

Patient safety review and response report October 2017 to March 2018

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

25 September 2018

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 fourth of its kind: it explains how we reviewed reports in the period October 2017 to March 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.

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 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.

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 need to issue advice and guidance to reduce risks in a **Warning Alert**, or if we can influence or support others to act. You can watch a [short video](#) on how we do this.

A national system can also develop or promote new resources that help the NHS improve a known safety issue. We do that by issuing a **Resource Alert**. When a specific technical change or safer procedure has been developed and tested, we may also issue a **Directive Alert**.

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.

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 GPs, 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 through postgraduate courses.

In the six months covered by this report our clinical teams reviewed



9,991

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



4,257

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



519

NRLS incidents from areas of special focus (currently including all GP eform reports of moderate harm, all anaesthetic eform reports)



236

Potential and confirmed Never Events reported to StEIS*



39

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



22

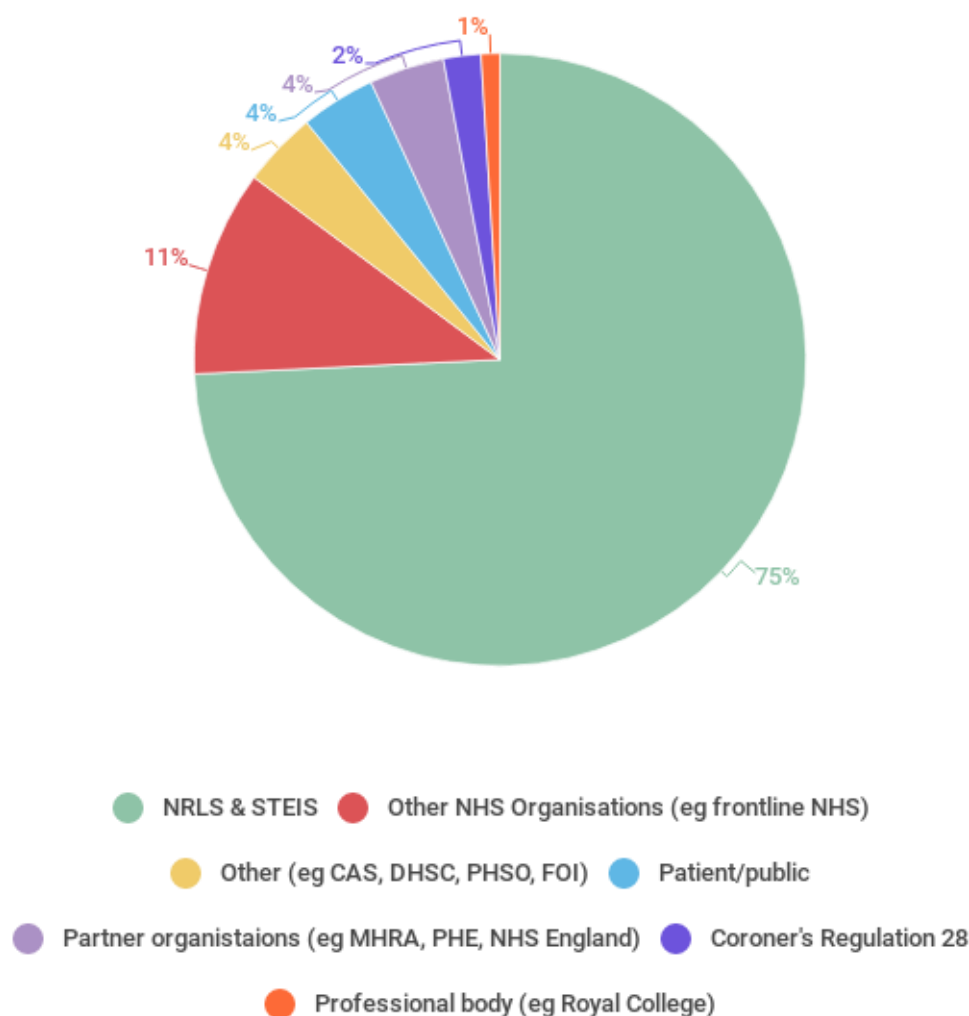
Regulation 28 letters (letters from coroners where they have identified a need for action to prevent further deaths)

*View our [StEIS](#) and [Serious Incident Framework](#) webpages for further information

Where any of these sources suggest 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 other similar incidents reported previously, including no harm ‘near miss’ incidents – and we focus on what could go wrong in future.

Figure 1 below gives the sources of the 85 issues our clinical teams identified between October 2017 and March 2018 and took forward for potential national action.

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





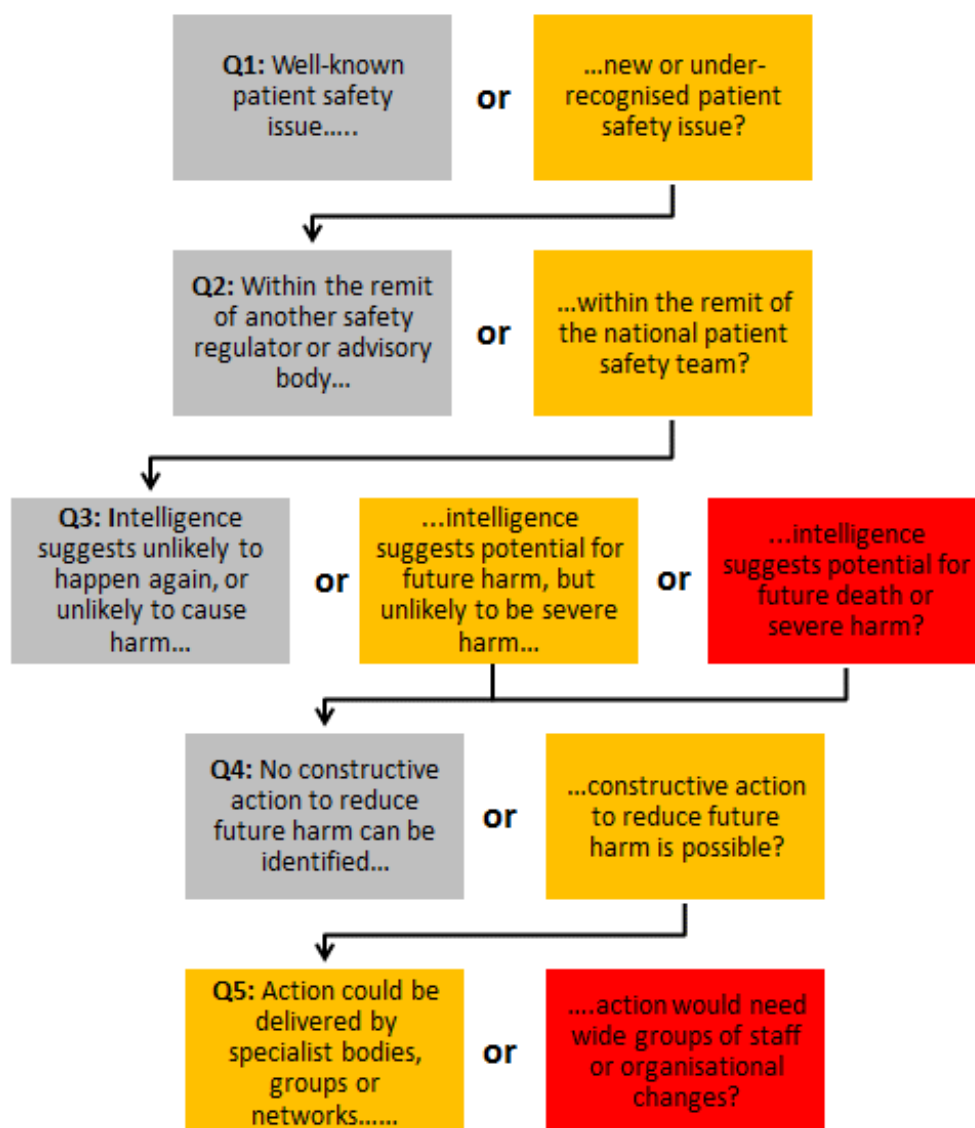
Should we issue a Warning Alert?

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

1. Talk to experts, patients and their families, and frontline staff to confirm the risk is **new or under-recognised**; these groups may have different perspectives.
2. 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. Other patient safety issues can be addressed at source, for example by the manufacturer of a device.
3. 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**.
4. 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).
5. Consider our audience; if an issue is only **relevant to a specialist group or specialist service**, it can be more effective to communicate with them directly rather than to issue an alert.

These five questions are also illustrated in Figure 2:

Figure 2: Identifying and responding to new or under-recognised risks



If an answer falls into any grey box, the risk is **not** a new or under-recognised issue that we can act on.

If answers for a risk fall into amber boxes only, we look to share our findings with partners working in the relevant specialty, such as a royal college, and support them to develop ways to further prevent the risk; examples of where we have done this are given later in this report (see section 'Issues where we advised or influenced others on action').

If answers fall into both of the red boxes and no grey boxes, a Warning Alert will be planned and issued.



Should we issue a Resource Alert?

These are typically issued in response to a patient safety issue that is already well-known either because an earlier Warning Alert has been issued or because awareness has been raised through other publications or national initiatives. Resource

Alerts are used to make healthcare providers aware of any substantial new resources that will help to improve patient safety; they ask healthcare providers to plan implementation in a way that ensures sustainable improvement. We ask the following questions before planning or issuing a Resource Alert:

Are the resources...

Why is this important?



Addressing an issue that causes, or has potential to cause, severe harm or death?

This helps healthcare providers implement resources where they are most needed. Resources addressing less serious issues can be shared through less formal routes.



New, or include some new or under-recognised content?

Resource Alerts have their greatest impact if they are part of an overall plan to support uptake and implementation of new resources.



Published by one or more national¹ bodies, professional or patient organisations or networks, bearing their logo and hosted on their website?

This ensures the resources are developed with the necessary specialist expertise to give them credibility, and ensures they 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 relates to 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.

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



Practical and helpful?

Publications that serve only to 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.



Relevant to most healthcare providers in at least one healthcare sector?

If the resources apply only to a specialist service provided by the minority of providers in a sector, their communication can be directly targeted instead.



Should we issue a Directive Alert?

These are typically issued because a specific, defined action to reduce harm has been developed and tested to the point where it can be universally adopted, or when an improvement to patient safety relies on standardisation (all healthcare providers changing practice or equipment to be consistent with each other) by a set date. All types of alert carry equal weight; Directive Alerts differ from Warning and Resource Alerts only in terms of how specific and defined the actions are.

We ask the following questions before issuing a Directive Alert:

Are the actions required...

Why is this important?



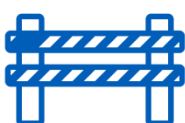
Addressing an issue that causes, or has potential to cause, severe harm or death?

To help healthcare providers focus their efforts where they are most needed.



Developed and tested to the point we can be confident the actions are the sole or best current approach to improving safety, are practical and do not introduce new risks?

In complex healthcare systems, even with the best possible proactive risk assessment, a change that is expected to make an improvement can have unintended effects. Unless the required actions have already been successfully implemented by a number of healthcare providers, it is usually appropriate initially to allow more flexibility for local adaptation through a Warning or Resource Alert.



Provides an effective barrier to error **or** requires standardisation to a single consistent approach across the NHS?

Where no strong or moderately strong barrier has been identified a Warning or Resource Alert is usually more appropriate. Directive Alerts are appropriate where they provide an effective barrier to error **or** standardisation is required to ensure a single consistent approach across the NHS (eg requiring a standard crash call number).



Is the cost (especially new and direct costs such as equipment purchase) proportionate to the reduction in harm the actions can be expected to achieve?

Calculating the scale and cost of current harm and the impact of the intervention is not straightforward for most patient safety issues, but we work within the principles of cost per year of quality-adjusted life used by NICE, so that finite NHS resources are directed at the patient safety issues where they have the greatest impact. For some issues, potential to reduce costs of litigation may also need to be factored in.



Acceptable without wider public consultation?

For actions where our National Patient Safety Response Advisory Panel is concerned about adverse impacts or costs, or has conflicting views on which of two or more current approaches to adopt as standard, a wider public consultation may be needed.



Relevant to most healthcare providers in at least one healthcare sector?

If the actions apply only to a specialist service provided by the minority of providers in a sector, their communication can be directly targeted instead.

Who advises us?

Insight to help us understand each patient safety issue 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

Our panel is made up of representatives encompassing a range of roles within 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*
- Healthcare Safety Investigation Branch*
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Mothers Instinct
- National Association for Safety and Health in Care Services
- NHS Wales*
- NHS Wales Delivery Unit*
- Royal College of Emergency Medicine
- Royal College of General Practitioners
- Royal College of Midwives
- Royal College of Nursing
- Royal College of Obstetricians and Gynaecologists
- Royal College of Ophthalmologists
- Royal College of Paediatrics and Child Health
- Royal College of Pathologists
- Royal College of Physicians
- Royal College of Psychiatrists
- Royal College of Radiologists
- Royal College of Surgeons
- Royal Pharmaceutical Society
- Safer Anaesthesia Liaison Group (SALG)
- The Patients Association

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

Interested in finding out more about review and alerts?

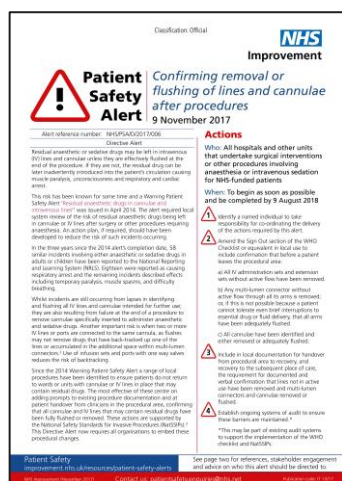
If you would like to know more about why we have designed our clinical review and response process as we have, and developed three types of Patient Safety Alert, read this [journal article](#) which links our process to the underpinning patient safety theories.

What action did we take?

Patient Safety Alerts

Our Patient Safety Alerts are issued through the [Central Alerting System \(CAS\)](#) and NHS trusts publicly declare when they have completed the actions required. 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.²

Between October 2017 and March 2018 we issued two Patient Safety Alerts:



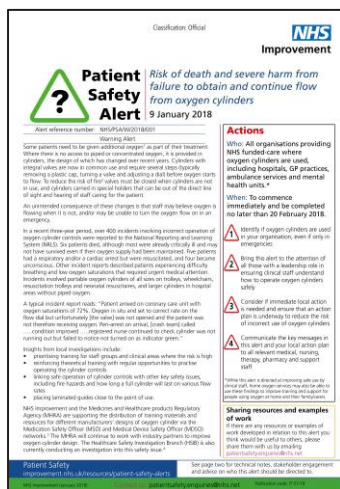
Confirming removal or flushing of lines and cannulae after procedures

Issued: 9 November 2017 Directive Alert

This alert asked providers of NHS-funded care that undertake surgical interventions or other procedures involving anaesthesia or intravenous sedation to amend the Sign Out section of the WHO Checklist, or equivalent in local use. It should include confirmation that before a patient leaves the procedural area cannulae and intravenous (IV) lines have been removed or flushed, and this action should be documented.

If IV lines and cannulae are not removed or effectively flushed, residual anaesthetic and sedative drugs can later be inadvertently introduced into the patient's circulation. This can cause muscle paralysis, unconsciousness, and respiratory and cardiac arrest.

² To subscribe to CAS alerts, contact the CAS helpdesk by emailing safetyalerts@mhra.gov.uk



Risk of death and severe harm from failure to obtain and continue flow from oxygen cylinders

Issued: 9 January 2018 Warning Alert

Oxygen cylinder design has changed over recent years with the intention to make them safer to use. Cylinders with integral valves are now in common use and require several actions before oxygen starts to flow (typically, removing a plastic cap, turning a valve and adjusting a dial). To reduce the risk of fire, valves must be closed when cylinders are not in use and cylinders carried in special holders that can be out of the direct line of sight and hearing of staff caring for the patient.

An unintended consequence of these changes is patient safety incidents have occurred where staff believed oxygen was flowing when it was not, and/or they have been unable to turn on the oxygen flow in an emergency.

This alert asked providers that use oxygen cylinders to determine if immediate local action is needed to reduce the risk of these incidents, and to ensure an action plan is underway to support staff to prevent them.

We share our alerts with the devolved nations of Scotland, Wales and Northern Ireland and they choose whether or not to use or adapt learning in their own countries.

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

- *Risk of death and severe harm from failure to obtain and continue flow from oxygen cylinders* (NHS/PSA/W/2018/001) ([issued as a Safety Action Notice – SAN\(SC\)18/02 – on 17 January 2018](#))
- *Confirming removal or flushing of lines and cannulae after procedures* (NHS/PSA/D/2017/006) (disseminated to NHS Scotland on 15 November 2017).

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

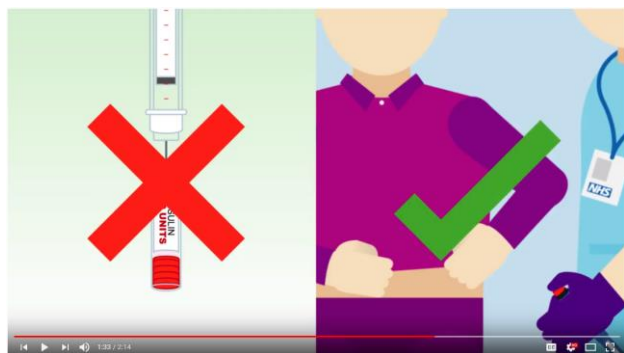
- *Risk of death and severe harm from failure to obtain and continue flow from oxygen cylinders* (NHS/PSA/W/2018/001) ([issued as PSN041 on 23 April 2018](#))
- *Confirming removal or flushing of lines and cannulae after procedures* (NHS/PSA/D/2017/006) ([issued as PSN040 on 15 January 2018](#)).

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

- *Risk of death and severe harm from failure to obtain and continue flow from oxygen cylinders* (NHS/PSA/W/2018/001) (issued as HSC(SQSD)1/18 on 23 February 2018)
- *Confirming removal or flushing of lines and cannulae after procedures* (NHS/PSA/D/2017/006) (issued as HSC(SQSD)37/17 on 20 November 2017).

‘Ask why’ 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 aim to produce an ‘ask why’ video around the time the alert actions need to be completed. These videos are promoted via social media and encourage staff to ‘ask why’ if those changes have not been made in their workplace.



In October 2017 we published an ‘ask why’ video to support our *Risk of severe harm and death due to withdrawing insulin from pen devices* alert. This can be viewed on the [alert webpage](#) and [YouTube](#).

Issues where we advised or influenced others on action

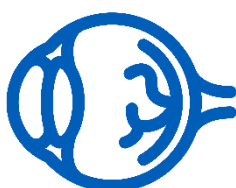
Below we give examples of the actions we took through routes other than alerts in the period covered by this report.



Medication via nasogastric tube in unconscious cardiology patients

An incident identified through our regular review of Never Event reports described a patient who needed emergency treatment following a cardiac arrest. The patient had been intubated and urgently needed dual antiplatelet therapy (DAPT); a nasogastric (NG) tube was inserted to give this. After DAPT had been administered the NG tube was identified to be in the patient's lung. The [essential checks of NG tube placement](#) had not been done. Investigation suggested local training plans had not recognised the need for staff involved in this emergency cardiology procedure to understand how to insert and use NG tubes safely.

Cardiology experts advised us that, given the relative rarity and urgency of this situation, developing and maintaining skills in confirming NG tube placement would not be realistic for all relevant teams, and it would not be appropriate to delay giving DAPT while seeking support from other units or teams. Instead, together with the British Cardiovascular Society we have developed [guidance](#) that reinforces [our earlier advice](#) on confirming NG tube placement and provides information on alternative intravenous or rectal antiplatelet medication for unconscious patients in whom NG tube placement cannot be safely confirmed.



Risk of harm from ophthalmic cannula detachment during surgery

The Medicines and Healthcare products Regulatory Agency (MHRA) contacted us about a small number of incidents of ophthalmic cannula detachment during ophthalmic surgery. The ophthalmic cannula is attached to a syringe and when pressure

is applied to the plunger can produce significant hydraulic force. Should the cannula detach, it will do so with an intensity that can cause injury and visual impairment.

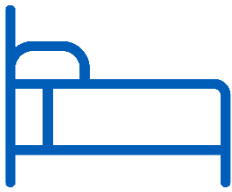
An NRLS search for a two-year period identified 23 incident reports of cannula detachment during an ophthalmic procedure. Reviews by MHRA concluded cannulae were detaching because of how they were being used rather than a design issue with the equipment concerned. MHRA issued a short safety message via the Medical Device Safety Officer (MDSO) network advocating that only Luer lock syringes should be used in ophthalmic surgery and only after their secure connection has been checked. We asked the Royal College of Ophthalmologists to disseminate the information from MHRA and the NRLS through its networks.



Harm to patient's skin from the use of iodophor drapes during surgical procedures

A surgical team asked us if we had received any reports of skin damage from using iodophor impregnated adhesive drapes during surgical procedures. These drapes are important for preventing wound infection and the standard instructions for their use emphasise the importance of assessing the patient's skin condition and using adhesive removal formula when they are no longer needed.

We identified 102 incident reports over a two-year period that referred to skin damage when iodophor drapes were removed, predominantly in orthopaedic surgery. This suggests awareness should be raised of the importance of recognising patients whose skin needs extra care during drape application and removal. We asked the Association for Perioperative Practitioners and the College of Operating Department Practitioners to bring this to the attention of their members, and they used a variety of routes to do so including social media.



Entrapment due to bed/bedrail/mattress incompatibility; assessing 'hybrid' mattresses

The risk of fatal entrapment gaps created by bed frames, mattresses and bedrails with incompatible dimensions has long been recognised, and many resources are available to support staff when purchasing, assessing, prescribing or installing such equipment, including:

- [safe use of bedrails](#)
- [prescribing beds for a domestic setting](#)
- [sector information minute: bed rail risk management](#).

Our regular clinical review of Serious Incidents reported to StEIS identified an incident of entrapment involving a patient in the community and a 'hybrid' mattress (in a healthcare context, this is a mattress that can be switched between foam and alternating pressure modes). The mattress appeared to compress to such an extent that the patient was able to thread their legs between the mattress and the lower rail of the bedrail. An important aspect of assessing whether any combination of mattress, bedframe and bedrail is safe is testing the compression properties of the mattress. This incident suggested that the need to assess hybrid mattresses twice – in both their standard mode and alternating pressure mode – might be under-recognised.

We shared this information with:

- the MDSO's network so that MDSOs could consider the need to adapt local equipment checks
- MHRA to inform any future updates of its guidance
- National Association for Safety and Health in Care Services, which has agreed to share key learning messages with relevant forums such as the National Association of Equipment Providers.



Renal colic or abdominal aortic aneurysm?

Renal colic and leaking or rupturing abdominal aortic aneurysm (AAA) can present with similar symptoms, but identifying AAA as soon as possible is vital so that potentially life-saving urgent surgery can be considered. Regular clinical review of incidents reported to the NRLS as death and severe harm identified three in emergency departments (EDs) where patients were treated in line with the renal colic clinical pathway before excluding a diagnosis of leaking/ruptured AAA.

The incidents gave insight into local changes to improve patient safety, including clearer criteria for abdominal scanning to exclude AAA; improving local triage guidance to encompass more examples of how pain from AAA can present; and ensuring a previous diagnosis of AAA is highlighted in a patient's ED records. We shared this information with the Royal College of Emergency Medicine which confirmed that such patients often present with a difficult clinical picture. Our insight from these incidents was considered potentially helpful to other EDs and RCEM have agreed to consider issuing a safety newsflash via their networks on this topic.

The RCEM have also supported the [Think Aorta](#) campaign; this aims to improve patient outcomes by increasing the identification and early diagnosis of aortic dissection in ED, using posters and podcasts.



Carbohydrate counting and insulin dose adjustment in non-specialist care settings

Dose adjustment of insulin for normal eating ([DAFNE](#)) is becoming common practice and patients are encouraged to continue their usual [self-management when admitted to hospital](#) whenever possible.

We identified an incident concerning a patient in a mental health hospital who came to harm when they were temporarily unable to self-manage and the ward staff had therefore taken over. The clinical staff incorrectly calculated the amount of carbohydrate

the patient had eaten and, because of this miscalculation, gave the patient too much insulin.

In its [guidance](#) to support staff, the Joint British Diabetes Societies – Inpatient Care Group (JBDS-ICG) includes advice for when a patient is temporarily unable to undertake their usual care.

We consulted experts and frontline staff who confirmed that only specialist staff in diabetes can be expected to have the necessary skills to calculate insulin dosing based on carbohydrate intake. Where specialist support cannot be provided 24/7, it is usually safer to move the patient onto a less complex diet and insulin regimen until they regain the ability to self-manage.

We asked JBDS-ICG to extend the reach of its guidance to mental health units and to encourage specialist diabetic services to support all types of inpatient services.



Risk of bowel perforation when self-administering rectal irrigation

We identified an incident where a patient sustained a perforated bowel while self-administering trans-anal irrigation. Such specialist systems are used to manage chronic bowel dysfunction and patients, carers and staff need specialist training in their use.

We were concerned that the risks of harm are not always fully appreciated. We asked MHRA, who had previously published a [medical devices alert on a trans-anal irrigation system](#), to review company training guidance manuals and instructions for use, to ensure risks were adequately described.

The National Institute for Health and Care Excellence (NICE) has published [medical technologies guidance](#) (MTG) on these systems, referencing the risk of perforation in published research studies but not the MHRA's alert. We brought our concerns and

MHRA's alert to its attention and NICE plans to update its MTG development processes to ensure any relevant alerts are included.

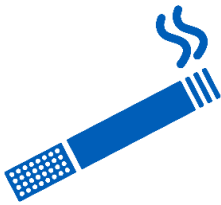


Maintenance of 'critical to life' medical devices in patients' own homes

Following concerns raised by a patient, we reviewed incidents involving problems with maintaining or servicing 'critical to life' medical devices in patients' own homes; such as ventilators, suction machines and non-invasive ventilation therapy devices. Such devices tend to be issued by acute care organisations but are then used in the patient's home for prolonged periods, sometimes for the rest of their life. This means they require different maintenance and servicing arrangements from most medical equipment issued for use in the home, which is typically not 'critical to life' and used for shorter periods before being returned to an equipment store.

Although MHRA has provided guidance ([Managing medical devices 2015](#)) on maintenance and service requirements, device failures where no maintenance or service schedule has been in place have been reported. A robust planned preventative maintenance (PPM) programme can help to prevent device failures, and all users of 'critical to life' devices need clear contingency plans for what to do and who to contact if problems occur.

The National Association of Equipment Providers, the Institute of Physics and Engineering in Medicine and the National Performance Advisory Group agreed to share our findings with their members and reinforce the requirement to give 'critical to life' devices a particular focus in their equipment provision systems.



Alternating pressure system mattress and fire risk

We became aware of reported incidents of patients not being issued an alternating pressure system (APS) mattress for pressure ulcer prevention because healthcare professionals believed APS were banned for patients who smoked. This belief is likely to have come about because air circulation in APS mattresses is pump driven, and if a cigarette burn penetrates a mattress, air escaping from the puncture could accelerate any fire. However, this risk must be weighed against the patient's risk of developing a pressure ulcer, and any other factors that might increase or reduce the risk of fire in their environment. The dangers of smoking in bed whatever the type of mattress need to be emphasised to patients, their carers and family. For any patient who needs an APS, and is thought likely to smoke in bed despite this advice, healthcare staff can ask local fire services to undertake a home safety assessment/check.

The Tissue Viability Society, the Stop the Pressure Programme, the Royal College of Nursing District Nurse Forum and our patient safety advisor for care homes all agreed to share this information with their professional members. They included a reminder of the importance of reporting such incidents to the [MHRA Yellow Card scheme](#) as well as through their local incident reporting system (and via that to the NRLS).



Unintended injury from cutting umbilical cords

As [NHS Choices describes](#), parents increasingly see cutting a newborn's umbilical cord as a symbolic part of the birth. After healthcare staff have clamped the cord in two places, they supervise parents or birth partners to cut it, and this is done safely for hundreds of thousands of newborn babies each year.

We received a report of a father accidentally cutting the tip of his baby's toe when cutting the umbilical cord. A review of the NRLS revealed 18 similar incidents over a two-year period, mostly

resulting in superficial cuts or scratches, but also one further incident of a serious cut to the toe.

We have asked for these findings to be included in the next Maternity Patient Safety Champion newsletter, to reinforce careful positioning of a baby when their cord is to be cut by parents or birth partners.



Birthing balls that burst during use

We identified an incident of a woman in labour falling to the floor when the birthing ball she was using burst.

Physiotherapy balls were developed in the 1960s for use in rehabilitation programmes. Similar balls are now widely used antenatally to relieve back discomfort, maintain fitness during pregnancy and encourage optimal fetal positioning. They are often used during labour for comfort, to encourage progression of labour and to maintain an active labour.

A search of the NRLS revealed 76 reports of birthing balls bursting while in use in a maternity setting, generally without harm following the fall from the ball, with women being supported back to their feet by midwives or birthing partners. A small number of injuries were described such as lower back pain, spontaneous rupture of membranes and a dislodged cannula. Following the incidents, care generally involved a fetal wellbeing check (fetal heart rate, cardiotocograph (CTG) and fetal movements) and observation for physical injury to the mother.

MHRA confirmed that birthing balls are not classified as medical devices and therefore they cannot directly influence their design or durability. We therefore asked for this risk to be described in the next Maternity Patient Safety Champion newsletter with the request that steps are taken to reduce the risk of balls bursting by reviewing how they are purchased, inflated, maintained and used.



Safe removal of umbilical central venous catheters in neonates

Central venous catheters (CVCs) are essential in neonatal care for the intravenous delivery of fluids and medication. The British Association of Perinatal Medicine (BAPM) produced a framework for insertion of umbilical CVCs in neonates in 2015, to help address safety issues identified through the NRLS.

Our regular review of the NRLS identified an incident where unexpected and severe bleeding from the cord site occurred following removal of an umbilical CVC; this resulted in bradycardia and the baby needed resuscitation. Haemorrhage is a known complication of umbilical CVC removal, but no other incidents with such a serious outcome were found when we searched the NRLS. However, we did find variation in what is done to ensure removal is as safe as possible.

We worked closely with BAPM to produce an addendum to its [framework](#) that gives further advice on best practice for safe removal.



Risk of air embolus when inflating radial artery compression device

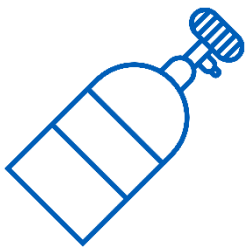
We identified a Serious Incident in which air was injected into a patient's circulation during removal of a sheath from their radial artery.

Radial artery sheaths are commonly used in angiography procedures and inflatable compression devices may be used to prevent bleeding when they are removed. The device is inflated over the insertion site of the sheath using an air-filled syringe and compresses the radial artery to stop bleeding. In the reported incident the air was mistakenly injected via the radial artery sheath into the patient's circulation.

A search of the NRLS for the previous two years revealed no similar incidents. However, we asked MHRA to investigate whether equipment design may have contributed to the error.

This revealed that the inflation syringe provided with the compression device had a Luer lock, which can be connected to arterial sheaths.

The manufacturer has withdrawn the Luer lock syringes in the UK and they will be phased out across the European Union in 2018.



Use of nitrous oxide in patients with a gas bubble in their eye post retinal surgery

Surgery for retinal detachment can involve ‘splinting’ the repaired retina in position with a gas or silicone oil bubble. Depending on the gas used, the bubble remains in the eye for 3 to 12 weeks, with the gas gradually resorbed over time. Patients must not be given nitrous oxide (including as part of general anaesthesia or in the form of Entonox®/Equanox® for pain relief) while the gas bubble is in situ, as it will expand the gas bubble and increase the pressure in the eye to harmful levels.

We identified a Serious Incident where a patient with a gas bubble in their eye following retinal detachment repair was given nitrous oxide during orthopaedic surgery; the patient’s vision subsequently deteriorated due to raised pressure in the eye. A search of the NRLS for a three-year period found a similar incident where a patient with a gas bubble was given Entonox®.

The Royal College of Ophthalmologists (RCO) agreed to issue advice to their members regarding gas in the operated eye and associated risks. This is currently out to consultation among relevant stakeholders including the British Ophthalmic Anaesthesia Society and Safe Anaesthesia Liaison Group (SALG); a partnership between the Royal College of Anaesthetists, Association of Anaesthetists of Great Britain and Ireland and NHS Improvement



Risk of serious harm and death in infants and children from accidental ingestion of camphor oil

We were informed of a young child's death from the accidental ingestion at home of a product containing camphor oil.

Camphor oil is an essential oil widely used for aromatherapy and in products such as chest decongestants. It is highly toxic, even in very small amounts and especially to children, and can cause vomiting, seizures, acute respiratory distress and death. Products available in the UK usually contain 5% to 10% camphor, enough to cause death if ingested, whilst those brought into the country or purchased online can be pure camphor oil.

While the child did not ingest the camphor oil in a healthcare setting, we believed advice to clinicians about the immediate care of such patients could be strengthened. We worked with Toxbase, the National Poisons Information Service resource for clinicians, to strengthen the warning on its database for products with a high concentration of camphor and to emphasise the potential impact on infants and children, even when small amounts are ingested.



'Vaginal seeding'

We were alerted to publicity being given to, and the anecdotal increase in, women and their families asking clinicians to facilitate vaginal seeding when delivering babies by caesarean section.

Vaginal seeding involves swabbing the baby's skin, eyes, nose, ears and mouth with fluid from the mother's vagina in an attempt to replicate their exposure to maternal vaginal bacteria. The practice followed studies suggesting infants delivered by caesarean section have different skin and body bacteria from those delivered vaginally.

Among the concerns shared with us was a case where a mother, who had requested 'vaginal seeding', was identified by staff to have an infection that could have put her baby at risk.

The Royal College of Obstetrics and Gynaecology (RCOG) [published a summary](#) of the available evidence in the *British Journal of Obstetrics and Gynaecology* which concluded there is no robust evidence to support vaginal seeding and that healthcare professionals should promote infant immunity with other early interventions of proven benefit such as skin to skin contact and breastfeeding.

We were concerned that, in the face of increasing interest in this procedure, no clear processes were available to support healthcare staff in their responses to requests for 'vaginal seeding' and to ensure mothers, who might undertake the procedure themselves, understood the potential risks. The American College of Obstetrics and Gynaecology issued an opinion statement and educational resource to support clinicians deliver the message that vaginal seeding is not recommended and to enable a fully documented discussion about the risks should parents decline this advice. We asked the Royal College of Obstetricians and Gynaecologists (RCOG) to issue a similar statement to their members and it has agreed to do this, jointly with the Royal College of Midwives and BAPM, to reach and support all relevant staff groups.



Ambulance tail-lift failures

We identified an incident that raised safety concerns about emergency ambulance tail lift hoists. As tail-lift hoists are being used in emergencies, any problems with their operation could delay treatment for critically ill patients.

A search of the NRLS highlighted regional variations in the scale of reported problems and we worked with three ambulance services to identify if this was because of differences in equipment, in how equipment is maintained or in staff skill in

operating the tail-lift hoists. All the trusts had robust systems for maintenance and regular testing, and supported and trained their staff appropriately, but there were differences in the type of tail lift hoist used; the most widely used system also appeared to be the most reliable.

Reported problems appeared to have occurred with a less commonly used tail lift system which was integrated with a specific vehicle design; which has advantages in certain operating environments. Extra training has been made available to users of this design. Our findings will inform wider work on standardisation of emergency ambulances design across England.



Enhancing operator skills for the Lifepak 15 monitor/defibrillator

We identified a small number of incidents involving the Lifepak 15 monitor/defibrillator during resuscitation episodes. These raised several concerns, involving capnography monitoring, switching on and off and changing functions rapidly, and switching from automatic to manual mode. Incidents had been appropriately reported locally and investigations undertaken, including by MHRA, but no technical faults were found with the devices.

Subsequently, our patient safety leads for medical devices and for ambulance services met a clinical instructor at an ambulance service training college to work through several clinical scenarios designed to test each of the concerns. They concluded that the problems did not stem from device functionality and could best be addressed with training focused on the specific device. Other ambulance trusts, that use Lifepak 15 monitor/defibrillator device, have used these findings to change their approach to training.

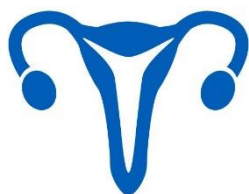


Confusion between opioid transdermal patches and wound dressings

We received a report describing the inadvertent use of fentanyl patches as wound dressings. A patient's relative found the fentanyl patches in a bag provided on discharge from hospital and used them as wound dressings in 'good faith'. Some transparent fentanyl patches have no distinct markings and can easily be mistaken for wound dressings. MHRA has commented the patches should be kept in their original container that provides information on use.

Review of reports to the NRLS identified one further similar incident where a patient at home mistook fentanyl patches for a dressing and applied them. Though these incidents are rare, there is potential for recurrence as patients at home often keep all their medical supplies together.

We shared our findings with all controlled drugs accountable officers via their CQC newsletter, so that they could take local action to reduce the risk of confusion.



Retained interventional radiological sheaths/balloons in obstetric cases

We identified an incident, reported as severe harm, caused by the post operative retention of interventional radiological (IR) sheaths inserted to manage severe bleeding in a patient undergoing caesarean section for placenta accreta. This resulted in severe vascular compromise.

The reporting organisation said the sheaths had been intentionally retained after the caesarean section, with their removal planned for the following morning. It also reported that no national guidance was available on how long sheaths can be safely left in situ postoperatively and, because of this incident, had initiated the development of regional guidelines.

A search of the NRLS revealed two similar incidents related to retained IR balloons. We shared our findings, and the insights

from the local investigation, with the British Society for Interventional Radiology and RCOG, which agreed to jointly consider the development of national guidance.



Oral administration of peppermint oil instead of peppermint water

We identified a serious incident in which a small number of patients were given pure peppermint oil instead of peppermint water in an inpatient setting. Fortunately, the peppermint oil tasted so unpleasant that the patients appeared to have immediately spat it out and therefore came to no significant harm.

Pure peppermint oil is highly toxic (including irritation of the mouth, throat and gastrointestinal tract) at adult doses as small as 3 mL, and for children 0.2 mL.

The reporting organisation revealed that the peppermint oil dispensed to the ward had been stored in the medicine trolley. Essential oils, including peppermint oil, may be available in some organisations that provide aromatherapy, typically in small 'dropper' bottles that are unlikely to be mistaken as containing peppermint water. In this case, peppermint oil had been issued in a larger bottle. This larger bottle appeared to have been in stock because of the local practice of using peppermint oil to mask unpleasant smells.

A search of the NRLS identified no similar incidents, and a survey of medication safety officers (MSOs) confirmed that peppermint oil is not routinely stocked and dispensed by pharmacy, its use as a 'air freshener' appeared to be unique to the reporting organisation, and pharmacy is not routinely involved in supplying aromatherapy products.

An MSO reported concerns about the way this product was displayed on their electronic prescribing system: with the ingredient first (peppermint oil) and then the product (peppermint water), creating significant potential to administer oil should the bracketed directions be missed.

Peppermint oil (Peppermint water BP 1973)

Dose: 10 mL – oral three times a day – Start on: 13/Jun/18
22:00:00

We contacted NHS Digital and NHS England, which oversee the dm+d database (the dictionary of standard medicine and device descriptions and codes used across the NHS). It confirmed that this would be an issue across all systems using the dm+d database and NHS Digital agreed to change the entry to 'Peppermint (Peppermint water BP 1973)'.



Using anti-syphon valves during intravenous infusion therapy

We identified a serious incident in which a patient, who was accidentally given more potassium chloride than intended, sustained a cardiac arrest. The patient was receiving fluids through a gravity IV administration set and potassium chloride through an infusion pump. Both infusions were flowing into a central line which was inadvertently clamped, stopping all fluid going into the patient. As the potassium chloride in the infusion pump was being given under pressure, it tracked up into the administration set attached to the gravity IV bag. When the central line was subsequently unclamped, the patient received a rapid infusion of the potassium chloride that had accumulated in the gravity IV administration set.

Fluid backtracking into the gravity administration set and IV bag can be prevented by using a syringe pump line with an anti-syphon valve incorporated. This would cause the pump to register resistance and this triggers an alarm. Accepted and

routine practice is to use anti-syphon valves when these two types of infusions are combined.

We searched the NRLS over a two-year period and found 76 incidents relating to failure to use intravenous lines with an anti-syphon valve where both pumped and gravity fluids were being administered.

We shared our findings with the Safer Anaesthesia Liaison Group (SALG) and it was confirmed that the labelling of anti-syphon valves contributes to these types of incidents as, when removed from their packaging, they look very similar to one-way valves and connectors. It considers this similarity in appearance means staff mistakenly believe an anti-syphon valve is in place. MHRA will consider how they can work with relevant partners to make it clearer what a device is by labelling the actual devices.



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

Publishing information on methods of self-harm is unsafe as this could 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 two risks through this route.



Issues shared with NHS Digital

We have worked closely with NHS Digital to establish an effective process to share issues relating to IT systems in the NHS; reported via the NRLS, StEIS or raised directly with the national patient safety team. These concerns are then

investigated by NHS Digital with the system suppliers or trusts, and solutions implemented where appropriate.

Examples of issues recently shared with NHS Digital are:

- running batch reports from a specific IT system
- backlog of clinic letters when new dictation solution introduced
- unclear methotrexate dosing instructions when using GP system template.

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 [regular patient safety bulletins](#)
- **MHRA**, which receives medication and medical devices data to support its regulatory functions
- the **Health Safety Investigations Branch (HSIB)**, which uses NRLS and Serious Incident data to provide wider context to specific [investigations](#).

Journal articles including review of NRLS data

Data sharing is an important aspect of ensuring that the insight from the NRLS supports learning and we share data with a diverse range of interested parties; including 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, conference presentations or is used to inform further research. In the period covered by this report, in addition to our regular arrangements with the royal colleges, clinical groups and the other bodies listed above, we shared patient safety incidents with a variety of organisations or individuals. A recent publication, featuring the NRLS data we shared, concerned analyses of incidents from neonatal units (see Appendix 1).

Acting through our MSO and MDSO networks

MHRA and NHS Improvement 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. Many new and under-recognised patient safety issues relate to medications or medical devices, partly because of the level of innovation and new products, making these networks a key route for communicating new or under-recognised risks. Work is not limited to this and also includes updating network members on developments relating to known issues.

The MDSO network

MHRA and NHS Improvement support the MDSO network through:

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

The web events involve speakers from a variety of backgrounds (MDSOs, NHS Improvement, MHRA and specialists from healthcare, procurement and industry), sharing relevant safety-related information, providing updates on the most recent MHRA medical device alerts and our Patient Safety Alerts, and highlighting medical device safety issues identified through review of NRLS incident reports. Circulating key information across the MDSO network generates specialist feedback, allows sharing of both national and local resources to assist and enable local implementation of alerts, and identifies potentially under-recognised safety issues.

We always welcome input from new MDSOs, and especially those working in the community, ambulance service and mental health, to broaden and expand the group and ensure all areas providing patient care are supported. We also encourage engagement with the MSO network, again both nationally and locally, as there is substantial cross-over between these two disciplines.

In the period covered by this report, an average 65 MDSOs and/or MSOs logged into each web event and each month the forum was accessed on average by 100 users. In addition to regular updates on recent alerts relevant to MDSOs, specific web event topics included:

- **October 2017:** Review of manufacturer obligations to adopt ENFit standards and sharing of home nebuliser recommendations in the treatment of paediatric asthma. Focus theme of [human factors guidance](#), the blood pressure toolkit and blood pressure device training. Shared update to the medical device driving licence (MDDL) and feedback from the NAMDET conference.
- **November 2017:** Focus on aspects of managing plus size or bariatric patients, including defining plus size, the challenges of providing suitable and safe equipment, presentation from industry on finding the right product, with specific reference to training and manual handling in the community setting. An ergonomics expert at MHRA also talked about plus size management and safe systems of work.
- **December 2017:** Presentations from industry and MDSOs on inter-hospital transfer and best practice management of medical devices used in inter-hospital transfer of critically ill patients.
- **February 2018:** Shared additional information relating to recent alert on [failure to obtain and continue flow from oxygen cylinders](#), including; signposting to national resources from manufacturers, presentations on

safe use of oxygen and medical gases, and practical oxygen application. Shared the [MHRA 10 top tips for O₂ safety](#), where to find them and when to check them. Update on the revised [Never Event list](#), published in January 2018; which includes accidental connection to air instead of oxygen.

- **March 2018:** Further update on the safe transition to NRFit alert. Focus on decontamination of medical devices, the risk of device damage from using decontamination products and feedback shared from decontamination incidents reported to the NRLS, and best practice in sourcing ready-to-use products.

Web events allow us to share information and encourage action on safety issues that do not meet the criteria for an alert. For example, an incident was reported to the NRLS where a patient in a hospital bed required resuscitation, but staff were unable to remove the head of the bed. This incident appeared to have happened because beds had been urgently sourced to create escalation wards. 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.

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. Registration, and to receive forum login details, is via 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 contacting safetyalerts@mhra.gov.uk

The MSO network

The MSO network is a collaboration between NHS Improvement Patient Safety, MHRA and Specialist Pharmacy Service (SPS). Through email and the discussion forum hosted by MHRA, we routinely include updates on all recent Patient Safety

Alerts, focusing on how MSOs can support effective implementation. We also use the MSO network to share advice and guidance issued through routes other than alerts.

The network is supported by a one-hour web event held each month. Alongside MSOs in England, invitations are sent to guest attendees from the devolved nations (Northern Ireland, Wales and Scotland), America, Canada and Australia. Over 100 attendees commonly participate in these events, which are recorded and made available for streaming along with copies of presentations and supporting materials. From January 2018, the web event recordings, including the presentations and the edited chat, have been available via a new platform that gives MSOs and those who regularly attend the web events greater accessibility and facilitates easier sharing with colleagues.

The web events include the sharing of patient safety issues identified through our review of NRLS incident reports and also those identified by MSOs and other sources. As with the MDSO network, we involve the MSO network in our exploration of patient safety issues at an early stage to seek opinion and advice from ‘frontline’ practitioners before deciding the best way to act. MSOs have been invaluable in providing local intelligence on specific potential safety issues.

In addition to the monthly observatory report provided by the United Kingdom Medicines information (UKMi) of SPS, and updates on recent alerts relevant to MSOs, web event specific topics have included:

- **October 2017:** Overview of North East and North Medicines Safety Officers Network, a critical incident experience as it relates to a MSO’s involvement at HM coroner’s court, improving insulin safety through collaboration and an update on issues related to hand-held information for patients on steroids.
- **November 2017:** Outline of the SPS and the Medicines Safety and Use team, updates on IV line flushing, an anticoagulant safety audit and the HSIB: investigating wrong route error investigation.
- **January 2018:** Trialling of a podcast, including an interview with the new SPS - medicines use and safety lead for supporting and developing the MSO network, urgent prescriptions on the Electronic Prescription Service (EPS) system, and a description of the supply chain national team.

- **February 2018:** Update on the Midlands Medication Safety Group activities, overview of summary care records, strong potassium infusions and medication without harm: WHO Global Patient Safety Challenge.
- **March 2018:** Update on the Eastern Medication Safety Group activities, a second critical incident experience as it relates to a MSO's involvement at HM coroner's court, update on concomitant use of enoxaparin and direct oral anticoagulants (DOACs).

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

In April 2018, 405 MSOs were registered from organisations providing NHS-funded care in England including: acute and foundation trusts (162), CCGs (81), mental health providers (51) and community pharmacy (25). An additional 40 MSO guests from the devolved nations of Wales, Scotland and Northern Ireland and 26 MSOs in 'other' posts, including various charities, the Ministry of Defence, MHRA, CQC and SPS are registered.

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 is the MSO 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:

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- Graeme Kirkpatrick, Head of Patient Safety Advice and Guidance
- Nima Vekaria, Review and Response Manager
- James Nicholls, Patient Safety Communications Manager
- Lucy Gardner, Editor

Additional content was provided by:

- Taofikat Agbabiaka, Evidence and Evaluation Lead, Patient Safety
- Dr David Gerrett, Senior Patient Safety Pharmacist
- Fran Watts, Patient Safety Lead, Surgical Specialties and Never Events
- Jayne Wheway, Patient Safety Expert Advisor – Children, Young People and Patient Safety Concerns
- Sarah Jennings, Patient Safety Lead, Medical Devices
- Wayne Robson, Patient Safety Lead, Clinical Review
- James Petter, Patient Safety Expert Advisor – Ambulance Services
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Appendix 1: Journal publications including review of NRLS data

Stuttaford L, Chakraborty M, Carson-Stevens A, et al (2018) Patient safety incidents in neonatology: a 10-year descriptive analysis of reports from NHS England and Wales. Conference abstract no G190. *BMJ Arch Dis Child* 103:A78.

Contact us:

NHS Improvement

Wellington House
133-155 Waterloo Road
London
SE1 8UG

0300 123 2257

enquiries@improvement.nhs.uk
improvement.nhs.uk

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