Patient safety review and response report October 2018 to March 2019

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

24 September 2019

NHS England and NHS Improvement

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 October 2018 to March 2019 and describes the action we took as a direct result; whether by issuing an NHS Improvement Patient Safety Alert [1] 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.

Based on the benefits estimates within the NHS Patient Safety Strategy, the actions described within this report will save 40 lives and prevent 120 disabilities in each following year, with associated financial savings of £3.4 million annually.

[1] Note that whilst NHS England and NHS Improvement are operating jointly, they retain separate names when publications are related to statutory functions. For this reason, our Alerts will continue to be referred to as NHS Improvement Patient Safety Alerts.

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 and other initiatives. 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 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 have developed and improved our processes for issuing alerts and are the first organisation to be accredited to issue the new National Patient Safety Alerts. The work of NaPSAC ensures that safety-critical and mandatory national advice and guidance stands out from other communications, so that providers are clear about 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 six months covered by this report our clinical teams reviewed

10,103

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

4,156

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

225

Potential and confirmed Never Events reported to StEIS*

27

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

19

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.

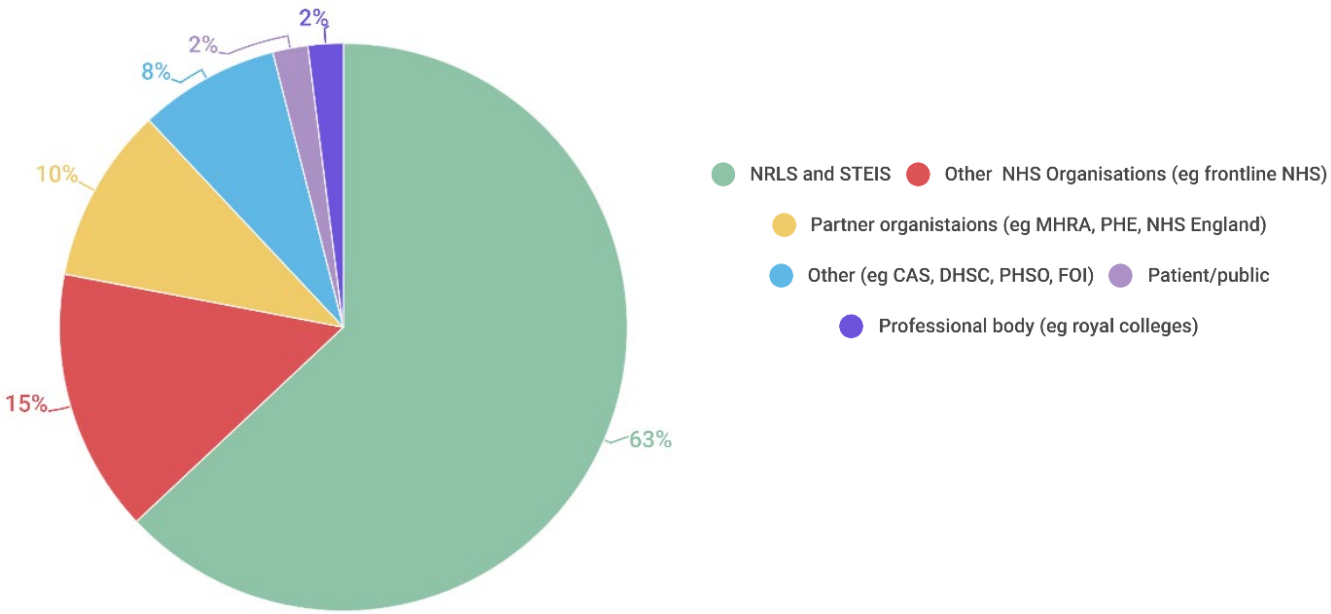
* View our StEIS, Serious Incident framework and Never Event webpages for further information.

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 48 issues between October 2018 and March 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.

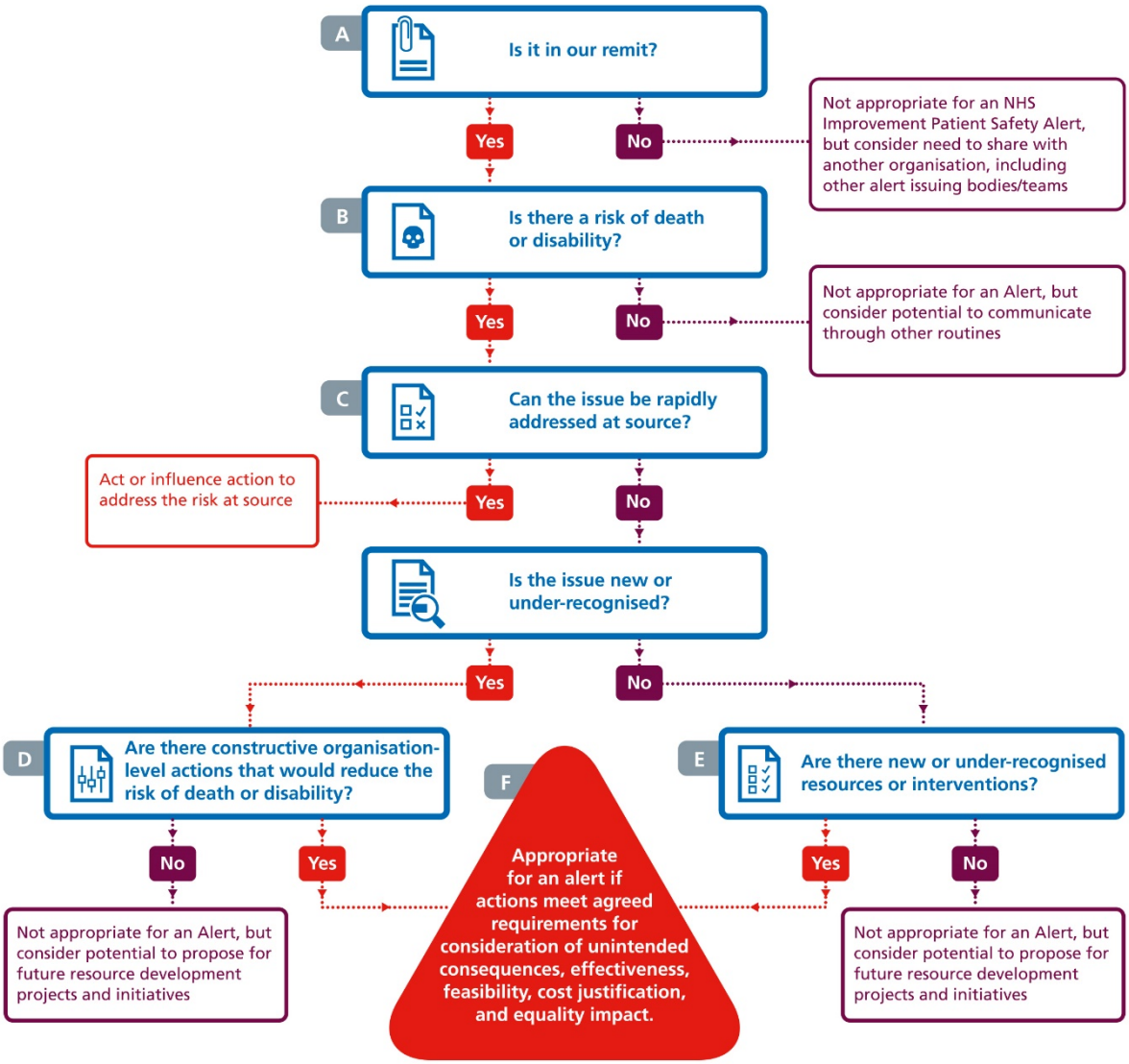
4. Talk to experts, patients and their families, and frontline staff to identify if the patient safety issue is **new or under-recognised**; these groups may have different perspectives.

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 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 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/

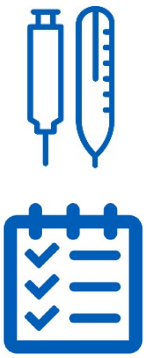
Box 1: Resources linked to alerts

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[2] 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.

[2] 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)
- Royal College of Paediatrics and Child Health (RCPCH)

- 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 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 subsequent alert for a patient safety issue if new resources and/or new interventions become available that provide more effective barriers to error.

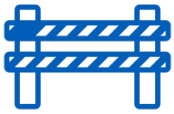
We work within NaPSAC criteria when developing the actions required by our alerts. We ask the following questions to comply with these criteria:

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 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.



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[3] 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 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

[3] 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.

		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 about review and alerts?

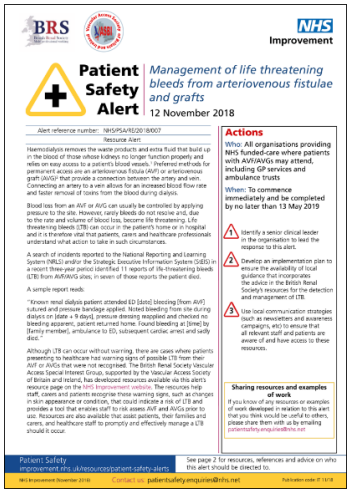
If you would like to know more about why we have designed our clinical review and response process as we have, read this journal article which links our process to the underpinning patient safety theories.

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 they have completed the required actions in an alert 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.[4]

Between October 2018 and March 2019, we issued four Patient Safety Alerts:

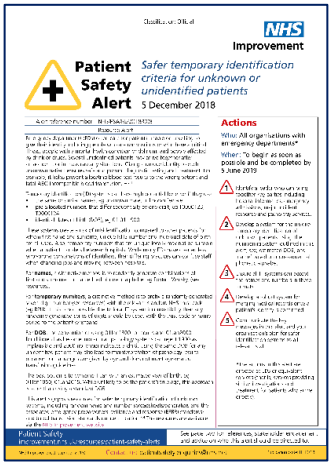

BRS
NHS Improvement
Patient Safety Alert
Management of life threatening bleeds from arteriovenous fistulae and grafts
12 November 2018
Alert reference number: NHS/PSA/RS/2018/007
Resource Alert
Actions
Who: All organisations providing NHS funded-care where patients with AVF/AVGs may attend, including GP services and ambulance trusts
When: To commence immediately and be completed by no later than 13 May 2019
Identify a senior clinical leader in the organisation to lead the response to this alert.
Develop an implementation plan to ensure the availability of local guidance that incorporates the advice in the British Renal Society's resources for the detection and management of LTB.
Use local communication strategies (such as newsletters and awareness campaigns, etc) to ensure that all relevant staff and patients are aware of and have access to these resources.
Sharing resources and examples of work
Patient Safety
See page 2 for resources, references and advice on who this alert should be directed to.

Management of life-threatening bleeds from arteriovenous fistulae and grafts

Issued 12 November 2018
Resource Alert

The alert signposts providers to resources produced jointly by The British Renal Society and the Vascular Access Society of Britain and Ireland to help staff, carers and patients recognise the warning signs of life-threatening bleeds from arteriovenous fistulae and grafts. Providers are required to ensure local guidance incorporates the advice in these resources, and to make them available to staff and patients.

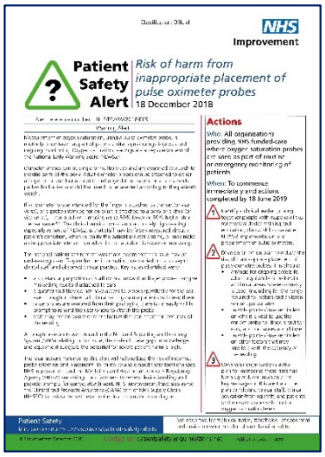
[4] To subscribe to CAS alerts, contact the CAS helpdesk by emailing safetyalerts@mhra.gov.uk



Safer temporary identification criteria for unknown or unidentified patients

Issued: 5 December 2018
Resource Alert

To ensure safer temporary identification of unknown or unidentified patients, this alert outlines standard criteria for organisations to adopt and signposts a set of resources to support their implementation.

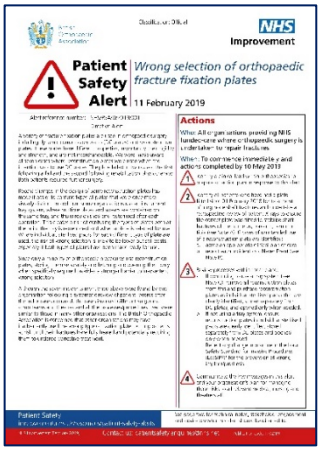


Risk of harm from inappropriate placement of pulse oximeter probes

Issued 18 December 2018
Warning Alert

Oximeter probes can be single or multiple use and are designed to attach to specific parts of the body. Adult oximeter probes can be attached to either a finger or an ear, but are not interchangeable between these sites, whilst probes for babies and children need to be selected according to the patient's weight.

This alert requires providers to ensure staff have access to appropriate equipment and the information they need to use these devices correctly and safely.



Wrong selection of orthopaedic fracture fixation plates

Issued 11 February 2019
Directive Alert

The alert required organisations to review X-rays for patients fitted with an orthopaedic fracture fixation plate for specific procedures, to identify and manage any patients who may have had the wrong plate fitted. The alert also required organisations to implement process changes to reduce the risk of wrong selection happening in the future.

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:

- Management of life-threatening bleeds from arteriovenous fistulae and grafts (NHS/PSA/RE/2018/007) (issued to NHS Scotland on 29 November 2018)
- Risk of harm from inappropriate placement of pulse oximeter probes (NHS/PSA/W/2018/009) (issued to NHS Scotland on 18 December 2018)

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

- Management of life-threatening bleeds from arteriovenous fistulae and grafts (NHS/PSA/RE/2018/007) (issued as PSN047/November 2018)
- Risk of harm from inappropriate placement of pulse oximeter probes (NHS/PSA/W/2018/009) (issued as PSN048/February 2019)
- Wrong selection of orthopaedic fracture fixation plates (NHS/PSA/D/2019/001) (issued as PSA 009/February 2019)

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

- Management of life-threatening bleeds from arteriovenous fistulae and grafts (NHS/PSA/RE/2018/007) (issued as HSC (SQSD) 33/18 on 20 November 2018)
- Safer temporary identification criteria for unknown or unidentified patients (NHS/PSA/RE/2018/008) (issued as HSC (SQSD) 37/18 on 8 January 2019)
- Risk of harm from inappropriate placement of pulse oximeter probes (NHS/PSA/W/2018/009) (issued as SC (SQSD) 38/18 on 8 January 2019).

‘Ask why’ and patient story videos

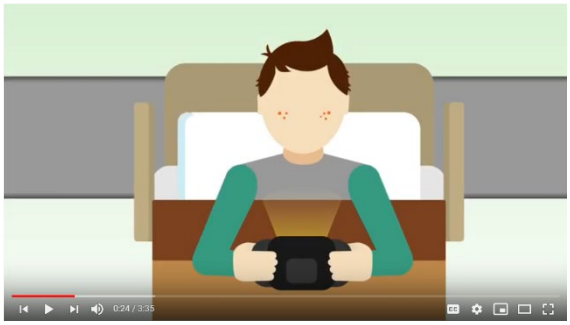
Our alerts ask for co-ordinated action at an organisational level, as that is the most effective way of addressing patient safety issues. If an alert requires specific changes, we may produce an ‘ask why’ video around the time the alert actions need to be completed. These videos encourage staff to ‘ask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

We have also begun to produce 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 NHS Improvement YouTube channel.

Between October 2018 and March 2019 we published two videos:

In December 2018 we released ‘Tracy’s story’ to support our Resources to support safer bowel care for patients at risk of autonomic dysreflexia alert. This can be viewed on the alert’s resources webpage and YouTube.



Also in December 2018 we released a babies, children and young people version of the ask why video to support our Resources to support safe and timely management of hyperkalaemia alert. This can be viewed on the alert’s resource webpage and on 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.

Catastrophic bleeding following mini-tracheostomy insertion

Mini-tracheostomies are typically used to manage bronchial secretions in intensive care patients. Their insertion is usually uncomplicated, but an incident described a patient's death following this procedure under local anaesthetic where large blood vessels overlying the tracheostomy site were punctured, followed by catastrophic bleeding.

We contacted SALG who agreed that individual patient and environmental factors need to be considered before deciding whether a mini-tracheostomy should be inserted in a critical care unit or an operating theatre. We asked for this incident to be described in a SALG update to raise awareness among anaesthetists and other clinicians of this risk and the need to take it into account when planning mini-tracheostomies.

Cardiovascular effects of apraclonidine eye drops

Apraclonidine eye drops are used in a diagnostic test for Horner syndrome in babies and children and are known to have potential cardiovascular and respiratory side effects in this group. A baby with a reduced heart rate and breathing difficulties after administration of apraclonidine 1% eye drops needed to be admitted to a paediatric intensive care unit.

Following a review of the NRLS, we took this issue to the Royal College of Ophthalmologists who issued recommendations that apraclonidine eye drops are not used in small babies, and only in more dilute preparations and with careful observation in older babies and children, via an Ophthalmic Safety Alert.

We also identified incidents reporting hypotension in older people given these eye drops for ophthalmic conditions. The National Falls

Prevention Co-ordination Group has included these concerns in its work.

Pain and injury from removing pigtail drains without unlocking the coil

A patient suffered severe bleeding when their pigtail drain was removed with its tip still locked in a rigid curled shape; the vital step of unlocking the coils was missed in the procedure.

Review of the NRLS identified other attempts to remove pigtail drains without unlocking the coils. Once inserted, pigtail drains look similar to more commonly used drains that do not require unlocking, and do not display a warning that the coils must be unlocked before the drain is removed.

We brought this issue to the attention of the MHRA, who asked pigtail drain manufacturers to review their labelling. They confirmed that manufacturers include appropriate warnings in their 'instructions for use' and recommend that these instructions or warning labels are held in a patient's case notes to alert staff that the drain has a locking mechanism.

However, in light of our findings MHRA recognised this may not be an effective way of warning staff when they are about to remove the drain, and plans to write to manufacturers regarding additional 'on-device' marking indicating the pigtail shape as per Section 13 of the Essential Requirements in the Medical Devices Directive.

Understanding the importance of 'HI' or 'LO' display on blood glucose meters

Some blood glucose meters use non-numerical values to indicate a dangerously high or low blood glucose level. Following an incident where the display 'HI' was not understood and acted on, we asked users from different care settings to complete a questionnaire to learn more about levels of understanding. Whilst most respondents understood the significance and urgency of 'HI' and 'LO', we were concerned that some people who perform blood glucose monitoring

infrequently may be confused by these terms and therefore fail to act on them.

We asked Diabetes UK, the Association of British Clinical Diabetologists and NHS Choices to review their website resources for healthcare staff and people with diabetes to check these emphasise the importance of acting immediately when a meter displays 'HI' or 'LO'. MHRA will also highlight this in its diabetes social media campaign during 2019.

Harm from retention of long-term vaginal pessaries for longer than intended

Long-term vaginal pessaries are used for prolapse and urinary incontinence. A woman developed a fistula when a pessary was retained for longer than the intended six months. Our review of the NRLS suggested these devices are sometimes used in older women with memory problems who may not remember that their pessaries need to be regularly replaced, and that healthcare systems for ensuring review are not robust.

We shared our concerns with RCOG and NICE. NICE has updated its recommendation on what should be considered before starting a woman on pessary treatment. This includes extra advice on pessary clinic appointments for women at risk of complications or those with physical or cognitive impairment that might make it difficult for them to manage the ongoing pessary care.

Air embolism during CT contrast procedures

CT contrast is injected rapidly under high pressure which means that if there was any air in the administration system, the patient will be at risk of an air embolism and life-threatening and immediate deterioration. We identified a report of severe harm from an air embolism during CT administration and while our search of the NRLS found no similar incidents, it did identify situations that increase the potential for air to enter the system.

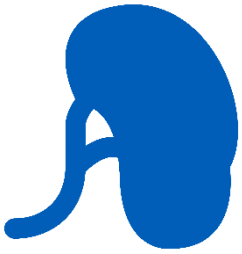
We shared our review with The Society of Radiographers who will be incorporating our findings into their training materials and their next review of their quality imaging standard.

Patients with diabetes who require additional support

From our regular review of patient safety incidents we identified several issues related to the care of patients with diabetes (type 1, type 2 or gestational) in combination with other clinical conditions. These included:

- inpatients who had been self-administering insulin without the knowledge of clinical staff, and administering doses despite low blood sugar levels
- inpatients who were initially suitable to self-administer but were not reassessed as their condition deteriorated, leading to complications.
- risk of harm due to the need for additional expert support to re-establish diabetic control in the postnatal period
- where inpatients had been trained to base their insulin dose on the carbohydrate content of food (e.g. DAFNE/Desmond), but were too unwell to continue whilst an inpatient, staff were incorrectly calculating the carbohydrate content of hospital food leading to incorrect insulin dosing. This was due to a lack of expert support to ensure alternative, less complex regimens were in place until the patient was well enough to self-manage.

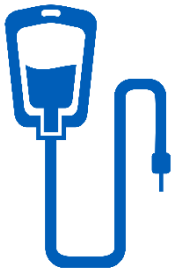
These issues were brought to the attention of the joint clinical leads for the diabetes Get It Right First Time workstream to help inform their ongoing work.



Patient not added to an organ transplant list

An incident described a patient not being added to a transplant list because the request to do so was sent to a generic email address and not the specific one for the pathology administration staff, as was the agreed process.

We asked NHS Blood and Transplant to take action and they shared the learning via their Cautionary tales update.



Harm from uncontrolled infusion of parental nutrition in neonates

A Serious Incident with significant clinical consequences occurred where a newborn baby received a rapid over-infusion of parenteral nutrition because this was inadvertently administered without an infusion pump. The circumstances of this incident were therefore different from those described in the national Patient Safety Alert Risk of severe harm and death from infusing total parenteral nutrition too rapidly in babies.

To highlight the issue to frontline neonatal unit staff, we shared details of the incident via the MSO and MDSO networks, the Pharmaceutical Aseptic Services Group and the Specialist Pharmacy Service website, so that they can consider changing their local procedures to reduce the risk of this error.

Incorrect use of multi-well biopsy cassettes

Multi-well biopsy cassettes are used when multiple tissue samples are taken from the same patient, with each sample placed in its own well. Some cassettes are pre-labelled with body sites such as quadrants of the breast or parts of the gastrointestinal tract.

An incident was identified in an endoscopy unit where multiple tissue samples were placed in each well. This practice risks mixing up biopsy samples from different body sites, which could delay diagnosis and/or mean further investigations for the patient.

The Royal College of Pathologists have agreed to revise their Tissue Pathways Guidance to clarify when multi-well cassettes should be used and how they are used safely.

Harm from swallowing solutions of betamethasone soluble tablets intended for use as a mouthwash

The steroid betamethasone is licensed as an anti-inflammatory and is typically prescribed as an oral preparation. Dissolved tablets are sometimes used as a mouthwash to treat severe and distressing oral inflammation in, for example, patients undergoing chemotherapy.

Prescribing and dispensing software systems do not currently have a 'mouthwash' option, which has led to errors in prescribing or dispensing. Even when the preparation is correctly dispensed as a mouthwash, the patient information leaflet does not include mouthwash as an indication and therefore the patient is not given adequate information on how to use as mouthwash. This has led to swallowing of the mouthwash solution. This can cause serious harm, especially if continued long enough to supress the patient's own production of corticosteroids, and potentially causing an Addisonian crisis when the course ends.

We have asked NHS Digital to raise with software suppliers the need for prescribing/dispensing systems to include a mouthwash option. We have also; asked for a summary of the medicines safety concern to be added to the Specialist Pharmacy Service website, shared a summary with the authors of the NICE Clinical Knowledge Summary for a future update on Aphthous ulcer, and encouraged the MSO network to use a poster and tailored patient information leaflet to highlight this issue.

Administration of end-of-life medicines at home

Patients who know they are dying often choose to die at home. As part of their end-of-life care, the medicines for symptom management are usually kept in the patient's home.

We have identified incidents where injectable medicines, including controlled drugs, intended for administration by visiting healthcare staff have unexpectedly been given to the patient by a family

member or carer. In some cases, these family members were healthcare professionals.

The National Clinical Director for End-of-Life Care has incorporated this issue into wider work relating to end-of-life care. This work recognises the need for a balance between ease of access to this medication and appropriate safeguards, support and advice for family members and carers.

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. 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 17 patient safety incidents with NHS Digital including those relating to:

- delayed transfer of radiology and pathology results to GP systems
- process for entering patient details into theatre systems
- lack of patient follow-up due to system process issues.

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
- **NHS England and NHS Improvement colleagues with responsibilities for emergency care pathways**, who use incidents related to NHS 111 services to inform the 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 their specific investigations.

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

- incidents reported on the prescribing and administration of methotrexate in NHS hospitals; to inform the rheumatology GIRFT workstream

- incidents relating to accidental ingestion of denture cleaning tablets or solution; to support safe and effective delivery of the national programme in Wales to improve oral health for older people living in care homes

- incidents relating to IV medication errors in critical care; for a project to develop guidance on the issues that most commonly result in errors

Journal articles including review of NRLS data

Data sharing is an important aspect of ensuring that insights from the NRLS support learning. In addition to regular data sharing, 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 used to inform further research. In the period covered by this report, journal publications featuring NRLS data included analyses of medication administration errors reported in acute care and resulting in death[5], the nature and causes of unsafe out-of-hours palliative care[6] and conference abstracts included a review of medication safety incidents reported within mental health hospitals.[7]

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 Improvement and MHRA support the MDSO network through:

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

[5] Härkänen M, Vehviläinen-Julkunen K, Murrells T, Rafferty AM, Franklin BD (2019) Medication administration errors and mortality: Incidents reported in England and Wales between 2007–2016. *Res Social Admin Pharm* 15(7): 858–63.
[6] Williams H, Donaldson SL, Noble S, Hibbert P, Watson R, Kenkre J, Carson-Stevens A (2019) Quality improvement priorities for safer out-of-hours palliative care: Lessons from a mixed-methods analysis of a national incident-reporting database. *Palliat Med* 33(3), 346–56.
[7] Alshehri GH, Keers RN, Ashcroft DM, Nguyen J, Carson-Stevens A (2019) Examining medication safety incidents in in-patient mental health settings: A 7-year analysis of incidents reported to the National Reporting and Learning System. *Pharmacoepidemiol Drug Saf* 28(S1): 5–6.

- **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 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:

- **October 2018:** Updates from CQC, National Association of Medical Device Educators and Trainers and presentations on medical gas incidents.
- **November 2018:** Updates on NHS Medical Devices PAQ (pre-acquisition questionnaire), HSIB and their *Design and safe use of portable oxygen systems* report.
- **December 2018:** Changing roles of MDSOs, updates on General Data Protection regulation (GDPR) requirements and DHSC's *Review of the action set out in 'Safer ambulatory syringe drivers'*.
- **January 2019:** MSO/MDSO conference 'Championing patient safety'.
- **February 2019:** Potential hazards of oxygen availability in areas of escalation and look-alike devices for point-of-care blood testing; *Developing the patient safety strategy for the NHS*, regulatory landscape of the MHRA and CE marking process.
- **March 2019:** The standard for small bore connectors, introducing new devices and incidents relating to procurement; update on Brexit and medical device supply, and on getting the most out of CAS.

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 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. At the national MSO/MDSO conference on 31 January 2019 in London, Aidan Fowler, NHS National Director of Patient Safety, set the stage for future patient safety activity.

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:

- **October 2018**: Update on covert administration of medicines, details of a non-steroidal anti-inflammatory drug (NSAID) safety audit and *Human factors in health & social care*.
- **November 2018**: Enzyme deficiency and chemotherapy side effects, introduction of cannabis-based products and insulin safety needles.
- **January 2019:** MSO/MDSO conference Championing patient safety.
- **February 2019**: Overview from the Northern Ireland Medicines Governance team of current activity, including work on insulin safety and tacrolimus supply issues in transplant medicine. The national update covered an update on the WHO Medication Safety Board and development of the NHS Patient Safety Strategy.
- **March 2019**: Look-alike sound-alike (LASA) packaging, magnesium sulfate safety procurement and support for CMU (Commercial Medicines Unit) tenders.

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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