NHS Improvement

Patient safety review and response report April to September 2017

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

21 March 2018

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

Contents

Why publish this report?

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

Year-on-year reporting to the National Reporting and Learning System (NRLS) continues to grow and we now receive over two million incident reports each year. This report is the third of its kind: it explains how we reviewed reports in the period April to September 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 previous review and response reports 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

10,490

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

4,258

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

616

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

218

Potential and confirmed Never Events reported to StEIS*

56

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

14

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

5

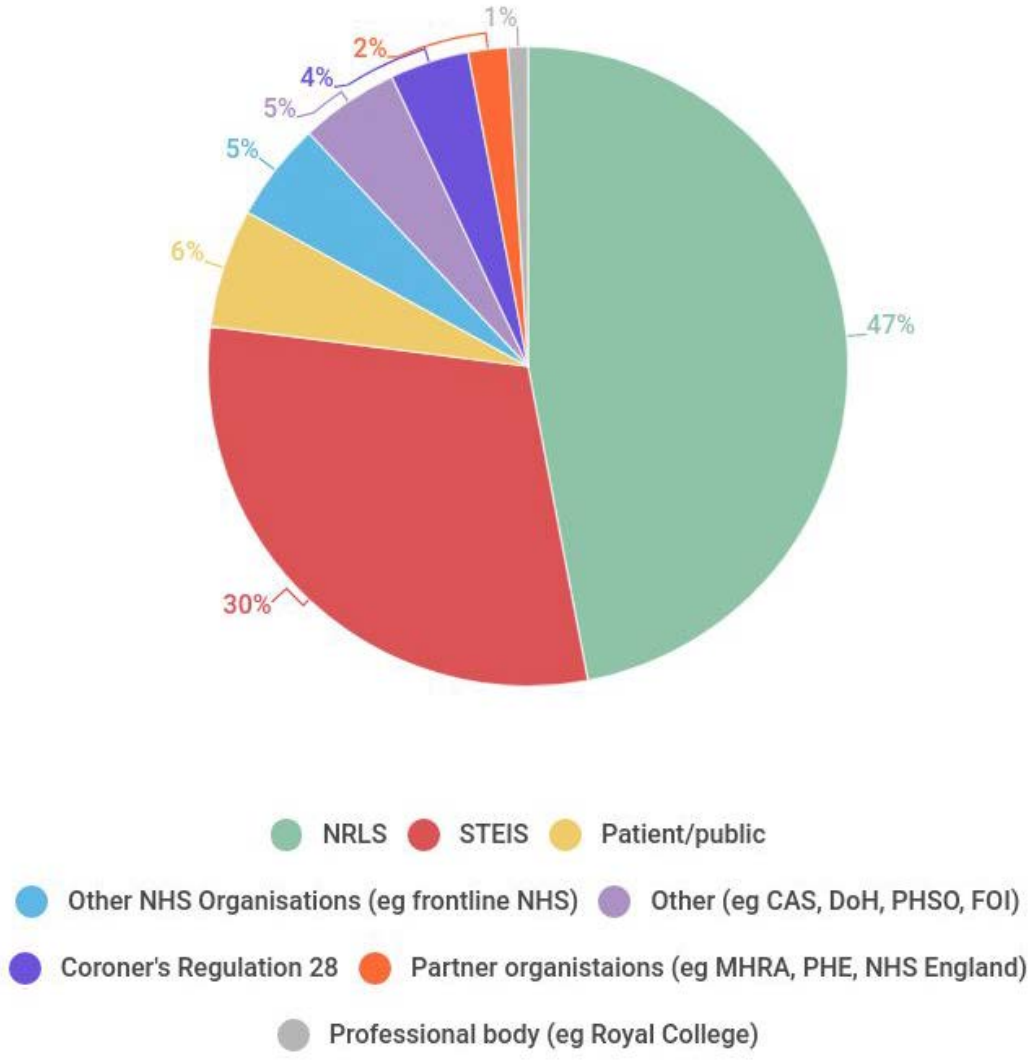
Issues raised by direct communication (eg emails or phone calls to the national patient safety team)

*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 81 issues our clinical teams identified between April and September 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.

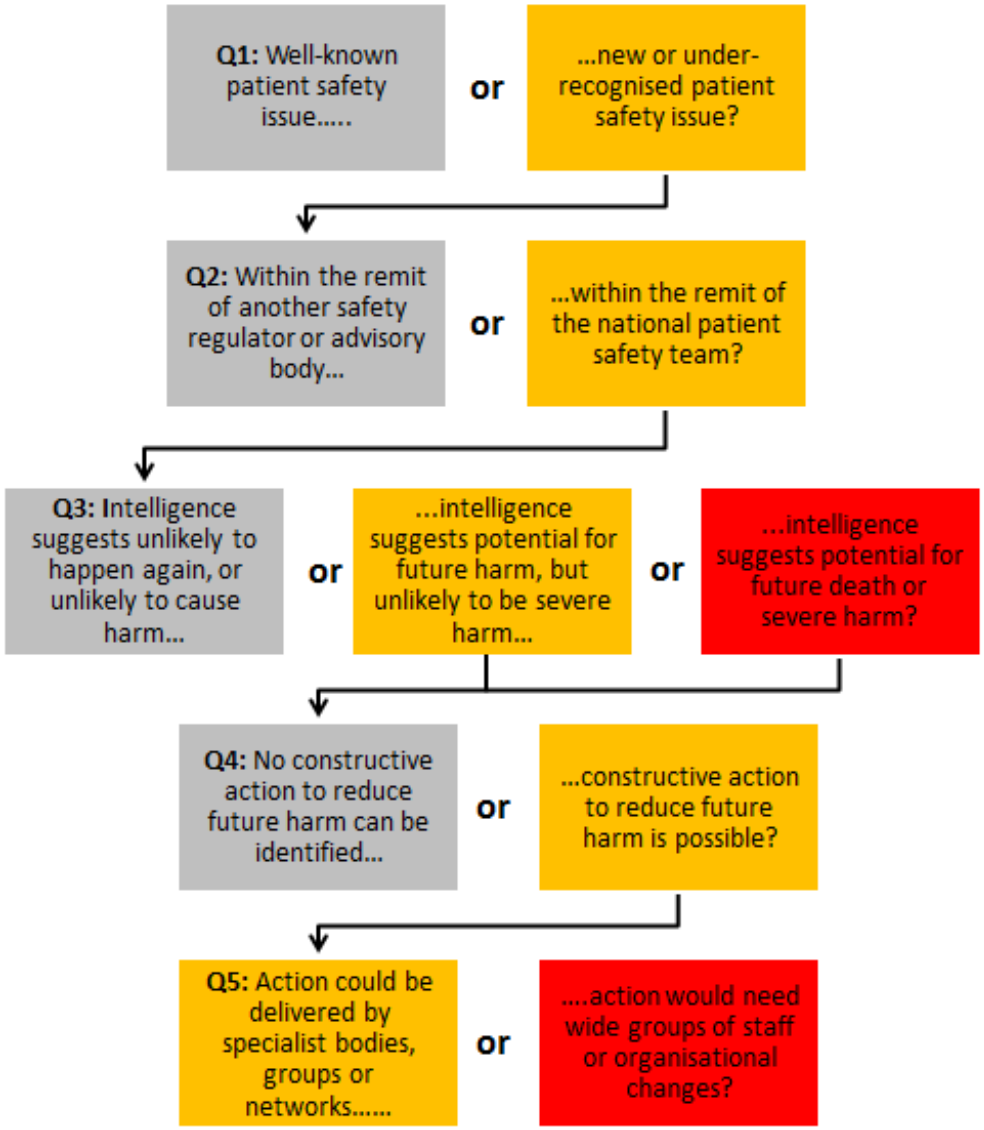
3. Look for up-to-date detail about the issue in the NRLS, research studies and other published material, and seek advice from specialists and frontline staff to help identify the **likelihood of this happening again and the potential for harm**.

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 national[1] 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.

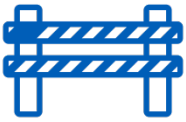
Practical and helpful?	Publications that serve only to deepen our understanding of a problem have value, but in isolation they are not resources and can be disseminated through other routes.

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?

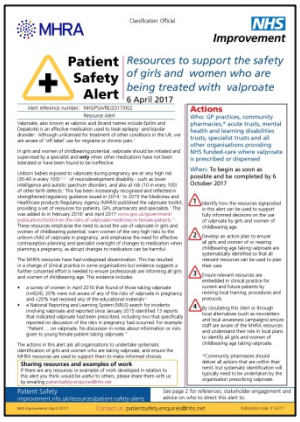
If you would like to know more about why we have designed our clinical review and response process as we have, and developed three types of Patient Safety Alert, read this journal article which links our process to the underpinning patient safety theories.

What action did we take?

Patient Safety Alerts

Our Patient Safety Alerts are issued through the Central Alerting System (CAS) and NHS trusts 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 April and September 2017 we issued four Patient Safety Alerts:


MHRA

Classification: Official

NHS Improvement

Patient Safety Alert

Resources to support the safety of girls and women who are being treated with valproate

6 April 2017

Alert reference number: NHSPSA/RE/2017/003

Resource Alert

Actions

Who: GP practices, community pharmacies,* acute trusts, mental health and learning disabilities trusts, specialist trusts and all other organisations providing NHS funded-care where valproate is prescribed or dispensed

When: To begin as soon as possible and be completed by 6 October 2017

1 Identify how the resources signposted in this alert can be used to support fully informed decisions on the use of valproate by girls and women of childbearing age.

2 Develop an action plan to ensure all girls and women of or nearing childbearing age taking valproate are systematically identified so that all relevant resources can be used to plan their care.

3 Ensure relevant resources are embedded in clinical practice for current and future patients by revising local training, procedures and protocols.

4 Via circulating this Alert or through local alternatives (such as newsletters and local awareness campaigns) ensure staff are aware of the MHRA resources and understand their role in local plans to identify all girls and women of childbearing age taking valproate.

*Community pharmacists should deliver all actions that are within their remit, but systematic identification will typically need to be undertaken by the organisation prescribing valproate.

Sharing resources and examples of work

If there are any resources or examples of work developed in relation to this alert you think would be useful to others, please share them with us by emailing patientsafetyenquiries@nhs.net

Patient Safety Improvement dhs.uk/resp.aces/patient-safety-alerts

See page 2 for references, stakeholder engagement and advice on who to direct this alert to.

NHS Improvement April 2017

Contact us: patientsafetyenquiries@nhs.net

Publication code: P Jan17

Resources to support the safety of girls and women who are being treated with valproate

Issued: 6 April 2017
Resource Alert

This alert was issued jointly with Medicines and Healthcare products Regulatory Agency (MHRA) to support the safety of girls and women of childbearing potential being treated with valproate.

Unborn babies exposed to valproate are at very high risk of neurodevelopment disability and other birth defects. In girls and women of childbearing potential, valproate should be initiated and supervised by a specialist and only when other medications have not been tolerated or have been found to be ineffective.

It is vital where valproate is prescribed to girls and women of childbearing potential that they are made aware of the risks of taking the medication in pregnancy. The need for effective contraception planning must also be emphasised, along with the requirement for specialist oversight to safely change their medication if planning a pregnancy.

The alert signposted providers to the updated MHRA valproate toolkit and required them to take steps to systematically identify all girls and women of childbearing potential who could be at risk.

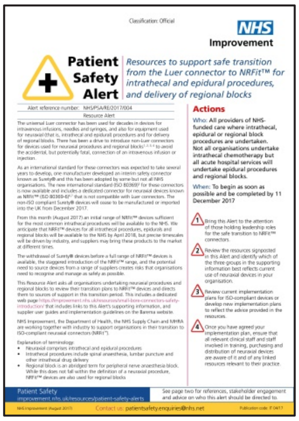
[2] To subscribe to receive CAS alerts, contact the CAS helpdesk by emailing safetyalerts@dh.gsi.gov.uk

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

Issued: 5 July 2017
Warning Alert

Superabsorbent polymer gel granules are widely used in health and social care, typically as small sachets placed in urine and vomit bowls. On contact with liquid, the sachet opens and the granules almost instantaneously absorb, expand and solidify the liquid. This can protect patients' bedding and clothing and reduce the risk of slips.

If the gel granules are put in the mouth they expand on contact with saliva, risking airway obstruction. This has happened where patients have mistaken the sachets for sweets, or sugar or salt packets, but some incident reports also describe attempts of deliberate self-harm.

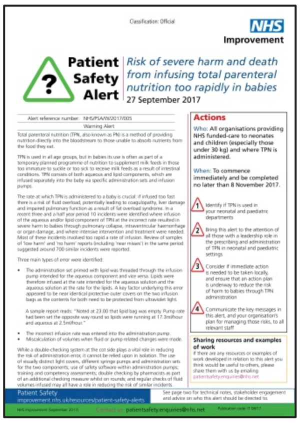


Resources to support safe transition from the Luer connector to NRFit™ for intrathecal and epidural procedures, and delivery of regional blocks

Issued: 11 August 2017
Resource Alert

This alert supports providers with the safe transition from the Luer connector to NRFit™ for intrathecal and epidural procedures, and delivery of regional blocks, in accordance with the International Standard for small bore connectors ISO 80369-6.

Devices with the NRFit^{TM} connector are not compatible with Luer connectors, preventing the risk of drugs being delivered through the wrong route. Industry has adopted this new ISO standard for use throughout the UK and NRFit™ is now the dedicated connector for neuraxial devices.


Classification: Official
NHS Improvement
Patient Safety Alert
Risk of severe harm and death from infusing total parenteral nutrition too rapidly in babies
27 September 2017
Actions

Risk of severe harm and death from infusing total parenteral nutrition too rapidly in babies

Issued: 27 September 2017
Warning Alert

Total parenteral nutrition (TPN, also known as PN) is a method of providing nutrition directly into the bloodstream of those unable to absorb nutrients from the food they eat. In babies its use is often temporary as part of a planned programme of nutrition to supplement milk feeds in those too immature to suckle or too sick to receive milk feeds as a result of intestinal conditions.

The rate at which TPN is administered to a baby is crucial: if infused too fast there is a risk of fluid overload, potentially leading to coagulopathy, liver damage and impaired pulmonary function as a result of fat overload syndrome.

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 severe harm and death from infusing total parenteral nutrition too rapidly in babies* (alert issued to NHS Scotland with no changes added)
- *Resources to support safe transition from the Luer connector to NRFit™ for intrathecal and epidural procedures, and delivery of regional blocks* (Incident Reporting & Investigation Centre issued alert as a Safety Action Notice in August 2017)
- *Risk of death and severe harm from ingestion of superabsorbent polymer gel granules* (Incident Reporting & Investigation Centre issued alert as a Safety Action Notice in August 2017)
- *Resources to support the safety of girls and women who are being treated with valproate* (Healthcare Improvement Scotland worked with appropriate colleagues to produce its first NHS Scotland alert to ensure that the actions from the alert were appropriate and relevant for Scotland. The alert was sent to directors of pharmacy and medical directors).

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

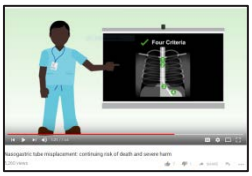
- *Risk of severe harm and death from infusing total parenteral nutrition too rapidly in babies* (issued in Wales October 2017)
- *Risk of death and severe harm from ingestion of superabsorbent polymer gel granules* (issued in Wales August 2017)
- *Resources to support the safety of girls and women who are being treated with valproate* (issued in Wales April 2017).

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

- *Risk of severe harm and death from infusing total parenteral nutrition too rapidly in babies* (issued in Northern Ireland October 2017)
- *Risk of death and severe harm from ingestion of superabsorbent polymer gel granules* (issued in Northern Ireland July 2017)
- *Resources to support the safety of girls and women who are being treated with valproate* (issued in Northern Ireland April 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 to be put in place, 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 the period covered by this report, we produced one ‘ask why’ video around our *Nasogastric tube misplacement: continuing risk of death and severe harm* alert. The video can be viewed on the alert webpage and YouTube.

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.

Inappropriate use of tracheostomy bib in patients with tracheostomy

We identified a serious incident where a patient's tracheostomy became blocked by thick secretions, resulting in a cardiac arrest. The patient had been using a tracheostomy bib for humidification. This was necessary because air inspired via a tracheostomy bypasses the normal site for humidification, the nasopharynx. The National Tracheostomy Safety Project UK states that the bib is one of the less effective methods of humidification but it is considered suitable for patients who do not require oxygen and who have normal secretions.

A search of the NRLS revealed no similar incidents but it did identify two potential problems with the use of bibs:

- the bib covers the tracheostomy and so staff may not see immediately that a tracheostomy tube has been displaced
- the bib is only effective if it is placed directly over the tracheostomy tube.

The National Critical Care Outreach Forum shared key messages with its members to help them improve safety for patients for whom tracheostomy bibs are considered or used. The National Tracheostomy Safety Project and The Difficult Airway Society were also made aware.

Harm to patients on non-invasive ventilation (NIV) from undrained pneumothorax

We identified a serious incident where a patient on home NIV was discharged from the emergency department (ED) with an undrained pneumothorax. The patient was readmitted the next day with a worsened pneumothorax.

NIV is used in hospital to treat type 2 respiratory failure and in the

community for obstructive sleep apnoea, neuromuscular disorders affecting respiration, and chronic obstructive pulmonary disease (COPD). British Thoracic Society guidance cites 'undrained pneumothorax' as one of the exclusion criteria for NIV. This is because the positive pressure from NIV will force more air into the pneumothorax.

A search of the NRLS found no similar incidents relating to patients on home NIV being discharged with an undrained pneumothorax. It did however identify two potential problems with the use of NIV in hospital (particularly in the ED) in patients with a pneumothorax:

- starting NIV before a chest x-ray is obtained
- missing a pneumothorax on chest X-ray and starting NIV.

These findings were shared with the British Thoracic Society and the Royal College of Emergency Medicine.

O_2

Harm to patients from delivery of nebulisers using medical air in oxygen-dependent patients

We identified a serious incident where an oxygen-dependent patient was given a nebulised medication with air as the driving gas. The patient's oxygen levels dropped, resulting in a cardiac arrest. We searched the NRLS and found 29 incidents describing a similar mistake but with less serious consequences in a three-year period.

The use of oxygen as the driving gas for nebulisers can be harmful for patients at risk of hypercapnia (eg those with severe COPD) and so for many healthcare staff, using air as the driving gas has become normal practice. But in patients who are dependent on higher levels of oxygen, discontinuing their oxygen, even for the few minutes required to deliver a nebulised medication, exposes them to the risk of hypoxia and can be fatal.

This is a recurring patient safety issue; in March 2013 the National Patient Safety Agency issued the Signal *Selecting oxygen or medical air to give nebulisers*, to inform NHS organisations of the risks associated with

selecting the wrong driving gas to deliver nebuliser therapy.

We shared our findings with the National Critical Care Outreach Forum and the British Thoracic Society (BTS) and asked the BTS to consider providing more explicit advice on managing patients reliant on high concentrations of oxygen who require nebulised medication in the next update of its “BTS Guideline for Oxygen use in Adults in Healthcare and Emergency Settings”.

Harm from delayed ophthalmology review

This issue was highlighted in 2009 by a National Patient Safety Agency Rapid Response Report *Preventing delay to follow-up for patients with glaucoma*. NRLS review has continued to indicate significant levels of harm to patients as a result of failures in systems for the timely follow-up of serious ophthalmology conditions. Review identified a complex range of reasons for delay, including deferral or cancellation of appointments or not entering patients into the follow-up system. In a two-year period 172 patients were reported to have suffered delays in review and deterioration in their vision or loss of vision. Although some deterioration may have occurred even with timely treatment, a number of reporters believed the delay had a direct impact.

We shared these findings with the Royal College of Ophthalmologists and supported it to use the data in partnership work to address some of the underlying systemic issues. The NRLS findings have also recently been used to influence commissioning practice and are the subject of a focused work stream coordinated by the NHS England Elective Care group.

Harm to solid organ transplant patients as a result of quality and/or retrieval issues with donor organs intended for transplantation

After an incident was identified in our regular review of incidents reported as causing death or severe harm, we searched the NRLS for harm to solid organ transplant patients as a result of quality and/or retrieval issues with donor organs.

In an eight-year period we identified 24 incidents in which the reporter believed opportunities had been missed to detect problems with the quality of the organ in advance of the donation and/or the quality of the organ had been affected during retrieval and transport. The transplant teams were concerned these issues had contributed to poor clinical outcomes such as acute rejection and delayed graft function.

We have shared our findings with the Human Tissue Authority and with Specialised Commissioning at NHS England to support continuous improvement in processes for the assessment and management of donor organs before, during and after retrieval.

Penile injury following the use of a complex postoperative dressing

Through our regular review of severe harm and death incident reports to the NRLS, we identified a patient who suffered postoperative penile tissue loss due to the type of dressing that had been applied following surgery to the penis.

Choosing an appropriate combination of dressings can be particularly challenging after surgery on the penis as the nature of erectile tissue within the penis means its size can change and dressings could fall off. The erectile tissue also makes the penis's blood supply very vulnerable to any tourniquet effect from the dressing. In the reported incident, following a buccal mucosal inlay graft, a plastic 'spear' was placed over a low-adherent sponge dressing and a stitch inserted to prevent the movement of the dressing; this was all covered with a self-adherent wrap. Postoperatively, the patient presented with a swollen and bruised penis with areas of necrosis that were thought to have been caused by the dressing acting as a tourniquet.

We shared this incident with the British Association of Urology Surgeons (BAUS) and the British Association of Urology Nurses (BAUN), and asked them to consider recommendations on types of dressings appropriate for buccal mucosal inlay grafts and similar procedures.

Tracheoesophageal Voice Prosthesis

Our regular review of NRLS incidents identified an incident where a patient with a tracheoesophageal voice prosthesis (TVP) developed aspiration pneumonia following admission. TVPs are placed in the wall separating the trachea and oesophagus, to enable a patient who has had their larynx removed to speak. The patient was in the early stages of dementia and was no longer able to check their TVP for leaks. Staff on the wards caring for the patient were unaware that TVPs can leak and, as a result, consuming fluids can cause the fluid to be inhaled into the lungs. We were concerned this could happen elsewhere as such devices are rarely encountered on general medical wards.

We contacted the National Critical Care Outreach Forum who were keen to work with the National Tracheostomy Safety Project to highlight relevant resources for ongoing care of TVPs to its membership of critical care outreach teams in hospitals. The National Association of Laryngectomee Clubs continues to raise awareness of this risk within their Education Programme.

Safety netting for paediatric patients leaving an Emergency Department following a first suspected afebrile seizure

When a child attends an Emergency Department (ED) following an afebrile seizure (a seizure without an associated fever) they may be referred to a specialist for further assessment, which is likely to include consideration of epilepsy. As this appointment may not be scheduled for up to two weeks, the family needs to be given clear ‘safety netting’ information when their child is discharged from the ED. The standards for assessment, produced by the Royal College of Emergency Medicine (RCEM), include providing the child and family with a leaflet that should highlight activities that may put their child at risk, such as swimming, bathing and cycling.

However, little detail is given on what the leaflet needs to cover and the information included varies across the country. We contacted colleagues in the RCEM and Royal College of Paediatrics and Child Health (RCPCH) and the RCPCH Epilepsy Programme Board has agreed to lead on work

with relevant partners to develop an agreed safety netting information leaflet for this situation.

Harm from failure to recognise and treat metastatic spinal cord compression

Spinal cord compression (SCC) can be caused by any condition that puts pressure on the spinal cord. Symptoms such as pain, numbness, or weakness in the arms, hands, legs or feet can come on gradually or more suddenly, depending on the cause. One of the most common types of SCC is metastatic spinal cord compression (MSCC). It is a neurosurgical emergency and NICE guidance emphasises that rapid diagnosis and management are essential to prevent permanent loss of function (paraplegia or quadriplegia).

An incident was identified during our regular review of Serious Incidents that detailed a failure to adequately treat a patient with this condition. A search of the NRLS found 26 incidents over a two-year period resulting in significant harm from a failure to diagnose or treat MSCC. Diagnosis in community and hospital settings was sometimes delayed because it was initially assumed that limb weakness or reduced mobility related to more general effects of cancer. There were also; delays in imaging to confirm a diagnosis; omission of medications to treat MSCC; and delayed senior review of the patient. In addition, confusion appeared to occur when patients were being treated palliatively for their cancer but still required acute and urgent treatment for the MSCC.

Given the complexity of the errors and the additional diagnostic challenges, inherent when an acute condition appears in the context of a long-term condition, we have suggested this as a potential focus for investigation by the Healthcare Safety Investigation Branch (HSIB).

Missing signs of patient deterioration when using paper-based systems for observations when electronic systems are in use

We identified an incident where an agency staff member who did not have access to the electronic observation system was recording patients' Early

Warning Scores (EWS) on paper. A colleague, who retrospectively entered the observations onto the electronic observation system, noted that for one patient these had markedly changed from their previous EWS. This patient would have been escalated for urgent review much earlier if all their observations had been entered contemporaneously.

We contacted a number of clinical staff and some national networks to identify how access of temporary staff to electronic observation systems was locally managed and if they believed lack of access could be a recurring risk. Our findings were inconclusive; although some respondents had experienced local problems with access to electronic EWS systems, most appeared to have access plans for temporary staff that worked well. Feedback also suggested it should be possible to safely identify and act on raised EWS even if a temporary mix of paper and electronic systems were in use.

We shared our findings with NHS England colleagues, who are supporting the introduction of the revised National Early Warning Score (NEWS2), and with the deterioration workstream of the Patient Safety Collaboratives, to consider temporary staff access to NEWS2 as part of the wider improvement work on the prompt recognition and treatment of the deteriorating patient.

Repeat prescribing practice risking abrupt cessation of vital medication

A patient contacted the national patient safety team to highlight their difficulties obtaining vital medicines on repeat prescription. They were concerned that processes, set up to avoid waste from repeat prescriptions being requested too soon, made no allowances for circumstances including being away on holiday. They also said that the interval between when they were first allowed to request a repeat prescription and their current supply running out was too short. Unless every step from request to dispensing worked perfectly, their supply of a medication critical to their health was interrupted. The issue was discussed at the National Patient Safety Response Advisory Panel, additional information was gathered from a survey of 121 GP practices in the north of England and current

guidance was explored.

The resulting summary report was shared with the Director of Primary Care Commissioning at NHS England who recognised the importance of this issue. The commissioning team is considering what actions to take: these may include a review of the evidence relating to prescription length and ensuring GP practices have access to guidance relating to the management of repeat prescribing processes.

Limb injury in MRI scanners

Magnetic resonance imaging (MRI) is a vital diagnostic tool in the NHS. Regular review of Serious Incidents reported to the Strategic Executive Information System (StEIS) identified an incident where a patient's arm was fractured when they were being removed from an MRI scanner by remote control. The patient's arm fell off the scanner bed when it was no longer supported by the bore of the scanner.

This incident was shared with the Society of Radiographers and the issue was discussed at the Magnetic Resonance Advisory Group. The group was clear that patients should only be removed from MRI scanners under remote control in specific situations; and only then with visual contact, verbal instructions, and ideally under supervision. The group is considering including specific guidance when they update their *Safety in magnetic resonance imaging* document and to include this in their 'pause and check' materials.

Knitted toys and mittens in neonatal units

A baby in a neonatal unit was found to have a necrotic finger as a result of a tightly wound thread from a knitted mitten. Mittens had been put on the baby to stop him pulling out his nasogastric tube.

The British Association of Perinatal Medicine (BAPM) previously raised awareness of this risk through a safety notification following a similar incident and many units had switched to using cotton mittens. A survey of frontline neonatal and midwifery staff regarding their understanding of the potential for harm from knitted mittens rapidly established this was not an

under-recognised risk and the incident appeared to be an isolated one.

However, in the course of checking for incidents involving knitted mittens, we identified growing use of knitted octopus toys in neonatal units. These are used as a comforter and developmental aid for premature babies, but the combination of loops inherent in any knitted item and the tiny fingers of these babies presents a potential new risk. No reports of harm from these aids were found in the NRLS but as they have only been recently introduced the potential for harm has been highlighted in a safety article published in the journal *Infant*.

Ethambutol and the side effect of ocular damage

During regular review of reports to the NRLS, an incident was identified where a patient developed the severe side effect of optic nerve damage in both eyes following treatment with ethambutol for tuberculosis. This was noteworthy as it appeared the patient had been left to self-monitor for a known, rare side effect which may not be appropriate in some groups of patients, such as vulnerable patients. Additionally, the rarity of this side effect may mean the cause is not recognised by ophthalmologists. We identified one similar incident through searching the NRLS, and the Medicines and Healthcare products Regulatory Authority (MHRA) identified three similar incidents reported to them in a recent two-year period. Through our medication safety officers network we identified that less than half of a sample of acute trusts had local guidance in line with the *British National Formulary* (BNF) 72 edition: under 'Monitoring requirements' it states "visual acuity should be checked by Snellen chart before treatment with ethambutol" and "patients should be advised to discontinue therapy immediately if they develop deterioration in vision".

Ethambutol is primarily used as part of a multidrug regimen to treat tuberculosis and treatment is monitored through the nine Tuberculosis Boards. We wrote to the Tuberculosis Boards and the Royal College of Ophthalmologists (RCOphth) detailing our findings and outlining concerns about the variability in monitoring practice, reliance on patients' self-monitoring and professional awareness.

In October 2017 the RCOphth sent a statement to its members reminding

them to be alert regarding ethambutol toxicity. Public Health England is also considering supporting this action by writing to the Tuberculosis Boards and reinforcing expectations of monitoring visual acuity for patients on ethambutol.

Issues shared with NHS Digital

Over the last 12 months, the national patient safety team has worked closely with colleagues in NHS Digital to ensure an effective process is established to share concerns in relation to IT systems used by 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 that have been shared with NHS Digital recently are:

- radiology reporting errors relating to the installation of an upgrade to a picture archiving and communication system (PACS)
- failure to run task reports in a primary care IT system
- poor project management when implementing a new IT dictation system.

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
- 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 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 the 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 primary care, dental services, electronic prescribing, neonatal care and medical devices 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 MDSO web events are held jointly by the MHRA and NHS Improvement with invaluable support from the MDSO editorial team.

Web events involve sharing of recent MHRA Medical Device Alerts and Patient Safety Alerts issued by NHS Improvement. They also highlight any relevant safety issues identified through review of NRLS incident reports relating to medical devices. Circulating key information through the MDSO network encourages specialist feedback and sharing of both national and local resources to assist and enable local implementation in relation to alerts, as well as identifying potentially under-recognised safety issues. We encourage engagement with the MSO network, again both nationally and at local level, as there is substantial cross-over between these two disciplines at times.

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 come from all areas including the MDSO network, NHS Improvement and the MHRA, and also specialists from healthcare, procurement and industry. Topics during the period covered by this report have included:

- **April 2017:** Accidental Injury from amniotic hooks and K wires retained after surgery; the safe use of oxygen, the use of privacy impact statements, and the life cycle of a Field Safety Notice (FSN).
- **May 2017:** The new Patient Safety Information Management System (PSIMS); emollients containing paraffin; the Strategic Technological Assets Network (STAN); supply issues with Ommaya reservoirs.
- **June 2017:** Drug error reduction software (DERS) survey to gauge a national picture for change; electronic monitoring; monitoring of safety alarms and tele-tracking; inadvertent use of silver nitrate sticks (confusion with cotton buds); review of alcohol hand gel safety ingestion risk.
- **July 2017:** Medical equipment management using GS1 barcoding; new EU regulations for medical devices; CE marking process; in-house software and the new regulations and ISO 9001:2015 (the new quality standard).

- **September 2017:** Sharing of resources to support safe transition from Luer connectors to NRFit; an update on syringe and associated consumables; Luer fittings on medical devices.

The national networks are supported by the MHRA MSO and MDSO forum which is a website where members can develop new themes, raise concerns and communicate with each other. All presentation slides are also available on the forum after each web event.

In the period covered by this report, an average 65 MDSOs and MSOs (the topics are often relevant to both groups) logged into each event and over 600 healthcare professionals registered on the forum pages.

The MDSO network is developing, with special interest groups looking at development of the MDSO role, improving the management of FSNs and resources to support new issues and alerts. In addition, we would welcome input from MDSOs working in the community, ambulance service and mental health, to broaden and expand local intelligence from MDSOs in those areas.

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; members can obtain more information from the forum or from the MDSO handbook. 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

The MSO network is a collaboration between NHS Improvement Patient Safety, the MHRA and Specialist Pharmacy Service (SPS). Through email and the discussion forum hosted by MHRA, we routinely included 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 meeting held each month. Alongside MSOs in England, invitations were sent to guest attendees from the

devolved nations (Northern Ireland, Wales and Scotland), America, Canada and Australia. Over 100 attendees regularly participate in these events, which are recorded and made available for streaming along with the presentation slides and supporting materials.

The web event 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 seek opinion and advice from 'frontline' practitioners before deciding the best way to act. MSOs have been invaluable in providing local intelligence in relation to 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 topics have included:

- **April 2017:** Experiences of a community pharmacy MSO from a large multiple; mannitol incident; an update from the Pharmaceutical Human Factors and Ergonomics Group.
- **May 2017:** Experiences of a mental health MSO; Novel Oral Anticoagulant related incident; the medicines optimisation dashboard.
- **June 2017:** Medication safety metrics; electronic prescribing and medicines administration; labelling of insulin infusions.
- **July 2017:** Specialist pharmacy services; post-partum haemorrhage and Syntometrine®; pump survey; nil-by-mouth issues for medication.
- **August 2017:** Potassium concentrated ampoules; hyperkalaemia.
- **September 2017:** Yellow card reporting; networking making stronger links to MDSOs; survey feedback on labelling.

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

On 27 September 2017, 403 MSOs were registered from organisations providing NHS-funded care in England, including acute trusts and foundation trusts (161), CCGs and other commissioners (80), 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@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.

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Appendix 1: Journal publications including review of NRLS data

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