

Patient safety review and response report October 2016 to March 2017

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

17 January 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 second of its kind: it explains how we reviewed reports in the period October 2016 to March 2017 and describes the action we took as a direct result, whether by issuing a Patient Safety Alert or working with partners. You can find the [report covering April to September 2016](#) on our website.

First and foremost this publication is a thank you to all the staff, patients and members of the public who have taken the time to report incidents. By showing the difference your efforts have made, 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 take action. 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



9,769

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



782

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



214

StEIS incidents from areas of special focus (currently including all Never Events)



43

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



3

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



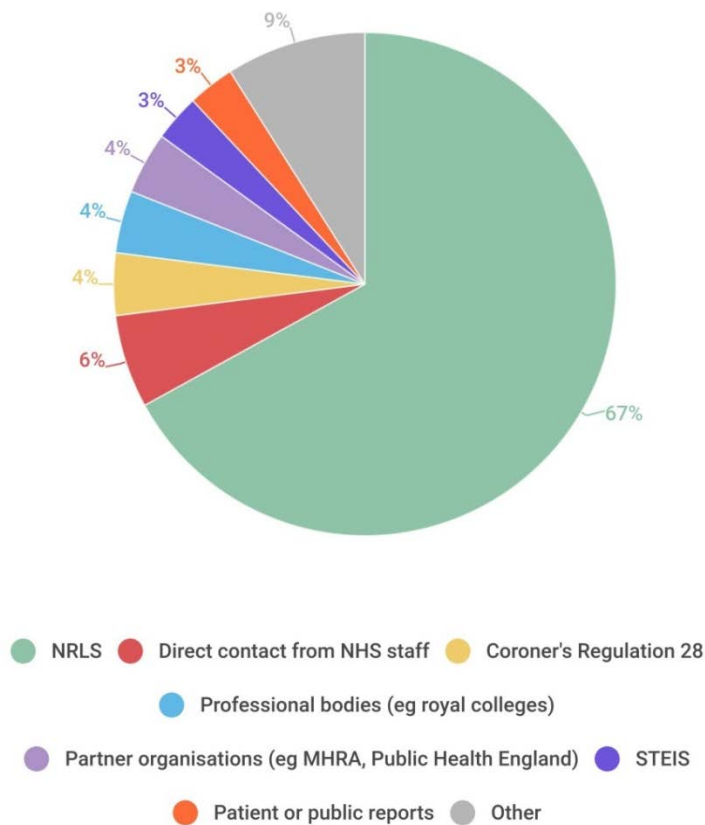
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Issues raised by direct communication (eg emails or phone calls to the national patient safety team)

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 70 issues our clinical teams identified between October 2016 and March 2017 and took forward for potential national action.

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





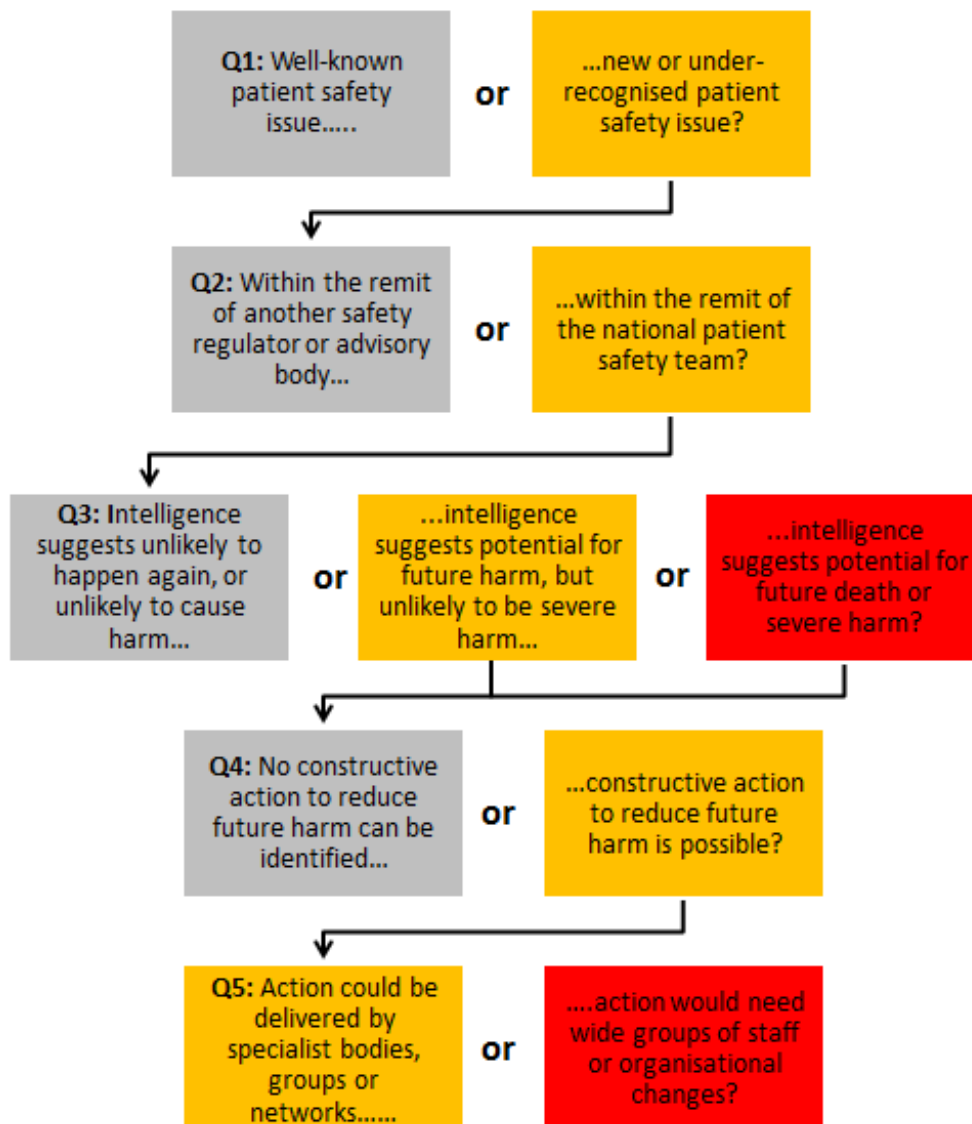
Should we issue a Warning Alert?

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 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?



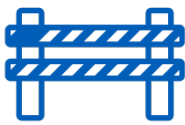
Addressing an issue that causes, or has potential to cause, severe harm or death?

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 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 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 College of Emergency Medicine
- Royal College of General Practitioners
- 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 Alerts, 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 publically 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 2016 and March 2017 we issued four Patient Safety Alerts:



Reducing the risk of oxygen tubing being connected to air flowmeters

Issued: 3 October 2016 Directive Alert

This alert asked NHS providers that supply medical air using medical gas pipeline systems (MGPSs) to take specific actions to reduce the risk of harm from oxygen tubing being connected to air flowmeters. Severe harm or death can occur if medical air is accidentally administered to patients instead of oxygen.

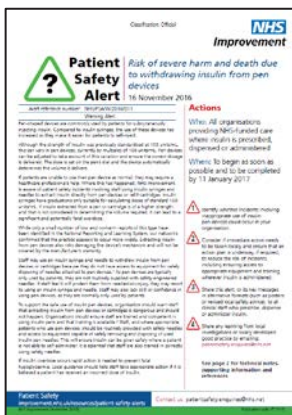


Risk of death and severe harm from error with injectable phenytoin

Issued: 9 November 2016 Warning Alert

Injectable phenytoin is used to slow and stabilise erratic electrical brain activity in, for example, status epilepticus, which is a life-threatening medical emergency. It is a particularly complicated drug to prescribe, prepare, administer and monitor. The alert asked providers to consider if they could do more to strengthen local guidance, training and teamwork related to the use of injectable phenytoin to reduce the risk of error.

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



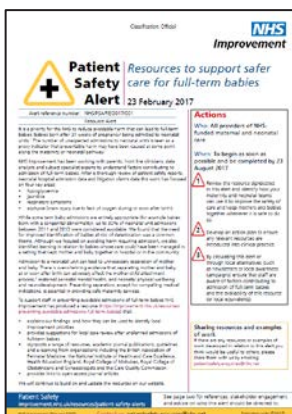
Risk of severe harm and death due to withdrawing insulin from pen devices

Issued: 16 November 2016 Warning Alert

Patient safety concerns have been identified where healthcare professionals use an insulin syringe and needle to withdraw medication directly from a patient's insulin pen device. As the strength of insulin in pen devices varies, this creates a risk of fatal overdose.

Reports suggest this practice has been followed where staff do not have access to equipment for safe disposal of needles attached to pen devices and/or lack training in the use of insulin pens.

The alert asked providers to ensure staff have access to appropriate equipment and training for administering insulin using a pen device.



Supporting safer care for full-term babies

Issued: 23 February 2017 Resource Alert

This alert asked all relevant providers to review the [resource we produced to support staff](#) in preventing avoidable admissions of full-term babies and to identify how teams can use it to improve the safety of care and keep mothers and babies together whenever it is safe to do so. The resource focused on reducing harm caused by hypoglycaemia, jaundice and respiratory symptoms.

A priority for the NHS is to reduce avoidable harm that can lead to full-term babies (babies born after 37 weeks of pregnancy) being admitted to neonatal units. The number of unexpected admissions to neonatal units is seen as a proxy indicator that preventable harm may have been caused at some point along the maternity or neonatal pathway.

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:

- [*Reducing the risk of oxygen tubing being connected to air flowmeters*](#) (Incident Reporting and Investigation Centre (IRIC) (issued as a Safety Action Notice, 26 October 2016)
- *Risk of death and severe harm from error with injectable phenytoin* (circulated via email to directors of pharmacy)
- *Risk of severe harm and death due to withdrawing insulin from pen devices* (circulated via email to directors of pharmacy).

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

- [*Reducing the risk of oxygen tubing being connected to air flowmeters*](#) (issued as a Patient Safety Notice, November 2016)
- [*Risk of death and severe harm from error with injectable phenytoin*](#) (issued as a Patient Safety Alert, January 2017).

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

- [*Reducing the risk of oxygen tubing being connected to air flowmeters*](#) (issued 31 October 2016)
- [*Risk of death and severe harm from error with injectable phenytoin*](#) (issued 15 November 2016)
- resources to support safer care for full-term babies were also disseminated.

Issues where we advised or influenced others on action

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



Diagnosing and treating testicular torsion

Testicular torsion occurs when the spermatic cord twists, blocking the blood supply to the testis. This is a surgical emergency and delayed diagnosis and treatment increases the rate of testicular loss, potentially resulting in subfertility or infertility, altered body image and psychological trauma. Testicular torsion often presents in boys and young men under 18 years of age.

Clinical review of the NRLS revealed healthcare staff frequently report cases of suboptimal management of testicular torsion, including issues at all stages of the patient pathway: initial investigation and diagnosis, timely access to specialist advice and urgent surgery, and variance in corrective surgical procedures.

Distinguishing testicular torsion from other causes of pain in the testes is not always straightforward, and we know simply raising awareness of diagnostic errors or delays is unlikely to be an effective way of preventing them. Therefore, with support from key national stakeholders, a proposal was developed and submitted to the [National Confidential Enquiry into Patient Outcome and Death \(NCEPOD\)](#) for this to be a future focus of its in-depth reviews. Although other topics were considered higher priority for its 2017 studies, NCEOPD will carry the proposal over for consideration in 2018 as it had strong support from stakeholders.

Once testicular torsion is suspected, optimal management relies on systems across all NHS sectors. The steps we took to influence improvements in cross-system working are described in the issue directly below.



Delays in urgent surgery for children and young people

Access to urgent surgery for children can become logistically complex. This is because not all hospitals with emergency departments (EDs) can safely provide surgery for younger children or for all urgent surgical conditions affecting children. Some children clearly need to be transferred to a specialist centre, but for some older children and more common types of surgery, anaesthetists, surgeons and other clinical staff need to agree where surgery is best performed. Once a decision is made to

urgently transfer a child to another hospital, transport, theatre time and a postoperative bed all need to be co-ordinated so timings align and there is no further delay.

Individual NRLS reports indicating challenges in accessing urgent surgery for children were shared with the specialised commissioning team in NHS England, and NRLS data was reviewed to inform its paediatric surgery review. This wider review of NRLS data did not indicate additional issues for a particular clinical presentation or parts of the system, but confirmed the commissioning team's existing understanding of the importance of clear agreements on service provision across local areas, especially for time-critical conditions such as testicular torsion.

We were also able to share information on incidents that highlighted the importance of commissioning arrangements for eye and dental conditions that need an urgent expert opinion before surgery is considered, and the need for clear allocation of responsibility for postoperative follow-up.



Wrong tooth extraction

Dentistry is one of the NHS's most common types of surgical intervention. Uniquely most dental surgery is done under local anaesthesia on conscious, anxious patients. This high volume, often complex work, creates opportunity for mistakes that can be devastating for both the patient and the clinician. Wrong site surgery in dentistry may not always result in significant physical harm, but can still cause significant distress and impact further treatment, and can be symptomatic of wider problems in the clinical systems and processes of the environment in which it occurs.

From 1 April 2016 to 31 March 2017 ([provisional data](#)) there were 42 wrong tooth/teeth extractions among 178 reported wrong site surgeries. Thirteen of these were in the under 18 age group. In 2016 the patient safety team at NHS Improvement worked with the Faculty of Dental Surgery, Royal College of Surgeons to review and share the learning from wrong tooth extractions, and produced [recommendations aimed at all clinical dental teams involved in dental extractions, to prevent the removal of wrong teeth](#).



Entanglement of babies and infants in intravenous (IV) lines or nasogastric (NG) tubes

Clinical staff contacted us for advice about local concerns regarding the risk of entanglement during unsupervised overnight NG feeds for children at home. They were aware of this risk because of [a past review of NRLS data](#) that described incidents

involving entanglement in feeding tubes, IV lines and monitoring wires, though none had caused severe harm. We were also contacted by staff after an infant in hospital intensive care became entangled in lines that were used for monitoring overnight.

Further review of the NRLS revealed five incidents where young children at home were found during the night with their feeding tube around their neck, all causing no or low harm. There appeared to be no patterns to the type of tubing, child's clinical condition or age or size in these incidents. The rarity of these incidents meant we could encourage the staff who contacted us to consider this specific risk alongside all the risks (including aspiration) and benefits that need to be balanced by staff and families when considering overnight tube feeding at home. Additionally, in the [Initial placement checks for nasogastric and orogastric tubes: resource set](#) we asked clinical networks to develop and share clinical guidelines, policies or protocols for patients receiving NG feeds at home, including overnight.

We asked the MHRA to add comment on risk assessment of entanglement for infusion devices in an infusion system publication that they expect to issue in early 2018.



Port wine stain (PWS) and monitoring for glaucoma

People with [PWS are more vulnerable to glaucoma](#) and should have regular monitoring. An incident reported via the NRLS described an adult with PWS who had not been monitored and was only diagnosed with glaucoma after their vision had deteriorated.

We sought advice from clinical experts and frontline staff, who confirmed that midwives and neonatal teams know to refer a baby found to have a PWS to a paediatrician and are aware of the importance of regular monitoring for glaucoma. However, healthcare staff may have been less aware at the time some of today's older children and adults were born, and occasionally PWS is not as visible at birth as it is later on. We found GPs encounter PWS mainly through patients requesting laser therapy for cosmetic reasons, and so may not know about the wider risks associated with PWS.

The National Director for Patient Safety wrote to the Presidents of the Royal College of Ophthalmologists (RCOphth) and the Royal College of General Practice, who agreed to work together to consider how best to address raising awareness of the associated risk among GPs.



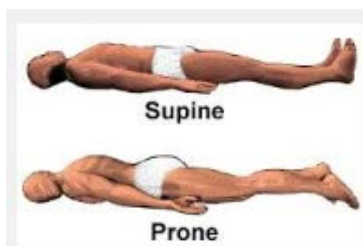
Oral glucose tolerance test (OGTT) affected by changes in Lucozade™

The manufacturer of Lucozade™ informed us of its plans to reduce the glucose content of Lucozade™ as part of national and international efforts to reduce obesity. As OGTT requires giving a specified amount of glucose before a blood test, a lack of awareness of these changes risked people being given too low a dose of glucose where an OGTT is used as the diagnostic test for diabetes. This would potentially give a false-negative OGTT result and lead to harm from undiagnosed and untreated diabetes. Delay in diagnosis of gestational (during pregnancy) diabetes was a particular concern, as this is potentially very harmful to mother and baby. Preliminary enquiries indicated that many units used glucose doses specifically intended for OGTTs, but some still used Lucozade™.

We worked with a number of organisations including the Royal College of Obstetricians and Gynaecologists and Royal College of Midwives to support the manufacturer's efforts to communicate the planned changes to clinical staff. In addition, the Medication Safety Officer Network helped spread news of the changes.



Eye injury (orbital apex syndrome) in patients in the prone position in critical care



Patients are sometimes positioned face down (prone) for surgery in operating theatres, and this position may also be adopted for some patients with severe respiratory conditions in critical care. In response to an NRLS report describing vision loss to a patient nursed in the

prone position in a critical care unit, we collaborated with nursing staff in critical care units and theatres, intensivists and specialists to fully understand the care pathway for such patients.

It became clear that while there is an abundance of research and guidance aimed at prone positioning in perioperative patients, there is a lack of national guidance for the safe management of prone positioning of critical care patients. These patients present different clinical challenges and require different protective equipment. We shared our findings with representatives from the RCOphth, the Intensive Care Society and the Faculty of Intensive Care Medicine, and appropriate guidance for prone positioning is now being developed. The RCOphth has also produced [guidance](#) to enable swift identification of ophthalmic conditions in critical care patients.



Patient found asphyxiated after slipping under a wheelchair waist belt

An incident was reported to the NRLS that described a person dying in their home (a supported independent living facility) after slipping downwards in their wheelchair until the waist belt was around their chest and neck, apparently from asphyxiation.

A previous [MHRA Device Alert](#) distributed widely to health, social care and schools in 2015 includes this advice:

- Ensure that all posture/safety belts for seating, stair lifts, hoists and wheelchairs are fitted, adjusted, used, cleaned, checked and maintained in accordance with the manufacturer's instructions.
- Ensure that guidance on how to check, adjust, clean and maintain each posture/safety belt is passed on to the user or carer.
- Before each use, ensure that the posture/safety belt is in a satisfactory condition, is appropriate for the user and is adjusted correctly.
- Ensure that reviews of an individual's needs include consideration of the appropriateness of the posture/safety belt for the user and carers.
- Report any inadequacies in the manufacturer's instructions to the MHRA.

We contacted the MHRA to inform it of the incident reported to the NRLS and of good practice identified via the Wheelchair Managers Forum. The forum told us that some services no longer automatically provide a waist belt or other posture/safety belt with a wheelchair, instead only issuing these after a specialist service user assessment. We also asked the independent standards body for disability equipment (CECOPs), National Association of Equipment Provider (NAEP) and National Wheelchair Managers Forum to raise awareness through their own communication networks, and linked them with the MHRA so they could work together to improve safety for wheelchair users.



Bridging prescriptions for people leaving custody/prison

A service user who was given a bridging prescription for methadone on discharge from prison died shortly after leaving custody.

We asked specialist service provider experts for advice. They confirmed there were significant challenges with timely and

appropriate referrals to partner organisations when prisoners leave custody. Bridging prescriptions are often needed to avoid greater risks in the period before an ex-prisoner confirms where they are living and registers with a local general practice, but they should not be issued without risk assessment, or only as part of a wider care and recovery plan.

We shared our findings with the Pharmaceutical Adviser to the Health and Justice, Finance, Commercial and Specialised Commissioning Groups at NHS England. They confirmed they are working on these challenges and will use this incident to inform their work.



Communication between fire and rescue and ambulance services

We reviewed a report that described the death of a bariatric patient following a fall at home. Because the patient's weight was known to be too great for the ambulance service to manage on its own, the fire service attended initially and retrieved the patient from the floor. Later the patient suffered a cardiac arrest and died. There seemed to be boundary-related gaps in communication systems and processes, as an ambulance should have also been dispatched automatically.

We discussed this incident with local services. Because fire and rescue services are increasingly engaging with health-related issues, they were keen to identify how to share the learning nationally. The local fire and rescue service summarised the incident in their national newsletter to highlight the importance of clarity of standard operating procedures for new services. A national cross-service Joint Organisation eLearning Platform is also being established, and this incident will be used on the platform to highlight the importance of clear service agreements when commissioning innovative service models.



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

Sharing information on methods of self-harm through published documents is unsafe as this could give patients or members of the public ideas on how to harm themselves. Prevention of self-harm ultimately relies on improvements to the therapeutic environment rather than a focus 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 four risks through this route.



Risks identified with maintaining body temperature of a neonate in an ambulance

Clinical review of the NRLS revealed a potential risk associated with the challenge of the immediate care and treatment of premature babies born at home or on the way to hospital in an ambulance. The particular concern was prevention of hypothermia during the journey to hospital.

In the hospital environment a premature baby is delivered wet into a plastic bag, and airway management/resuscitation is started under a radiant heat source. As this is not practical in an ambulance, even in neonatal adapted ambulances, this issue was shared with our ambulance network colleagues.

To provide the safest possible care in these circumstances, the ambulance network has developed a national ambulance standard paediatric kit list based on updated [Joint Royal Colleges Ambulance Liaison Committee \(JRCALC\) clinical guidance](#). This guidance now includes advice to dry premature babies and then leave them in skin-to-skin contact with the mother if possible, as well as covering them in dry towels and putting a hat on. This advice is reinforced when ambulance crews attend Neonatal Life Support Training where the management of neonates in the out-of-hospital setting is covered, and is included in the latest [Resuscitation Council UK algorithm](#).



Hyponatraemia from chemotherapy with hyperhydration

We identified an incident related to a form of chemotherapy used in children with central nervous system (CNS) tumours that can lead to hyponatraemia (low sodium levels). This type of chemotherapy requires a process called hyperhydration in which patients are given lots of fluid. Hyperhydration can cause sodium levels to drop dangerously low and needs careful monitoring. In this incident the child developed hyponatraemia and a delay in correcting this may have contributed to their death.

As we were concerned that this may be a new or under-recognised risk, we contacted the National Clinical Director for Children and Young People who liaised with the UK Children's Cancer and Leukaemia Group (CCLG). This confirmed the risk is known and that similar cases had been presented to the CCLG Central Nervous System special interest group, but that it will use this incident to emphasise the importance of monitoring, and as part of wider CCLG data collection on adverse effects of treatment for CNS tumours.



Procedural sedation in emergency departments

We identified two Serious Incidents describing harm from procedural sedation in the ED. Procedural sedation is the administration of drugs to promote calm and muscle relaxation for a procedure such as reducing a fracture or dislocated joint. The risk is that patients may become over-sedated and move into deep sedation which can result in airway complications.

This risk has been previously addressed in the Royal College of Anaesthetists and the Royal College of Emergency Medicine (RCEM) joint report [Safe sedation of adults in the emergency department](#) published in 2012. In 2016 the RCEM audited against the report's standards and found poor compliance with recommended processes overall, with adverse events identified in 4.7% of reviewed cases.

We searched the NRLS for similar incidents. Our findings suggest patients are still at risk of harm from procedural sedation in ED, including respiratory depression and respiratory arrest. We have shared our findings with the RCEM to inform its efforts to improve safety.



Delayed triage of unwell patients in ED 'pit stops'

We identified an incident in the NRLS that described harm from delays in treatment and which referred to a 'pit stop' area in the ED. The term 'pit stop' comes from Formula One racing, where a team of mechanics work seamlessly in a time-critical and space-limited environment to get a racing vehicle back onto the track as fast as it can. The term appears to have been adopted by many EDs to describe a rapid assessment area for patients arriving by ambulance.

We searched the NRLS and found a few similar incidents where harm to patients was associated with delays and a pit stop system was in operation.

None of the incidents appeared to suggest that use of the pit stop system had created a new or under-recognised risk, and it seems more likely that the incidents happened despite, not because of, the pit stop system.

However, it was obvious from the NRLS reports that very different models of pit stop are being used, involving different processes and varying types and numbers of staff. We have asked the RCEM to consider if guidance is necessary to describe what a good ED 'pit stop' looks like and how its role is distinct from that of

resuscitation areas and triage areas.



Faye's story – death related to opioids in chronic pain

A tragic case of the death of a young woman from respiratory depression related to high doses of opioids and other medication prescribed for chronic pain was highlighted to us by an MP. Working with the NHS England regional team in the South West, we helped to promote its excellent resources by getting them highlighted in national communications to GPs, clinical commissioning groups (CCGs) and providers, and to controlled drug accountable officers through the CQC newsletter. We also added the resources to the [NHS Improvement Hub](#).

In addition, we worked with the publishers of the *British National Formulary*. It has agreed to include a link to the Faculty of Pain resources in its opioid content and is considering what other evidence-based changes may be needed to improve safe prescribing for patients with severe and long-term pain.



Oxygen and smoking fire risk in hospices

A coroner contacted the national patient safety team after a fatal fire in a hospice involving a cigarette igniting the patient's oxygen supply.

When patients use oxygen in their own homes, the regional services that supply oxygen take steps to ensure patients and their families understand the risks of smoking anywhere near the oxygen supply. In hospitals, oxygen use is widespread, but smoking is banned and the safe management of medical gases, including oxygen, is part of the regular training for staff. However, in hospices, smoking may be permitted and oxygen may be directly prescribed and supplied, or brought in by patients who use it at home.

With the support of NHS England and CQC, we wrote to all hospice chief executives to highlight the resources provided by regional home oxygen services, the [Health and Safety Executive](#) and the [British Thoracic Society](#), and to ask them to ensure their staff, patients and families are aware:

- of the speed of spread and severity of fire in an oxygen-rich environment, as demonstrated in videos like this: [Awareness and Safety Training – Oxygen Therapy](#)
- that risks remain even after oxygen has been turned off, as higher oxygen concentrations can linger in clothing and hair, oxygen cannulas, tubing and masks

- that e-cigarettes as well as conventional cigarettes can ignite oxygen.

We also worked with our medication device safety officer (MDSO) and medication safety officer (MSO) networks to check that training in hospitals and mental health units covered these risks, and NHS England asked its regional home oxygen services to consider if care home staff needed additional support.



Silver nitrate sticks confused with cotton buds

We identified an incident where a silver nitrate applicator was used in error in an ED to remove a foreign object from a patient's eye. The clinician had confused the applicator with a cotton bud and the patient was reported to have suffered severe harm as a result.

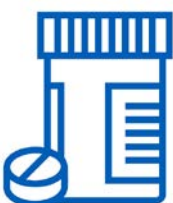
We subsequently identified another almost identical case in the NRLS and worked closely with colleagues from the hospitals involved to fully understand the circumstances. We then contacted the major supplier of silver nitrate applicators to discuss potential ways to reduce the risk

Following discussions, the supplier has agreed to change the carton and the accompanying product literature to emphasise the requirement that individual applicators must be stored in the original packaging. The RCEM was informed of the issue.



Cotton bud

Silver nitrate applicator



Safety issues in community pharmacy medicine delivery

Delivery of medicines in community pharmacy is not an NHS-funded service; however, it is a growing service often provided by community pharmacies to NHS-funded patients who have difficulty collecting their medications. A range of patient safety issues related to the delivery of medications by community pharmacies to

patients' homes were identified through the community pharmacy MSO network. These included delivery of medicines to the wrong patient and failure to deliver or delay in the delivery of critical medicines.

Delivery services face specific safety challenges relating to confirmation of address and identity. These include: not obtaining confirmation of address/patient identity when a delivery driver believes they have arrived at the correct address; drivers arriving at the wrong address; people with the same name living in the same household; and delivering to those with dementia or who are bed-bound.

To help address these challenges, the community pharmacy MSO network detailed the [steps that need to be addressed before agreeing to a delivery and provided insight into what constitutes good medicine delivery practice by delivery drivers and pharmacy teams](#) in a document that was promoted via the MSO network. Many pharmacies are now integrating these recommendations into their standard operating procedures.



Wrong route administration error: oral vaccine given parentally

Rotavirus vaccine is an active oral immunisation given to babies to prevent gastroenteritis due to rotavirus infection. An incident was submitted to the Strategic Executive Information System (StEIS) that described wrong route administration of Rotarix: the vaccine was administered subcutaneously rather than orally. Fortunately the baby was not harmed by this incident, but there was clearly potential for harm. It appeared the error was made because the vaccine was provided in a pre-filled syringe that, although intended for oral use, looked very similar to syringes used for injections. As staff believed the vaccine was for subcutaneous administration they modified the syringe to attach a needle.

Review of NRLS reports identified a small number of similar incidents and, following discussion with the reporting organisation's MSO, the incident was shared with the MHRA. The manufacturer of Rotarix now provides the vaccine in an oral tube that is squeezed to release the vaccine into the baby's mouth.

This change in product presentation makes the oral route obvious and acts as a physical barrier to preventing this wrong route error.

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](#)
- The **MHRA**, which receives medication and medical devices data to support its regulatory functions.

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 or 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 other bodies listed above, we shared patient safety incidents with a variety of organisations or individuals. Recent publications featuring the NRLS data we shared, including analyses related to community pharmacy, primary care, ambulance services and radiotherapy, are listed in Appendix 1.

Acting through our MSO and MDSO networks

The MHRA and NHS Improvement jointly support the medication safety officer (MSO) and medical device safety officer (MDSO) networks. These networks 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. But they do much more than this. Below we highlight what the MSO and MDSO networks have worked on in the period covered by this report.

The MDSO network

Monthly WebEx meetings for the MDSO network were jointly hosted by the MHRA and NHS Improvement.

The WebEx meetings give insight into patient safety issues identified through our review of NRLS incident reports or other sources. We involve the MDSO network at an early stage in our exploration of patient safety issues, before deciding the best way to act. The MDSO network has also been invaluable in bringing to our attention issues that may need national action, including through Patient Safety Alerts.

Each month presentations on areas of patient safety relevant to medical devices are selected and shared across the network, with viewers able to ask questions and provide feedback to a national poll. Speakers belong to the MDSO network, the wider NHS and the MHRA, or work in procurement and industry. WebEx topics have included:

- **October 2016:** Update on MHRA software guidance, medical devices and IT networks, IT connectivity, cyber security incidents in hospitals, point of care testing and blood gas analysers.
- **November 2016:** Local incident reporting and analysing data and reducing the risk of oxygen tubing connection to air flowmeters.

- **December 2016:** Electrocardiograms (ECGs), the ‘control of electromagnetic fields at work’ regulations, infusion pumps, and managing diabetes.
- **February 2017:** Assistive technology presentations, feedback from MSO/MDSO conference.
- **March 2017:** Implementation of barcoding and medical equipment management, GS1 and use of barcoding in Field Safety Notices (FSNs), protection of patient identifier data, impact assessments.

We also routinely include updates on all recent Patient Safety Alerts, focusing on how MDSOs can support effective implementation. We share advice and guidance issued through routes other than alerts; several examples are given earlier in this report.

The WebEx meetings are supported by a national ‘forum’ where members can develop new themes and raise concerns at an early stage.

In the period covered by this report, on average 65 MDSOs and MSOs (the topics are often relevant to both groups) logged into each WebEx and 664 healthcare professionals registered on the forum pages.

Want to find out more about MDSOs?

The role of the MDSO varies from organisation to organisation and may be allocated to more than one person. MDSOs are nominated by their organisation and can be registered and receive forum login details via safetyalerts@dh.gsi.gov.uk. If you are unsure who the MDSO is in your organisation, your risk manager or clinical governance team will be able to tell you.

The MSO network

One-hour WebEx meetings for the MSO network were held each month with the direct involvement of NHS Improvement, the MHRA and Specialist Pharmacy Service.

The WebEx meetings include calls for insights into patient safety issues identified through our review of NRLS incident reports, and cover incidents and issues 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 gauge

opinion and seek advice before deciding the best way to act. MSOs have been invaluable in providing local intelligence in relation to specific potential safety issues.

Through email and the discussion forum 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.

WebEx topics have included:

- **October 2016:** Ketamine shortages, penicillin allergy.
- **November 2016:** An introduction to medicines in the ambulance service, heparin, hospital GP systems.
- **January 2017:** Prescription receipt dockets – hydroxycarbamide, ECLIPSE: Exploring the Current Landscape of Intravenous Infusion Practices & Errors.
- **February 2017:** Tracking progress with medication-related Patient Safety Alerts, HIV–medicine interactions, nitrofurantoin and pulmonary toxicity, the Patient Safety Incident Management System.
- **March 2017:** The NEWT guidelines, aripiprazole depot, a carer’s perspective on medicines optimisation, capturing harms associated with new psychoactive substances.

In addition, each month there is an update on recent safe medication practice research, reports and publications.

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

In March 2017 393 MSOs were registered from organisations providing NHS funded care in England, and a further 40 registered from the devolved nations of Wales, Scotland and Northern Ireland. There were also 26 MSOs in ‘other’ posts, including various charities, the Ministry of Defence and CQC.

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@dh.gsi.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

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Appendix 1: Journal publications including review of NRLS data

Carson-Stevens A, Hibbert P, Williams H, Prosser Evans H, Cooper A, Rees P, et al. Characterising the nature of primary care patient safety incident reports in the England and Wales National Reporting and Learning System: a mixed-methods agenda-setting study for general practice. *Health Services and Delivery Research* 2016;4(27).

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