actions?

the actions

achieve?

Actions should be mindful of the needs of disadvantaged equality impact of the 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.

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.



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 our own 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 about review and alerts?

If you would like to know more about why we have designed our 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?

Patient Safety Alerts

Our 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 register compliance via CAS once they complete all the required actions. We publish monthly data on any trusts that have not declared that the actions required in an alert have been completed by the designated deadline. Compliance with alerts is also a focus of CQC inspections. 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 2018, we issued five Patient Safety Alerts:



Resources to support safe and timely management of hyperkalaemia

Issued: 8 August 2018 Resource Alert

The way the body responds to hyperkalaemia – a higher than normal level of potassium in the blood – is unpredictable; arrhythmias and cardiac arrest can occur without warning. It is potentially a life-threatening emergency. Timely identification, treatment and monitoring, during and beyond initial treatment is essential.

This alert signposts to a <u>set of resources</u> that can help organisations ensure their clinical staff have easily accessible information to guide prompt investigation, treatment and monitoring options. The resource webpage includes short videos organisations can use to help frontline staff recognise that hyperkalaemia is a medical emergency and encourage them to familiarise themselves with local guidance and equipment.

³ To subscribe to CAS alerts, contact the CAS helpdesk by emailing <u>safetyalerts@mhra.gov.uk</u>



Resources to support safer bowel care for patients at risk of autonomic dysreflexia

Issued: 25 July 2018 Resource Alert

Patients with spinal cord injury or neurological conditions may have neurogenic bowel dysfunction, which often means they depend on routine interventional bowel care, including the digital (manual) removal of faeces (DRF).

Some of these patients, especially those with spinal cord injury above T6, are particularly susceptible to the potentially life-threatening condition autonomic dysreflexia, which is characterised by a rapid rise in blood pressure, risking cerebral haemorrhage and death. Autonomic dysreflexia can be caused by non-adherence to a patient's usual bowel routine or during or following interventional bowel care.

Following reports of patient safety incidents around significant delays in providing DRF or an appropriate alternative, this alert provides links to a <u>resources</u> to support safer bowel care for patients at risk of autonomic dysreflexia, and highlights the publication of NHS England's updated <u>Excellence in continence</u> <u>care</u> framework, which addresses how providers can overcome implementation challenges.



Resources to support safer modification of food and drink

Issued: 27 April 2018 Resource Alert

Food texture modification is widely accepted as a way to manage dysphagia (the medical term for swallowing difficulties), as well as for others without dysphagia, for example, with lost dentures, jaw surgery, frailty or impulsive eating.

There continues to be local variation in the terminology

used to describe the thickness of modified food and fluids. This can lead to confusion for patients, carers and healthcare staff; and patient safety incidents have been reported where the this has caused harm, particularly when imprecise terms such as 'soft diet' have been used.

The International Dysphagia Diet Standardisation Initiative (IDDSI) has developed a standard terminology with a colour and numerical index to describe texture modification for food and drink.

This alert, issued jointly with The British Dietetic Association and Royal College of Speech and Language Therapists, provides links to <u>a range of resources</u> to assist providers with the transition to the IDDSI framework to standardise terminology and eliminate the use of imprecise terms, including 'soft diet'.



Resources to support the safe adoption of the revised National Early Warning Score (NEWS2)

Issued: 26 April 2018 Resource Alert

Failure to recognise or act on signs that a patient is deteriorating is a key patient safety issue. It can result in missed opportunities to provide the necessary care to give the best possible chance of survival.

Recognising and responding to patient deterioration relies on a whole systems approach and the revised NEWS2, published by the Royal College of Physicians in December 2017, reliably detects deterioration in adults, triggering review, treatment and escalation of care.

NHS England's aim is for all acute hospital trusts and ambulance trusts to fully adopt NEWS2 for adult patients by 31 March 2019. This alert has been jointly issued by NHS England, NHS Improvement and the Royal College of Physicians to highlight the existing resources to support adoption of NEWS2.



Risk of death or severe harm from inadvertent intravenous administration of solid organ perfusion fluids

Issued: 17 April 2018 Warning Alert

Perfusion fluids are mainly used during solid organ transplantation procedures to perfuse and preserve organs. If inadvertently intravenously administered to a patient, the high potassium content of some perfusion fluid can cause cardiac arrest.

Patient safety incidents have been reported where there has been confusion between solid organ perfusion fluids and other fluids intended for administration to patients.

To prevent this risk, the alert asks hospitals with transplant units to ensure that storage of organ perfusion fluids is reviewed to reduce the chance of confusion with other fluids intended for administration to patients. Other hospitals are asked to remove all solid organ perfusion fluids from clinical areas.

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 NHS Improvement alerts published in the period covered by this report:

- Risk of death or severe harm from inadvertent intravenous administration of solid organ perfusion fluids (NHS/PSA/W/2018/002) (alert issued unchanged to NHS Scotland)
- Resources to support safer modification of food and drink (NHS/PSA/RE/2018/004) (alert issued unchanged via the Allied Health Professional network)
- Resources to support safer bowel care for patients at risk of autonomic dysreflexia (NHS/PSA/RE/2018/005) (alert issued unchanged to NHS Scotland)

• Resources to support safe and timely management of hyperkalaemia (NHS/PSA/RE/2018/006) (alert issued unchanged to NHS Scotland).

Wales issued the following publications based on NHS Improvement alerts published in the period covered by this report:

- Risk of death or severe harm from inadvertent intravenous administration of solid organ perfusion fluids (NHS/PSA/W/2018/002) (<u>issued as PSN042 on</u> <u>24 April 2018</u>)
- Resources to support safer modification of food and drink (NHS/PSA/RE/2018/004) (issued as PSN045 on 9 August 2018)
- Resources to support safer bowel care for patients at risk of autonomic dysreflexia (NHS/PSA/RE/2018/005) (<u>issued as PSN046 on 23 October</u> <u>2018</u>).

Northern Ireland issued the following publications based on NHS Improvement alerts published in the period covered by this report:

- Risk of death or severe harm from inadvertent intravenous administration of solid organ perfusion fluids (NHS/PSA/W/2018/002) (<u>issued as HSC</u> (SQSD) 9/18 on 1 May 2018)
- Resources to support the safe adoption of the revised National Early Warning Score (NEWS2) (NHS/PSA/RE/2018/003) (<u>issued as HSC</u> (SQSD) 10/18 on 24 May 2018)
- Resources to support safer modification of food and drink (NHS/PSA/RE/2018/004) (issued as HSC (SQSD) 16/18 on 5 July 2018)
- Resources to support safer bowel care for patients at risk of autonomic dysreflexia (NHS/PSA/RE/2018/005) (<u>issued as HSC (SQSD) 19/18 on 22</u> <u>August 2018</u>)
- Resources to support safe and timely management of hyperkalaemia (NHS/PSA/RE/2018/006) (<u>issued as HSC (SQSD) 23/18 on 22 August</u> <u>2018</u>).

'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 have also begun producing patient story videos as a powerful way to make staff aware of how real patients 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 via the <u>NHS Improvement YouTube channel</u>.

Between April and September 2018 we published three videos:



In April 2018 we released 'Kathryn's story' to support our Confirming removal or flushing of lines and cannulae after procedures alert. This can be viewed on the <u>alert webpage</u> and <u>YouTube</u>.



In August 2018 we released one 'ask why' video specifically for hospital staff and one specifically for GPs to support our Resources to support safe and timely management of hyperkalaemia alert. These can be viewed on the <u>alert</u> webpage and on YouTube (<u>hospital staff</u> and <u>GPs).</u>

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.



Harm from flushing endoscope cleaning fluid into a patient's lungs

We identified an incident where endoscope cleaning fluid was inadvertently flushed into a patient's lung during a bronchoscopy and broncheo-alveolar lavage procedure. In this instance, concentrated detergent was stored on the unit in bottles and usually mixed with sterile water to be used at the bedside for the post procedure clean. The diluted detergent was confused with the sterile sodium chloride 0.9%, usually used for the lavage, and 20mls of this fluid was instilled into a patient during bronchial lavage. There was no standard operating procedure in place for bedside bronchoscopy, including the post-procedure clean.

Department of Health (2016)<u>guidance</u> for the cleaning of bronchoscopes indicates that there is no need to carry out decontamination within a clinical area, and therefore no need to keep detergent where it could be confused with products intended for clinical care. A search of the NRLS was undertaken for the previous three years and no similar incidents were found.

We contacted all trust decontamination leads asking them to review the systems in place for bedside bronchoscopy procedures in their organisations. This communication was also shared with the Intensive Care Society who communicated the incident to their members via their website, newsletter and social media streams.



Burns caused by heat pads or hot water bottles in maternity units

We found several cases of burn injuries from heat pads or hot water bottles used in maternity settings, mainly in women who have had epidural anaesthesia. Patients with epidurals should never use any form of heat pads or hot water bottle as the resultant lack of sensation creates a risk of burns.

This advice was shared via an article in the *Midwives* magazine (Winter 2018 issue; available to members on the <u>RCM</u> website) and via the Maternity Safety Champions newsletter.

Travel-related venous thromboembolism in pregnancy

Long distance travel (over four hours by land or air) when pregnant can increase the risk of <u>venous thromboembolism</u> (VTE). An NHS England regional team raised concerns that the NICE and RCOG <u>guidance</u> for long distance travel and the prevention of VTE in pregnancy was not being consistently applied in practice, increasing the risk of pregnant women not receiving appropriate advice or thromboprophylaxis.

We took this issue to the RCOG Joint Standing Committee for Patient Safety which agreed to highlight the current recommendations when revising its guidance and to share this with RCGP. In addition, Public Health England (PHE) updated the main websites giving information on travel in pregnancy, including the <u>NHS website</u>, and the national Maternity Transformation Programme agreed to share these safety messages via its newsletter.



Death after ingestion of cleaning products in hospital

A patient died following ingestion of cleaning materials that had been put in a drinking water jug.

We found 18 incidents in a 12-month period where patients who were confused or intended to self-harm had swallowed cleaning products in healthcare settings.

Many cleaning products used in healthcare premises are covered by the Control of Substances Hazardous to Health Regulations (CoSHH 2002). Learning from investigations



suggested CoSHH training and notices should consider the needs of staff with low literacy or whose first language is not English. It also identified that good local risk assessment can allow secure but convenient access to cleaning cupboards and this is important to ensure staff never decant cleaning products into other containers.

We worked with the NHS Improvement Estates and Facilities team to issue an Estates and Facilities Alert via <u>CAS</u>. This encouraged multidisciplinary assessment to identify CoSHH risks considering environmental, clinical and operational health and safety factors.



Delayed access to resuscitation medicines to treat cardiac arrest

We learned of a delay in accessing emergency resuscitation medicines due to the drugs being locked away. This practice can delay medicines administration and is contrary to the Resuscitation Council (UK) <u>policy statement</u>, but we identified potential confusion between the Resuscitation Council (UK) guidance and guidance used by CQC inspectors.

We sought clarity from CQC, which confirmed that these medicines do need to be readily available but should be supplied in tamper evident packaging if not locked away. CQC has updated its Medicines Optimisation framework and Medicines Checklist for Acute Hospitals used by its inspection teams to ensure consistency with the Resuscitation Council (UK) guidance.



Metallic objects and MRI scanners

Two incidents relating to MRI safety were shared with the Society of Radiographers (SoR): a patient with an implanted hearing aid who suffered pain and inflammation following an MRI scan; and an incident where a metal trolley with equipment was taken into an MRI scanner room. The large magnetic force generated by an MRI scanner will pull in, <u>at great speed</u>, any unsecured metal objects in the room with the potential to cause significant harm or death.

SoR believes more can be done to support and educate radiology and other staff around MRI safety. It is developing a series of eLearning modules to inform staff on key safety issues in MRI rooms. Full funding has been secured for this project and these modules will be available on the <u>eLearning for Healthcare</u> website when complete.

Suboptimal ventilation from combining two different brands of Mapleson C breathing circuits

During the resuscitation of a patient, two different brands of Mapleson C <u>breathing circuit</u> were attached in error. One was attached to the bag valve mask as is standard and another component of a different brand was connected incorrectly to the oxygen supply; this resulted in suboptimal patient ventilation.

Through SALG and the MDSO network we recommended trusts only use one brand of Mapleson C circuit to minimise any confusion in circuit set up, and only trained staff are involved in circuit set up.

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Implanting the wrong intraocular lens after changing manufacturers

A patient had the wrong intraocular lens (IOL) implanted during a cataract procedure. As the organisation was in the process of changing from one make of IOL to another, two sets of preoperative measurements (biometry) were included in the patient's notes, one for the specific make of IOL the trust was replacing and one for the make it was introducing. A lens matching the wrong biometry measurements was implanted and once this error was identified, the patient required corrective surgery to implant the correct IOL lens.

We asked RCOphth to take action to reduce the risk of this happening again. It agreed that invalid biometry (ie that

pertaining to a lens no longer in use) should be clearly struck through in hardcopy patient notes and deleted from electronic records, and any such lenses stored away from the surgical pathway pack. The WHO checklist for cataract surgery should include the exact make and model of the lens to be used. RCOphth set out these requirements in a guidance <u>update</u> on its website

Retained strands of Hawkins 3 wires used for breast localisation procedures

Tiny fragments of wire were identified in a patient following a breast localisation procedure. During the procedure a Hawkins 3 Flexistrand wire was passed through her breast lesion and its protruding ends cut. Investigation highlighted that the wire should not have been cut as this can cause it to unravel and shed strands into the operation site.

The reporting organisation identified 10 similar reports relating to Hawkins wire over a three-year period.

We sought clarity from the Association of Breast Surgery (ABS) about the risk to patients. It considered that the microscopic wire fragments were unlikely to pose a significant risk of harm and therefore that no alert needed to be issued. We asked ABS and RCR to remind their members not to cut these wires and to follow the manufacturer's instructions.

Polymer filling from dressing leaked into wound



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Wound dressings containing superabsorbent polymers are useful in controlling fluid leakage from a wound.

We were concerned to read that a patient required surgery to remove polymers that had leaked from one such dressing into their wound and adhered to the wound bed. The dressing had been cut to the size of the wound and this allowed the filling to spill out. Further investigation revealed that while similar



dressings are clearly marked 'Do not cut', the one used in this incident was not.

We have recommended that MHRA ensures consistency of labelling across all such dressings.



Pneumothorax from nasogastric tube insertion

Over two years we found 65 reports of <u>pneumothorax</u> from <u>nasogastric tube insertion</u>. These pneumothoraces required extra treatment, such as chest drain insertion, which will have compromised the survival of these already critically ill patients. While this risk is not entirely preventable, we aimed to identify any areas where risk could be reduced.

MHRA found no link to a specific type of nasogastric tube design. We found no obvious link between pneumothorax and a patient's condition but some suggestion of an association with the skill level of the staff inserting the tubes. In some incidents inexperienced staff appeared to have found it difficult to insert the tube, pushing through apparent resistance or making repeated attempts at insertion. Some nurses encountering difficulties contacted medical staff who made further attempts at unguided placement rather than placement under direct visualisation or fluoroscopy. However, some pneumothoraces occurred during apparently unproblematic nasogastric tube insertions by experienced staff.

We recommended the <u>British Association for Parenteral and</u> <u>Enteral Nutrition</u> (BAPEN) and the <u>National Nurses Nutrition</u> <u>Group</u> (NNNG) provide clinical guidance on how many insertion attempts should be made before seeking senior advice, and what to do if unguided placement proves difficult. BAPEN and NNNG are also considering whether current advice on estimating the required nasogastric tube length should be revised, and whether tube marking or training can be enhanced to help staff distinguish between expected and unexpected points of resistance during tube insertion.



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

Publishing 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. But 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 network of new or under-recognised methods of self-harm or methods of concealing items for self-harm.

In the period covered by this report, we shared information on one risk through this route.



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 12 patient safety incidents with NHS Digital including:

- incidents relating to transfer of pathology results to GP systems
- unclear methotrexate dosing instructions generated by a GPsystem template
- an electronic prescribing system defaulting to the wrong setting.

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
- **NHS England**, which uses incidents related to NHS 111 services to make continuous improvements to patient pathways
- 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 specific investigations.

We also share NRLS data with organisations and researchers who are looking into a specific patient safety topic. Examples of this include:

- types and reported level of harm from undiagnosed congenital heart defects in newborns; used to inform policy on national screening programmes
- incidents involving the use of controlled drugs; used to inform a Department of Health and Social Care review of The Controlled Drugs (Supervision of Management and Use) Regulations 2013
- incidents involving staff who are not registered nurses but have 'nurse' in their job title; to help inform work on whether the title 'nurse' should be protected
- non-invasive ventilation incidents; for a project linked to the <u>study</u> by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD)

 medication error incidents related to digital systems; to assist the delivery of the 'ePRaSE' project as part of the Global Digital Exemplar (GDE) programme.

Journal articles including review of NRLS data

Data sharing is an important aspect of ensuring that the insight from the NRLS supports learning. In addition to regular <u>data sharing</u> we respond to ad-hoc data requests from university researchers, royal colleges and other professional bodies or individuals. This information can be used for local learning, but often appears in peer-reviewed journal articles or conference presentations or is used to inform further research. In the period covered by this report, conference abstracts featuring NRLS data included analyses of the causes of death and adverse events in inpatients with diabetes insipidus,⁴ perinatal deaths and related indicators,⁵ and the safety of antimicrobials in patients with penicillin allergy.⁶

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 Improvement and MHRA support the MDSO network through:

 MDSO handbook – supports newly appointed MDSOs and signposts the responsibilities of the post

⁴ Prentice M (2018) The causes of deaths and adverse events in inpatients with diabetes insipidus. A suggested strategy for electronic prescribing and a change of name to pituitary insipidus to improve safety. *Clin Endocrinol (Oxf)* 89(SI): 64–65.

⁵ Reed K, Antoniou E, McCarthy A, Turier H, Roberts N (2018) Key indicators in multiple births care in the UK and their relationship with stillbirth and neonatal deaths. *BJOG* 125(S2): 12–14.

⁶ Jani Y (2018) Can we improve the safety of antimicrobials in patients with penicillin allergy by using incident reported to the national reporting and learning system? *Int J Qual Health Care* 30(2): 34-35.

- 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 Improvement, MHRA and specialists from healthcare, procurement and industry), sharing relevant safety-related information, providing updates on the most recent <u>MHRA medical device alerts</u> and our Patient Safety <u>Alerts</u>, 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 2018: Clarification from MHRA on when an app is classified as a medical device; news on the national clinical safety officer (NCSO) role in NHS Digital; <u>DPSIMS</u> update and discussion on General Data Protection Regulation (GDPR) implications for patient data stored on medical devices.

May 2018: Issues to consider when introducing and managing medical devices in community settings; exploration of community practitioner engagement with the MDSO network; MHRA yellow card reports on community beds. We shared an incident where a hospital patient required resuscitation, but staff were unable to remove the head of the bed. This occurred because beds had been urgently sourced to create escalation wards but without consideration of whether they met the <u>ISO standard for a hospital bed</u>. We asked MDSOs to check that any beds coming into their organisation as rented or on long-term loan meet the specification and regulations for hospital acute care.

June 2018: Awareness of patient safety reporting and learning systems across England, Scotland, Wales and Northern Ireland. Insight from Dorset Healthcare on the challenges for managing medical devices across their geographical location.

July 2018: Update on the ISO 80369 standard relating to syringes, small-bore connectors including inflation devices; presentation from NHS England on the <u>Life</u> <u>Science Industry Register (LSI)</u>; shared learning from incidents relating to acute bed specifications and retained guidewires, supported by a <u>poster resource from</u> the Royal College of Emergency Medicine.

September 2018: Relevance of <u>patient safety resource alert to support the safe</u> <u>and timely management of hyperkalaemia</u> for MDSOs; highlighting potential infusion pump pressure changes required when administering medication while being mindful of the risk of extravasation risk in these patients.

We also use the MDSO network for intelligence gathering and have received useful feedback following questionnaires on oximeter sensor placement and interpretation of blood glucose analysers. This information provides a basis for understanding whether national action may be needed, and the type of actions most likely to address the issue.

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 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, guest attendees 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 <u>alerts</u> relevant to MSOs, web events have covered the following specific topics:

- April 2018: <u>A Just Culture guide</u>; London Ambulance Service use of intravenous paracetamol for paediatric patients; new reporting system for collection of harms associated with new psychoactive substances; updates on the <u>Medicines Optimisation Dashboard</u> and <u>valproate in pregnancy</u>.
- May 2018: Medication safety work of the South West Area MSO local network; introduction to Life QI; the preparation and administration of metaraminol in theatres; a lithium patient safety incident; start of the safety theory series (STS) 'to err is human'.
- June 2018: Description of the safety work by the <u>Community Pharmacy</u> <u>MSO Patient Safety Group</u>; description of MSO involvement at a coroner's inquest; mental health first aid training; <u>WHO medication safety programme</u> <u>metrics</u>; STS – what should be investigated in a patient safety incident.
- July 2018: Specialist Pharmacy Service (SPS) <u>WHO Good Practice</u> <u>Repository</u>; STS – a senior nurse's personal experiences of errors and reporting; amphotericin medication errors (fungizone administered not ambisome).
- August 2018: Supporting junior doctors through the County Durham & Darlington NHS Foundation Trust 'buddy scheme'; <u>fire hazards with paraffin</u> <u>containing products</u>; the Valproate <u>PREVENT</u> Programme; an introduction to signal detection by MHRA.
- September 2018: Update on electronic prescribing and medicines administration; STS – quality improvement; LASA errors; use of the MSO Forum.

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. *Our approach to patient safety* explains our role across the whole system to help the NHS in England become the safest healthcare organisation in the world. It describes our statutory patient safety duties and what we are doing to lead and support patient safety improvement across the NHS.

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

Acknowledgements

This report was prepared by:

- Dr Frances Healey, Deputy Director of Patient Safety (Insight)
- Frances Wood, Head of Patient Safety (Review and Response)
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- Wayne Robson, Head of Patient Safety (Cross System Development)
- Debbi Scotting, Clinical Reviewer
- Michael Surkitt-Parr, Clinical Reviewer
- Joan Russell, Head of Patient Safety (Policy and Partnerships)
- Julie Windsor, Patient Safety Clinical Lead (Medical Specialties/Older People)
- Karen Hooper, Patient Safety Policy Lead (Maternity & Neonate Safety)
- Professor Ben Thomas, Patient Safety Expert Advisor (Mental Health)

With thanks to the NRLS analysts who support the review and response and advice and guidance functions within the national Patient Safety Team.

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