

How the new network of NHS Medication Safety Officers and Medical Device Safety Officers are affecting patient safety

9th December 2015
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Senior Pharmacist
Patient Safety NHS E



Agenda

1. Scene setting
2. MSO and MDSO responsibilities
3. Making it safer in the NHS
4. How are MSO and MDSO affecting patient safety?

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Medication safety in the NHS

At the heart of
future NHS
challenges



of people over 70 years old take five or more medicines. With an ageing population and multiple chronic medical conditions these numbers will just keep increasing



non-elective hospital admissions
are due to medicines



of these are preventable

5 classes of medicine
account for most admissions

NSAIDs

Antiplatelets

Anticoagulants

Diuretics

Antihypertensives



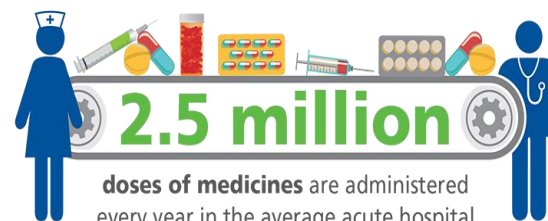
prescriptions are issued every year
in primary care



prescribing errors

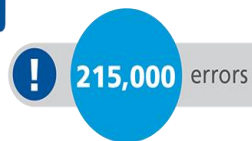


dispensing errors

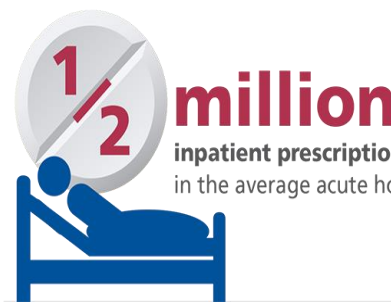


doses of medicines are administered
every year in the average acute hospital

NHS
England



errors



inpatient prescriptions every year
in the average acute hospital



prescribing errors

with 550 potentially fatal



dispensing errors



preventable deaths across all acute hospitals
are due to medicines



patients admitted to all acute hospitals
suffer from harm due to medicines

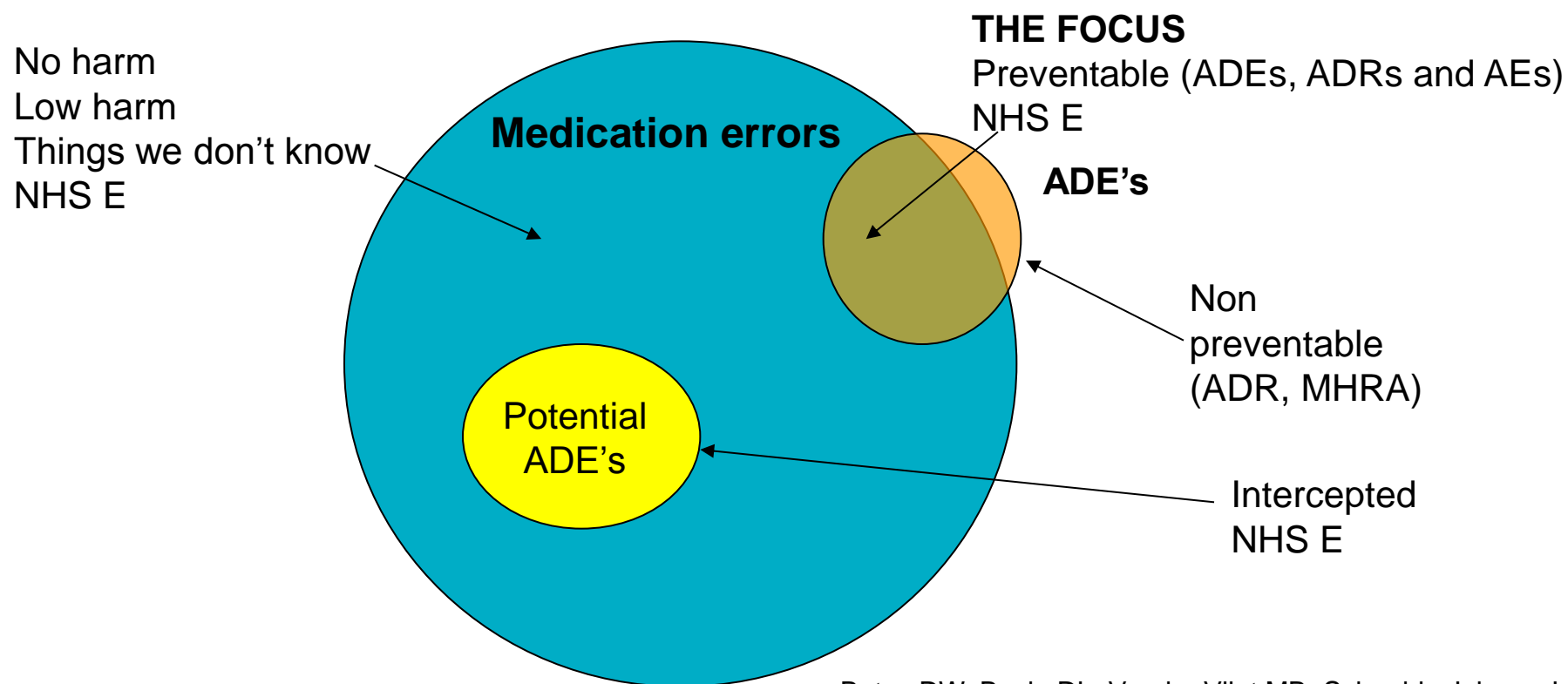
97% of medication errors reported to the NHS result in no or low patient harm

Directive 2001 - 2010/84/EU

Pharmacovigilance Under paragraph 5

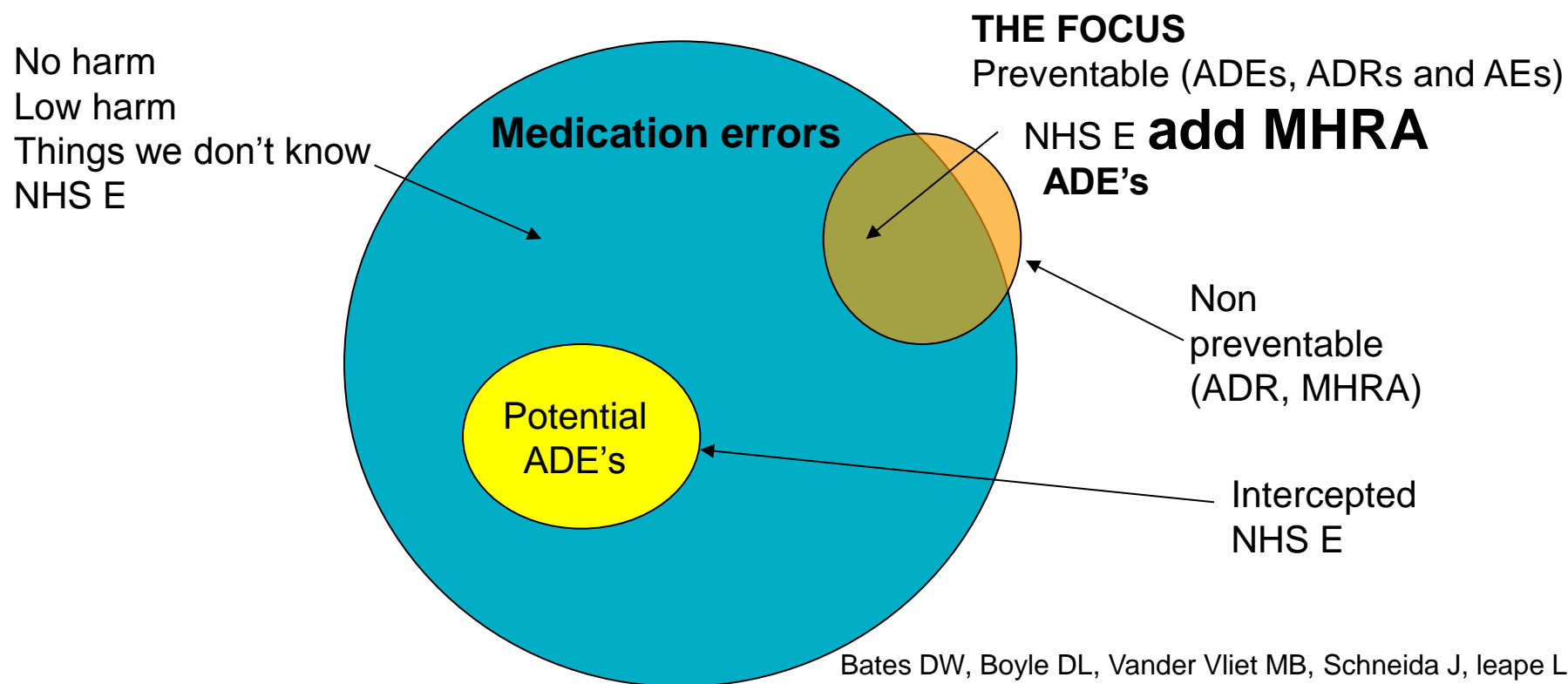
For the sake of clarity, the definition of the term ‘adverse reaction’ should be amended to ensure that it covers noxious and unintended effects resulting not only from the authorised use of a medicinal product at normal doses, but also from **medication errors** and uses outside the terms of the marketing authorisation, including the misuse and abuse of the medicinal product.

ADE's ADR's and Medication Errors



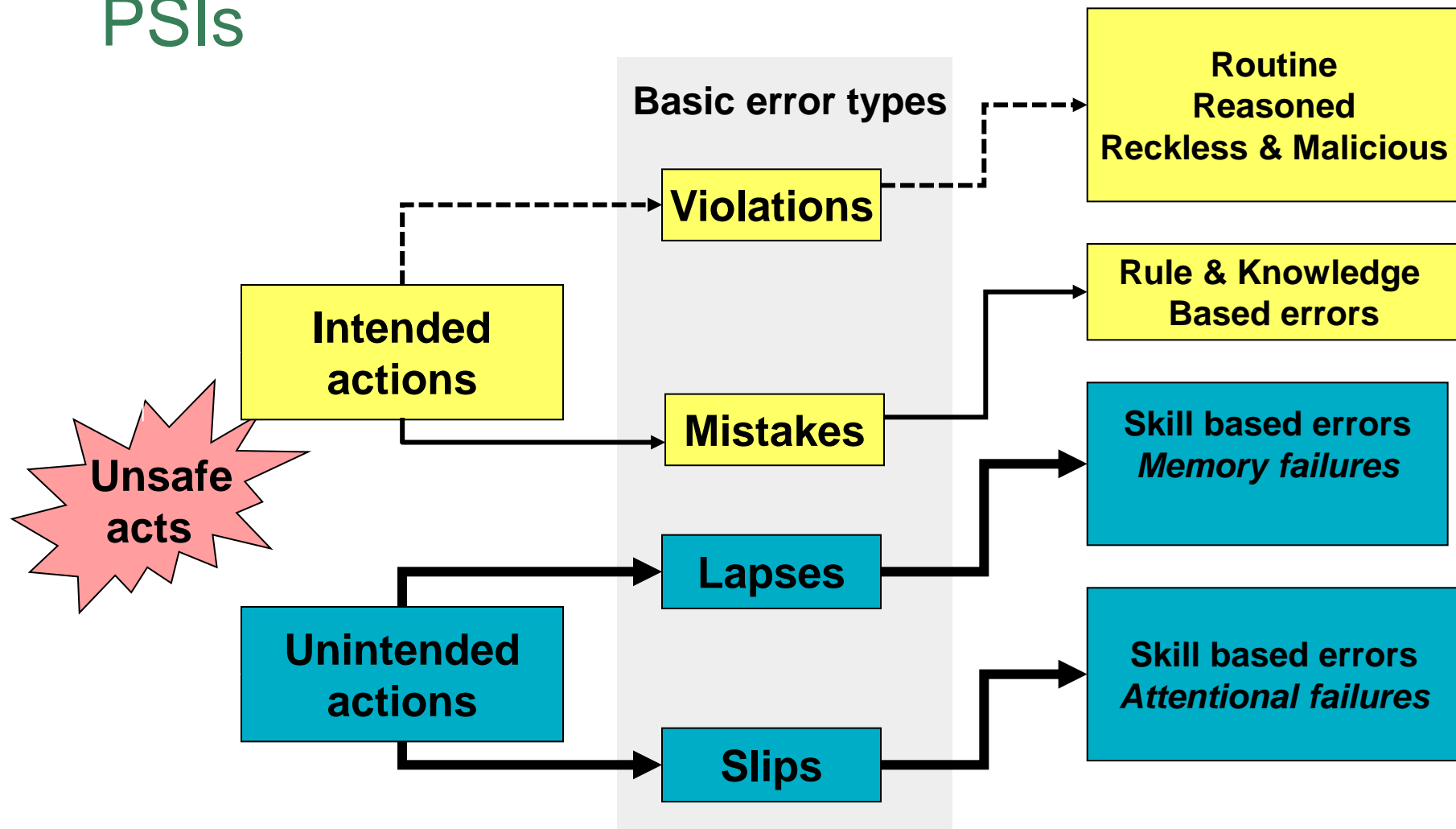
Bates DW, Boyle DL, Vander Vliet MB, Schneida J, leape L. Relationship between medication errors and adverse drug events. J. Gen. Intern. Med, 1995;10:199-205.

ADE's ADR's and Medication Errors



Bates DW, Boyle DL, Vander Vliet MB, Schneida J, leape L.
Relationship between medication errors and adverse drug
events. J. Gen. Intern. Med, 1995;10:199-205.

PSIs



Competence

Consciously incompetent

Assess
and learn
PSDA

Learn

Unconsciously incompetent

Consciously competent

Lapse

Practice

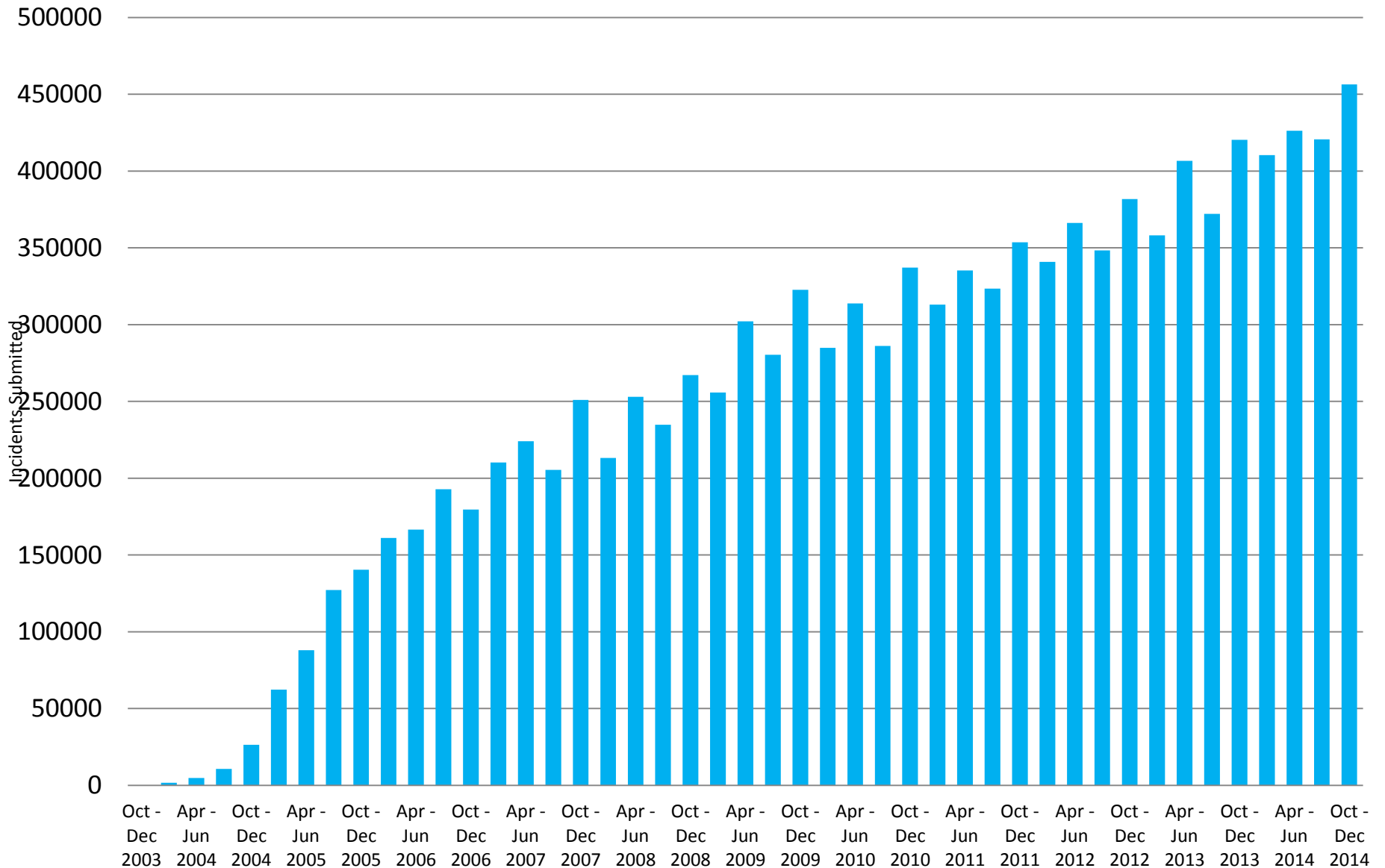
Unconsciously competent

The implications: we are all capable of error and things change

NPC. MeReC bulletin.2011;22(no1)

http://www.npc.nhs.uk/merec/mastery/mast3/resources/merec_bulletin_vol22_no1.pdf

Patient safety Incidents reported from Oct 2003 - Dec 2014

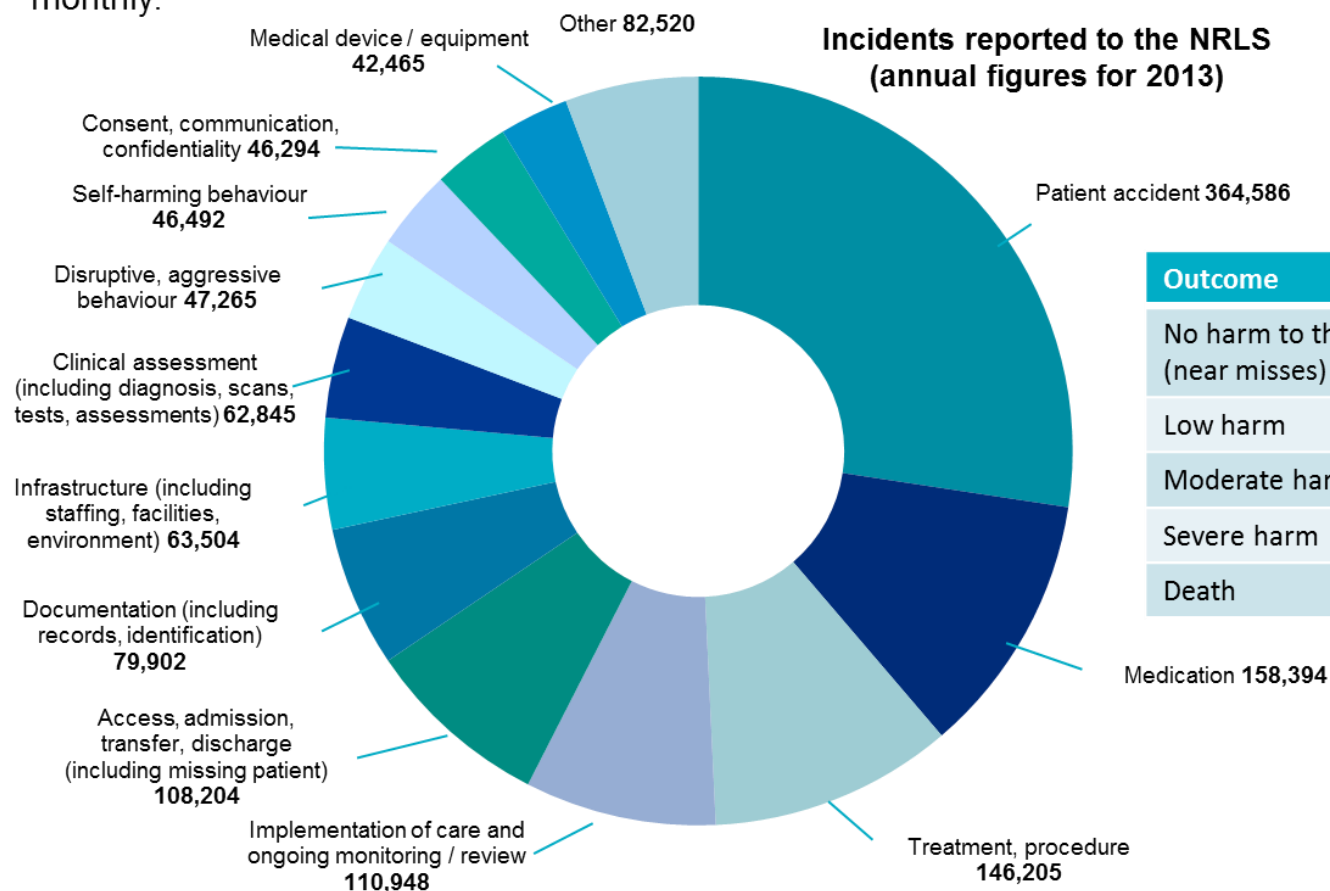


The National Reporting and Learning System

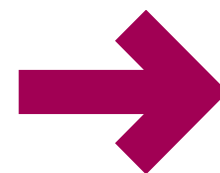
Estimates suggest that up to 10% of people may be harmed during the course of their healthcare

The NHS leads the world in incident reporting, with the National Reporting and Learning System. It has received over 9 million incident reports since late 2003, and receives over 100,000 incidents reported monthly.

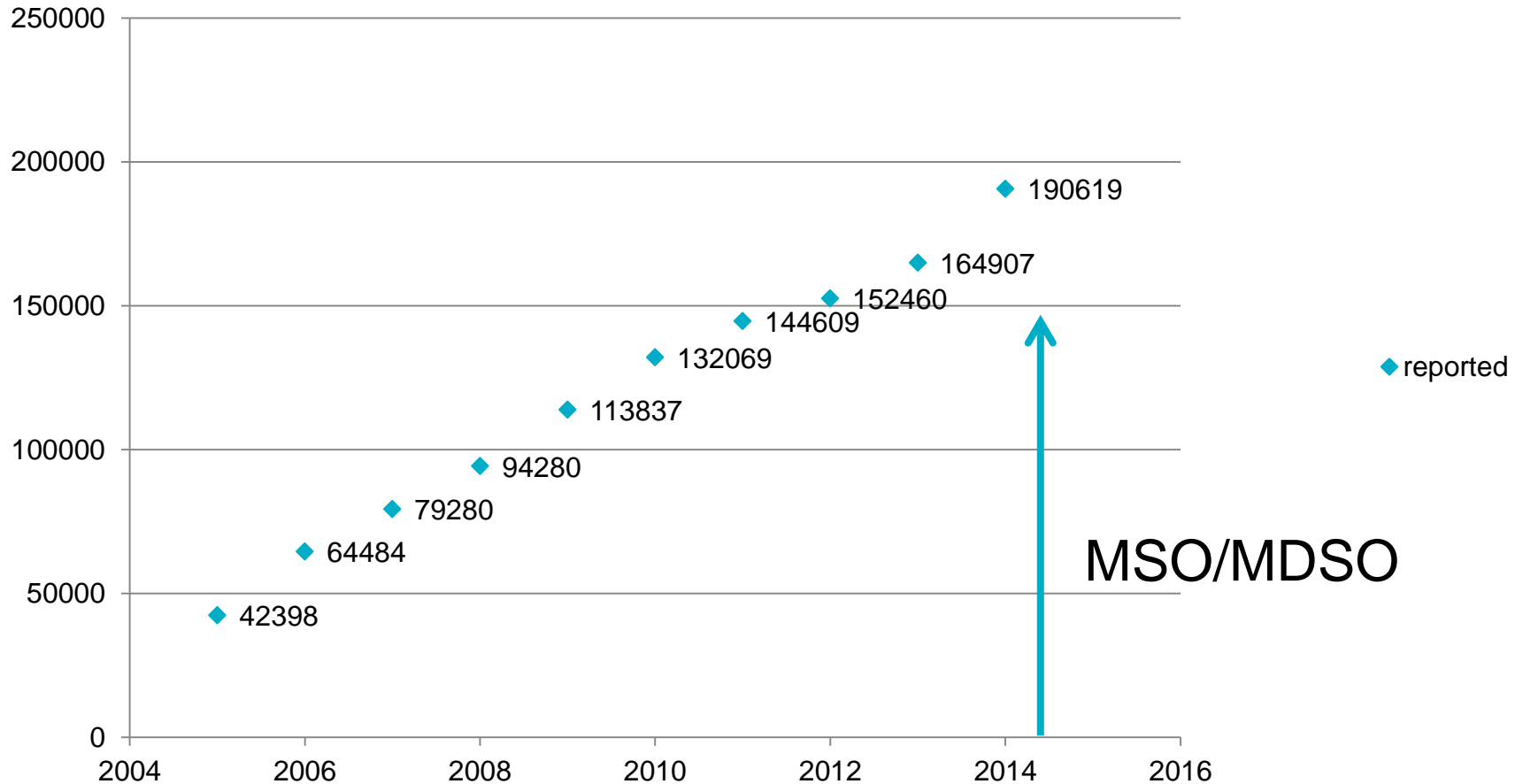
**Incidents reported to the NRLS
(annual figures for 2013)**



Outcome	Number	%
No harm to the patient (near misses)	892,525	68%
Low harm	333,982	25%
Moderate harm	82,597	6%
Severe harm	7,175	0.5%
Death	3,504	0.3%



Reported to NRLS 2005-2014




In 2014 the absolute number of medication reports to the NRLS increased more than in any previous year, representing a 15.6% increase on the year before.

New style Patient Safety Alerts (PSAs)

- **Stage One Alert: *Warning***
 - Warns organisations of emerging risk. It can be issued very quickly once a new risk has been identified to allow rapid dissemination of information
- **Stage Two Alert: *Resource***
 - Provision of resources, tools and learning materials to help mitigate risk identified in stage one
- **Stage Three Alert: *Directive***
 - Organisations are required to confirm they have implemented specific actions or solutions to mitigate the risk

Medication Safety Officer



Patient Safety Alert

Stage Three
Improving error incidence and learning
20 March 2014

Alert reference number: NHS/PSA/D/2014/005

NHS England and MHRA are working together to simplify and increase reporting and guide practice to minimise harm from medication errors by:

- sharing incident data between MHRA and NHS England reducing the need for new types of feedback from the National Reporting and Learning System at local level;
- clarifying medication safety roles and identifying key safety contacts to all national levels; and,
- setting up a National Medication Safety Network as a new forum for discussing identifying trends and actions to improve the safe use of medicines. The Network Improvement Collaboratives that will be set up during 2014.

The Yellow Card Scheme for reporting suspected adverse drug reaction remains normal.

Actions (Target date for completion 19 September 2014)

All large* healthcare providers including NHS Trusts, community pharmacy multiples, home healthcare companies and those in the independent sector should:

- 1 identify a board level director (medical or nursing supported by the chief pharmacist) or in community pharmacy and home health care, the superintendent pharmacist, to have the responsibility to oversee medication error incident reporting and learning;
- 2 identify a Medication Safety Officer (MSO) and email their contact details to the Central Alerting System (CAS) team. This person will be a member of a new National Medication Safety Network, support local medication error reporting and learning and act as the main contact for NHS England and MHRA; and,
- 3 identify an existing or new multi-professional group to regularly review medication error incident reports, improve reporting and learning and take local action to improve medication safety.

Small* healthcare providers including general practices, dental practices, community pharmacies and those in the independent sector should:

- 4 continue to report medication error incidents to the NRLS using the e-form on the NRLS website, or other methods and take action to improve reporting and medication safety locally, supported by medication safety champions in local professional committees, networks, multi-professional groups and commissioners.
- 5 identify a MSO and email their contact details to the CAS team. This person will be a member of the National Medication Safety Network, support reporting and learning and take local actions

Healthcare commissioners including Area Teams, and Clinical Commissioning Groups are invited to:

to improve medication safety. The MSO can also use learning to influence policy, planning and commissioning as part of clinical governance in the commissioning organisation; and,

regularly review information from the NRLS and the MHRA to support improvements in reporting and learning and to take local action to improve medication safety. This should be done by working with medication safety champions in local professional committees and networks, and with a new or existing multi-professional group.

Supporting information

*More detailed information to support the implementation of this guidance is available at:
www.england.nhs.uk/patientsafety/PSA

Patient Safety | Domain 5
www.england.nhs.uk/patientsafety

Contact NHS
Contact MH

Publications Gateway Reference 01322

Actions (Target date for completion 19 September 2014)

All large* healthcare providers including NHS Trusts, community pharmacy multiples, home healthcare companies and those in the independent sector should:

- 1 identify a board level director (medical or nursing supported by the chief pharmacist) or in community pharmacy and home health care, the superintendent pharmacist, to have the responsibility to oversee medication error incident reporting and learning;
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Supporting information

*More detailed information to support the implementation of this guidance is available at:
www.england.nhs.uk/patientsafety/PSA

Medical Device Safety Officer



Patient Safety Alert

Stage Three: Directive
Improving medical device incident reporting and learning
20 March 2014

Alert reference number: NHS/PSA/D/2014/006 Alert stage: Three - Directive

NHS England and the MHRA are working together to simplify and increase reporting, improve data learning and guide practice to minimise harm from medical device incidents by:

- sharing incident data between the MHRA and NHS England, reducing the need for duplicate staff by developing a new integrated National Learning and Reporting System (NRLS) which is becoming operational. Separate reporting to the MHRA will then no longer be necessary;
- giving new types of feedback from the NRLS and the MHRA to improve learning at local level;
- clarifying medical device safety roles and identifying key safety contacts to allow better communication and national level; and,
- setting up a National Medical Devices Safety Network as a new forum for discussing potential issues, identifying trends and actions to improve the safe use of medical devices. The network Patient Safety Improvement Collaboratives that will be set up during 2014.

Continue to report separately to the MHRA and the NRLS until the integrated reporting system is in place. Another patient safety alert will then be issued.

Actions (Target date for completion 19 September 2014)

All large* healthcare provider organisations including NHS trusts, community pharmacy multiples, home healthcare companies and those in the independent sector should:

- 1 identify a board level director (medical or nursing supported by a senior healthcare professional) or in community pharmacy, or home health care, a senior manager (for example a Superintendent Pharmacist) to have the responsibility to oversee medical device incident reporting and learning;
- 2 identify a Medical Devices Safety Officer (MDSO) and email their contact details to the Central Alerting System (CAS) team. This person will support local medical device incident reporting and learning, act as the main contact for NHS England and the MHRA and medical device manufacturers and be a member of the new National Medical Devices Safety Network; and,
- 3 identify an existing or new multi-professional group to regularly review medical device incident reports, improve reporting and learning and take local action to improve the safety of medical devices.

Small* healthcare provider organisations including general practices, dental practices, community pharmacies and those in the independent sector should:

- 4 continue to report incidents involving medical devices to the NRLS using the e-form on the NRLS website, or other methods. Report also to the MHRA's online reporting system. Take action to improve reporting and learning locally, supported by medical device safety champions in local professional committees, networks, multi-professional committees and commissioners.
- 5 identify a Medical Devices Safety Officer (MDSO) and email their contact details to the CAS team. The MDSO will be a member of the National Medical Device Safety Network, support reporting and learning and take local actions to improve medical devices safety. The MDSO can use learning to influence policy, planning and commissioning as part of clinical governance in the commissioning organisation; and,
- 6 regularly review information from the NRLS and the MHRA to support improvements in reporting and learning and to take local action to improve the safety of medical devices. This should be done by working with medical devices safety champions in local professional committees and networks, and with a new or existing multi-professional group.

*Supporting information: www.nhs.uk/contact-nhs-england/ Contact NHS England: patientsafety@nhs.uk Contact MHRA: ac@mhra.gov.uk

Patient Safety | Domain 5
www.england.nhs.uk/patientsafety

Actions (Target date for completion 19 September 2014)



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Supporting documents





Patient Safety Alert

Stage Three
*Improving medical device
error incident reporting
and learning*
20 March 2014

Supporting information

Alert reference number: NHS/PSA/D/2014/005

Alert stage: Three - Directive



Patient Safety Alert

Stage Three: Directive
*Improving medical device
incident reporting
and learning*
20 March 2014

Supporting information

Alert reference number: NHS/PSA/D/2014/006

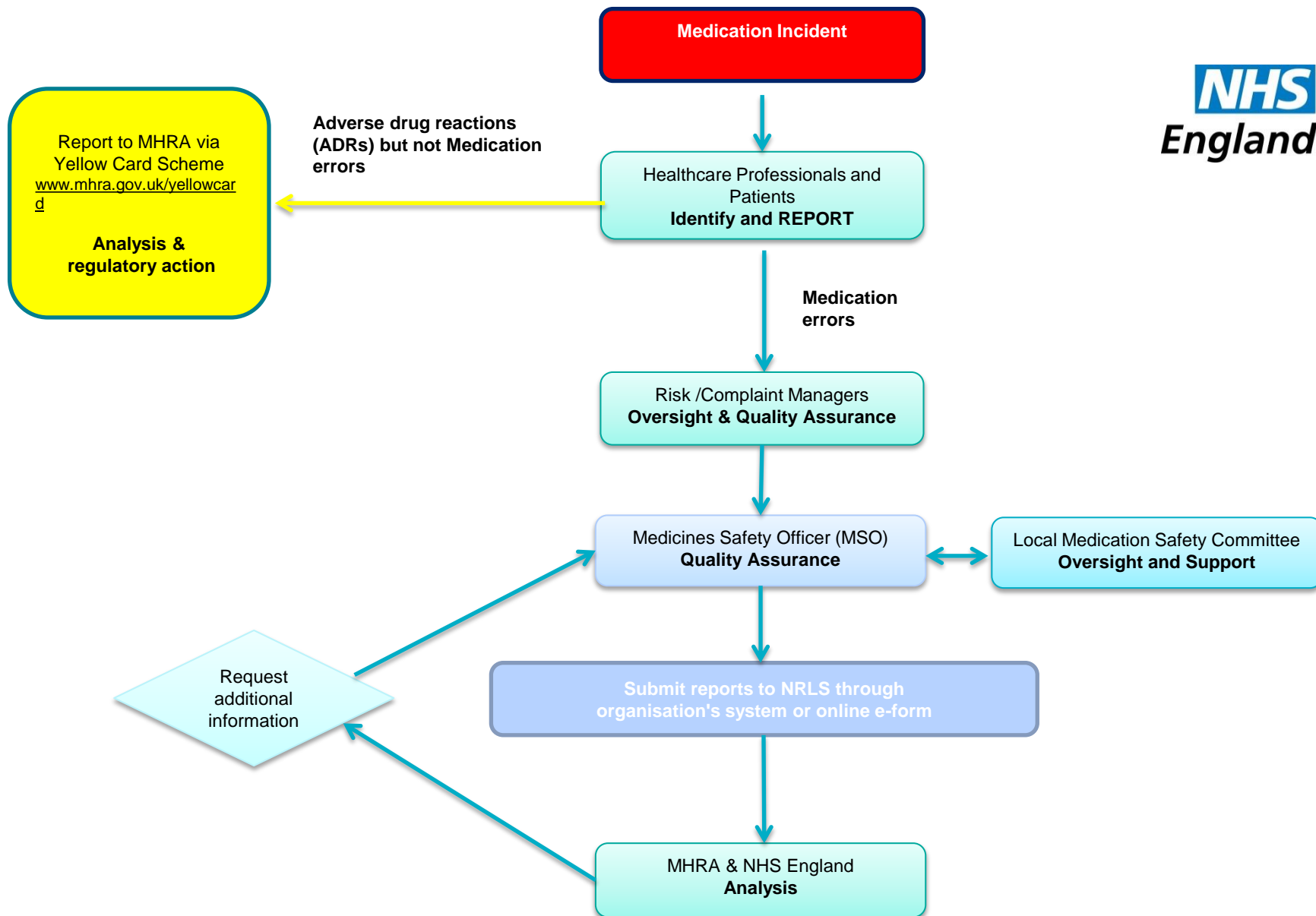
Alert stage: Three - Directive

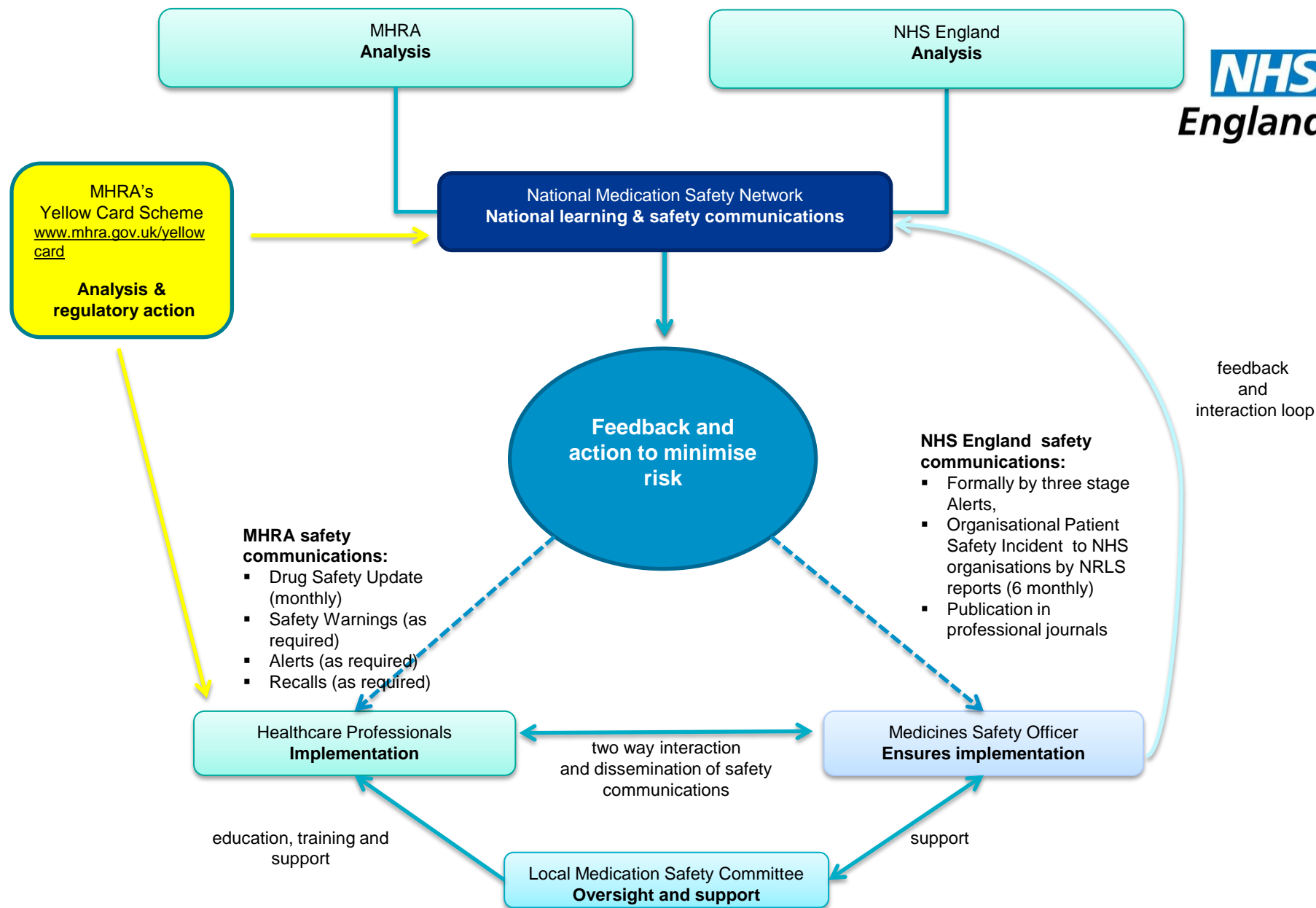
Which organisations?

As of 2nd November 2015

Guests: + 60

Row Labels	Count of Name
CCG	75
Community Interest Company	8
Community pharmacy sector	21
Cosmetic Surgery	1
Independent	1
Mental Health	1
NHS Acute Large	41
NHS Acute Medium	46
NHS Acute Small	25
NHS Acute Specialist	18
NHS Acute Teaching	30
NHS Ambulance Trust	9
NHS Community Trusts	16
NHS England Area Team	14
NHS Mental Health Trust	51
Other Independent Sector	20
Social Care Enterprise	1
Grand Total	378

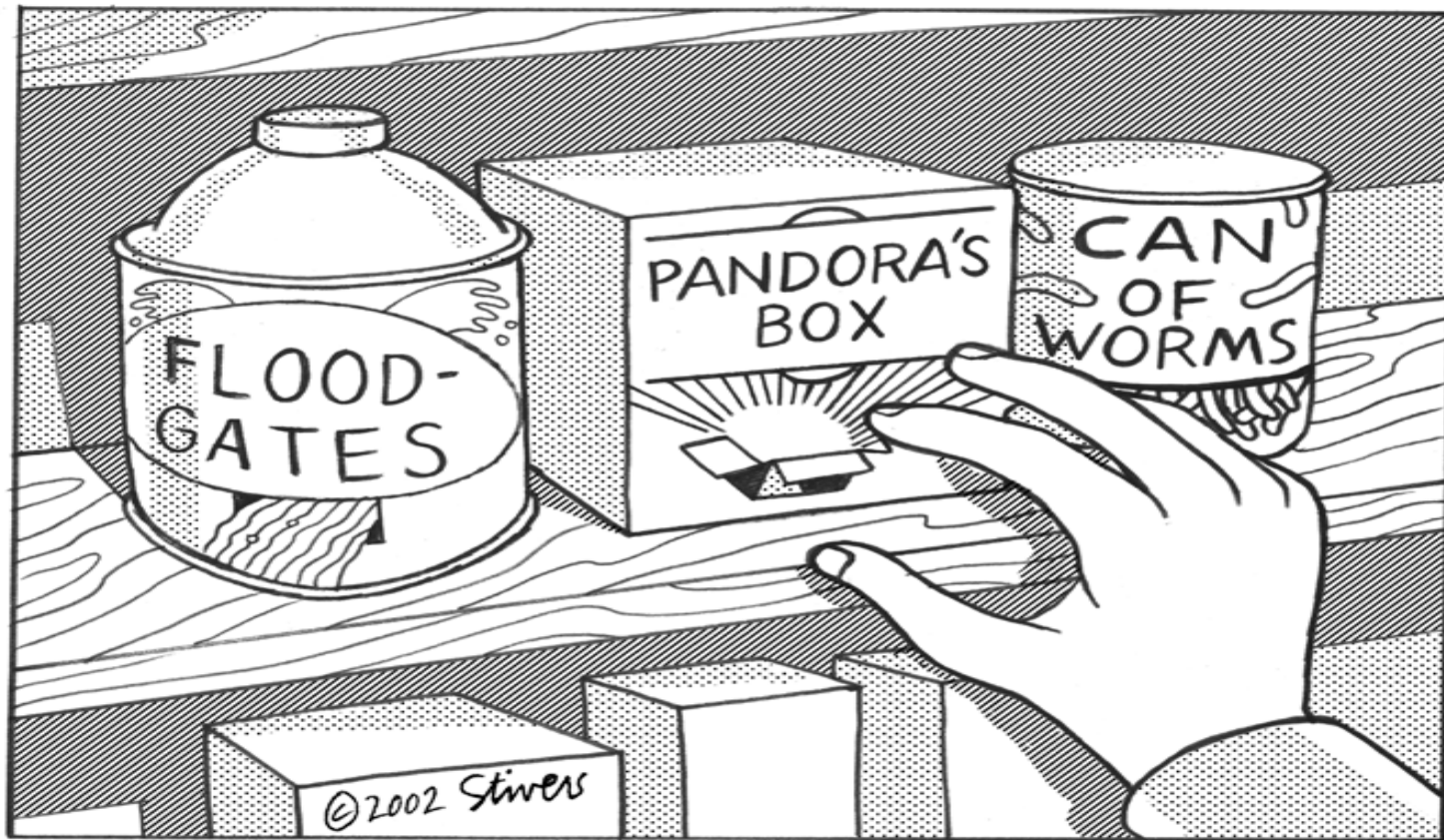




Agenda

1. Scene setting
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4. How are MSO and MDSO affecting patient safety?

Beware the detail



MSO responsibilities

Responsibilities should include the following:

- i. active membership of the National Medication Safety Network;
- ii. improving reporting and learning of medication error incidents in the organisation;
- iii. managing medication incident reporting in the organisation. This may entail reviewing all medication incident reports to ensure data quality for local and national learning and where necessary to investigate and find additional information from reporters. Also, to authorise the release of medication error reports to the NRLS each week;
- iv. receiving and responding to requests for more information about medication error incident reports from the Patient Safety Domain in NHS England and the MHRA;
- v. work as a member of the medication safety committee to deliver the responsibilities listed in 7.1.4; and,
- vi. supporting the dissemination of medication safety communications from NHS England and the MHRA throughout the organisation.

MSO responsibilities

Committee responsibilities should include the following:

- i. improving reporting and learning of medication error incidents in the organisation;
- ii. analysing incident data, audit and other data to identify, prioritise and address medication risks to minimise harm to patients;
- iii. identifying, developing and promoting best practice for medication safety. This will include supporting the implementation of external patient safety guidance from NHS England, MHRA, NICE and other organisations - implementation will require coordination and support for process and system changes to reduce the likelihood of serious medication errors occurring and recurring, providing regular feedback to clinical staff, patient care areas and hospital committees on medication risks and planned action to minimise these risks;
- iv. coordinating education and training support to improve the quality of medication error incident reports and safe medication practices; and,
- v. assisting in development and review of medication-use policies and procedures.

MDSO responsibilities

Role responsibilities should include:

- i. active membership of the National Medical Devices Safety Network;
- ii. improve reporting of and learning from medical devices incidents in the organisation;
- iii. manage medical device incident reporting in the organisation, review all medical devices incident reports to ensure data quality for local and national learning, where necessary investigate and get additional information from reporters;
- iv. make sure that medical device incidents are sent to the NRLS as soon as possible and at least every week;
- v. receive and respond to requests for more information from the Patient Safety Domain in NHS England and the MHRA about medical device incident reports;
- vi. work as a member of the medical devices safety committee to deliver the responsibilities listed in 9.1.4;
- vii. act as an additional senior point of contact for manufacturers and support local actions on Field Safety Notices; and,
- viii. improve reporting of medical devices incidents and support the dissemination of medical devices safety communications from NHS England and the MHRA throughout the organisation.

MDSO responsibilities

Committee responsibilities should include the following:

- i. improving reporting of and learning from medical device incidents in the organisation;
- ii. analysing of incident data, audit and other data to identify, prioritise and address medical devices risks to minimise harm to patients;
- iii. identifying, developing and promoting best practice for medical devices safety - this will include supporting the implementation of external patient safety guidance from NHS England, MHRA, NICE and other organisations. Implementation will need coordination and support for process and system changes to reduce the likelihood of serious medical device incidents occurring or reoccurring;
- iv. providing regular feedback to clinical staff, patient care areas and hospital committees on the risks of medical devices and planned action to minimise these risks;
- v. coordinating education and training support to improve the quality of medical devices error incident reports and safe medical devices practices; and,
- vi. assisting in the development and review of medical device use policies and procedures.

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National Patient Safety Agency

10 years of Medication 2002-2012
Devices 2010-2012


Medication

- 45 Alerts, Rapid Response Reports
- Signals
- 6 design guides
- Medication Safety updates

New style Patient Safety Alerts (PSAs)

Classification: Official

NHS
England

 **Patient Safety Alert**

Stage One: Warning
Risk of death or severe harm due to inadvertent injection of skin preparation solution

26 May 2015

Alert reference number: NHS/PSA/N/2015/005
Alert stage: One - Warning

The potential for inadvertent injection of solutions intended for topical use has been identified in the UK [1] and internationally [2]. Past errors usually occurred because skin cleansing antiseptic solutions and medication intended for injection had been placed proximally in 'open systems' such as gallipots. An Alert was issued in England in 2007 [3] stipulating that injections must be drawn up from the source bottle or ampoule directly into syringes that are labelled and checked prior to administration and that 'open systems' should never be used to contain medication prior to injection. This advice was intended not only to reduce the risk of skin preparation being injected inadvertently, but also to minimise the risk of the wrong injectable medication being selected. The particular risk of inadvertent injection of skin preparation was subsequently reinforced in 2010 [4].

However, errors are still being reported where open systems have been used. NHS England has identified three incidents involving inadvertent injection of skin antiseptic solutions since 2012, and one additional near miss. Two incidents involved severe harm from confusion between 2% Chlorhexidine and x-ray contrast media in circumstances where both substances were in unlabelled gallipots (one during a lower limb angiogram and resulting in leg amputation, and one during a pacemaker insertion resulting in cardiac arrest and resuscitation). The third incident involved a patient undertaking renal dialysis with assistance from healthcare staff; the line was flushed with Chlorhexidine from a gallipot instead of the intended saline solution and the patient became unwell but apparently recovered. The near miss also involved Chlorhexidine and x-ray contrast medium, and occurred despite the skin preparation being on a separate trolley.

The settings where these incidents occurred suggest that the practice of preparing medication intended for injection using gallipots may have persisted in some areas carrying out specific interventional procedures. We are working with relevant royal colleges and specialist professional organisations to understand the reasons for this, and to understand if any additional advice is required for specific procedures.

In the interim, organisations need to identify if the use of injectable medication in open systems has persisted in their organisations, and take all appropriate local actions to improve safety, including ensuring that any skin preparation solutions are removed from the environment before an invasive procedure begins.

Actions

Who:
All organisations providing NHS-funded care where skin preparation agents are used prior to an invasive procedure.

When:
As soon as possible but no later than 7 July 2015.

- 1 Identify if invasive procedures involving injection alongside skin preparation are taking place in circumstances where unintended injection of skin preparation solution has or could occur.
- 2 Consider if immediate action needs to be taken locally, and ensure that an action plan to reduce the risk of incidents occurring is underway if required.
- 3 Circulate this alert to all relevant staff.
- 4 Share any information on areas of clinical practice where use of open systems for injection appears to have persisted (and why), any learning from local investigations, and any locally developed good practice resources by emailing: patient.safetyenquiries@nhs.net



Patient Safety | Domain 5
www.england.nhs.uk/patientsafety

Contact us: patientsafety.enquiries@nhs.net

Publications Gateway Reference: 03484 © NHS England May 2015

- 1 Identify if invasive procedures involving injection alongside skin preparation are taking place in circumstances where unintended injection of skin preparation solution has or could occur.
- 2 Consider if immediate action needs to be taken locally, and ensure that an action plan to reduce the risk of incidents occurring is underway if required.
- 3 Circulate this alert to all relevant staff.
- 4 Share any information on areas of clinical practice where use of open systems for injection appears to have persisted (and why), any learning from local investigations, and any locally developed good practice resources by emailing: patient.safetyenquiries@nhs.net

New style Patient Safety Alerts (PSAs)



Patient Safety Alert

Stage One: Warning
Minimising risks of omitted and delayed medicines for patients receiving homecare services
10 April 2014

Alert reference number: NHS/PSA/W/2014/007
Alert stage: One - Warning

Medicine homecare services are commissioned by the NHS and are predominately provided by the commercial sector, delivering specialist medicines and medical devices, and nursing services needed to administer them, typically as packages of care. A wide range of treatments are provided including parenteral nutrition, chemotherapy, antibiotics, growth hormone and specialist treatments for HIV, cystic fibrosis and rheumatoid arthritis.

Medicine homecare services are largely commissioned by NHS Trusts. These services have expanded very rapidly in recent years and were the subject of a Department of Health report 'Homecare Medicines - Towards a Vision for the Future' issued in November 2011. A major home healthcare service provider withdrew from the market late in 2013. This caused transitional issues as patients were transferred to new providers and has increased pressure on existing suppliers. The number of reports of failure to supply homecare medicines and products on time has increased significantly. This has in turn resulted in an increased risk to patients of medicine doses being omitted or delayed.

In response to these problems the homecare industry is taking action to improve services, and some providers have suspended accepting new high risk patients until necessary service improvements have been made.

Patient safety is a primary concern, and can be compromised when medicine doses are omitted or delayed. Healthcare organisations that commission homecare services (usually NHS trusts) have a responsibility to ensure the safety of patients who receive homecare services. This may include assessing the current capability of a selected medicine homecare service before new patients or new services are commenced. Also ensuring that existing homecare patients are aware of how and when to contact them in the event that supplies of medicine/products run low after an expected delivery has not occurred and they have been unable to contact the homecare provider. Procedures to ensure alternative methods of supply will be required to support these patients in these circumstances.

Such interim measures will need to be agreed with all relevant clinical staff and should include control measures to ensure patient safety is not further compromised by the provision of duplicate medicine supplies by multiple agencies. It is also important for NHS organisations to minimise requests to clinical homecare companies for duplicate information already in the NHS organisation. A register of patients on homecare may be available in hospital pharmacy departments from records of prescriptions issued to homecare providers.

Actions

Who: All healthcare organisations that commission clinical homecare services

When: As soon as possible but no later than 9 May 2014

- 1 Establish if medicine homecare services are used within your organisation and if incidents of omitted and delayed medicines have occurred.
- 2 Consider if immediate action needs to be taken locally and develop an action plan, if required, to reduce the risk and the potential risk to patients.
- 3 Disseminate this alert to all medical, nursing, pharmacy and other staff who are involved in the care of patients receiving medicine homecare services.
- 4 Report relevant patient safety incidents, including those reported to you by patients, to the **National Reporting and Learning System**. Include in the report the term 'medicine homecare service' in the text description of the incident to aid analysis.
- 5 Share any learning from local investigations or locally developed good practice resources by emailing: patientsafety.enquiries@nhs.net.

Supporting Information
More detailed information to support the implementation of this alert is available at: www.england.nhs.uk/patientsafety/psa

Patient Safety | Domain 5
www.england.nhs.uk/patientsafety

Contact us: patientsafety.enquiries@nhs.net
Sign up for regular updates: www.england.nhs.uk/patientsafety

Publications Gateway Reference: 01491
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- 1 Establish if medicine homecare services are used within your organisation and if incidents of omitted and delayed medicines have occurred.
- 2 Consider if immediate action needs to be taken locally and develop an action plan, if required, to reduce the risk and the potential risk to patients.
- 3 Disseminate this alert to all medical, nursing, pharmacy and other staff who are involved in the care of patients receiving medicine homecare services.
- 4 Report relevant patient safety incidents, including those reported to you by patients, to the **National Reporting and Learning System**. Include in the report the term 'medicine homecare service' in the text description of the incident to aid analysis.
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New style Patient Safety Alerts (PSAs)



Patient Safety Alert

Stage One: Warning

Harm from using Low Molecular Weight Heparins when contraindicated

19 January 2015

Alert reference number: NHS/PSAW/2015/001

Alert stage: One - Warning

Low Molecular Weight Heparins (LMWHs) are frequently used for treatment and for prophylaxis of a variety of thromboembolic conditions. In the 26 months up to March 2014 the National Reporting and Learning System (NRLS) received 75 medication incidents where LMWHs were used despite known contraindications. Incidents included use of LMWH for either treatment or prophylaxis. Of these, 16 incidents resulted in severe harm or death, 29 involved inappropriately co-prescribed medication, 16 where there was concomitant bleeding, 11 failures to discontinue LMWH and 19 describing a range of other contraindications.

Although there are important benefits from the use of LMWHs, it is vital to assess each patient individually as to whether the benefits outweigh the risks. It is apparent from these incidents that there were missed opportunities to appropriately risk assess the patient for pharmacological or clinical contraindications to the use of LMWHs.

There can be various circumstances when the use of LMWHs may be contraindicated. These can include but are not limited to: active bleeding; acquired bleeding disorder (such as acute liver failure); concurrent use of anticoagulants known to increase risk of bleeding; concurrent use of anti-platelets and other interacting medicines; or, lumbar puncture/epidural/spinal anaesthesia within the previous four hours, or expected within the next 12 hours.^{1,2}

Examples of NRLS incidents read:

"Patient prescribed and given dalteparin with known head injury prior to consultant review; extensive head injury and therefore contraindication. Patient went on to develop a large subdural haematoma secondary to a slow bleed."





"Patient admitted on warfarin, co-prescribed enoxaparin, INR 3.6 on admission but not checked regularly thereafter, and on clarithromycin. Patient became unwell, (INR 10) bilateral subdural found five days later. Entered a phase of prolonged seizures and subsequently died."

Consideration of contraindications is a prominent feature of available local and national guidance for prescribing and administering LMWHs. This alert aims to reinforce the need for reliable systems to ensure that this always occurs.

Actions

Who: All hospitals and community services providing NHS funded care where Low Molecular Weight Heparins are prescribed, dispensed or administered.

When: To commence immediately and be completed by 2 March 2015

-  Establish if incidents have occurred, or could occur, in your organisation where Low Molecular Weight Heparins have been used despite a known contraindication.
-  Consider if immediate action needs to be taken locally and ensure that an action plan is underway, if required, to reduce the risk of further incidents occurring.
-  Disseminate this alert to all medical, nursing, pharmacy and other staff who are involved in the prescribing, dispensing and administering of Low Molecular Weight Heparins.
-  Share any learning from local investigations or locally developed good practice resources by emailing ENGLAND.Medication-Safety@nhs.net.



Establish if incidents have occurred, or could occur, in your organisation where Low Molecular Weight Heparins have been used despite a known contraindication.



Consider if immediate action needs to be taken locally and ensure that an action plan is underway, if required, to reduce the risk of further incidents occurring.



Disseminate this alert to all medical, nursing, pharmacy and other staff who are involved in the prescribing, dispensing and administering of Low Molecular Weight Heparins.



Share any learning from local investigations or locally developed good practice resources by emailing ENGLAND.Medication-Safety@nhs.net.

New style Patient Safety Alerts (PSAs)



Patient Safety Alert

Stage One: Warning

Risk of distress and death from inappropriate doses of naloxone in patients on long-term opioid/opiate treatment

20 November 2014

Alert reference number: NHS/PSA/N/2014/016

Alert stage: One - Warning

- Naloxone is an opioid/opiate antagonist licensed for use in:
- complete or partial reversal of central nervous system depression and especially respiratory depression, caused by natural or synthetic opioids; and
 - treatment of suspected acute opioid overdose or intoxication.

Naloxone must be given with great caution to patients who have received longer-term opioid/opiate treatment for pain control or who are physically dependent on opioids/opiates. Use of naloxone in patients where it is not indicated, or in larger than recommended doses, can cause a rapid reversal of the physiological effects for pain control, leading to intense pain and distress, and an increase in sympathetic nervous stimulation and cytokine release precipitating an acute withdrawal syndrome. Hypertension, cardiac arrhythmias, pulmonary oedema and cardiac arrest may result from inappropriate doses of naloxone being used for these types of patients.

The British National Formulary (BNF)⁽¹⁾ recommends a dose range to reverse acute opioid/opiate overdose in adults by intravenous injection of naloxone of 400 micrograms to 2mg. If there is no response, the dose is to be repeated at intervals of two to three minutes to a maximum of 10mg.

The BNF highlights that **doses used in acute opioid/opiate overdose may NOT be appropriate for the management of opioid/opiate-induced respiratory depression and sedation in those receiving palliative care and in chronic opioid/opiate use.** The recommended dose for adults in post-operative respiratory depression and for palliative care and chronic opioid/opiate use by intravenous injection is 100 to 200 micrograms (1.5 to 3 micrograms/kg). If the response is inadequate, give subsequent dose of 100 micrograms every two minutes. The naloxone doses in the BNF may differ from those in product literature. Even where doses are given as recommended, there is still a need for careful monitoring of vital observations and maintaining or restoring pain relief.

NHS England has received details of three patient safety incidents describing failure to follow the BNF guidance, including two incidents that resulted in death. Because this risk appears under-recognised, there may be significant under-reporting.

Additional safeguards that have been locally implemented include raising awareness of the risk of inappropriate doses of naloxone, the use of lower doses of naloxone in clinical protocols and resuscitation drug trays, teaching correct use of naloxone in annual cardiopulmonary resuscitation training sessions, and providing guidance on clinical monitoring and access to specialist pain relief advice after naloxone administration.

Actions

Who: All organisations providing NHS funded care where naloxone is prescribed, dispensed and/or administered.

When: As soon as possible but no later than 22 December 2014.

- 1 Establish if incidents involving inappropriate use of naloxone have occurred or have the potential to occur in your organisation.
- 2 Consider if immediate action needs to be taken locally and ensure that an action plan is underway, if required, to reduce the risk of further incidents occurring.
- 3 Disseminate this Alert to clinical staff who prescribe, dispense or administer naloxone injection.
- 4 Share any learning from local investigations or locally developed good practice resources by emailing: England.medication-safety@nhs.net

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Publications Gateway Reference: 02531

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Establish if incidents involving inappropriate use of naloxone have occurred or have the potential to occur in your organisation.



Consider if immediate action needs to be taken locally and ensure that an action plan is underway, if required, to reduce the risk of further incidents occurring.




Disseminate this Alert to clinical staff who prescribe, dispense or administer naloxone injection.



Share any learning from local investigations or locally developed good practice resources by emailing: England.medication-safety@nhs.net

New style Patient Safety Alerts (PSAs)




Patient Safety Alert

Alert reference number: NHS/PSA/2015/009
Alert stage: One - Warning

Further supporting information

- Following distribution of the recent inappropriate doses of naloxone in patients, there has been a period of helpful dialogue between the original alert. This document is a clarification on the use of naloxone.
- The alert noted that incidents involving excessive doses of naloxone in patients and under-reported; information received in the past may be higher.
- A number of naloxone practice resources are available on the Safety First website: <http://www.patientsafetyfirst.nhs.uk>
- Further clarification has been requested to be used for a patient following a management of reduced consciousness (some palliative care patients). We can provide this for clinicians. For example, there is a route of use; and there are some dilutions in the manufacturers' individual Patient Care Formulary (it is in all of these clinical scenarios).
- UK Medicines Information (UKMI) has advised that naloxone should be used in a patient with chronic pain or in end of life care, the safety of all patients depends on staff who understand that doses that can be life-saving for one patient group and set of circumstances, can be life-threatening for another patient group.

Official



Patient Safety Alert

Alert reference number: NHS/PSA/Re/2015/009
Alert stage: Two - Resources

Stage Two: Resources
Support to minimise the risk of distress and death from inappropriate doses of naloxone
26 October 2015

Actions

Who: All organisations providing NHS funded care where naloxone is prescribed, dispensed and/or administered

When: As soon as possible, and in parallel with any changes to naloxone use that are being considered in response to legislative change, but no later than 26 April 2016

- Bring this Alert and linked resources to the attention of those in the organisation with responsibilities for local training, procedures and protocols for naloxone use
- Use the resources in this Alert and any other relevant local or national resources to review, and if necessary revise, local training, procedures and protocols for naloxone use
- Commence implementation of procedures and practice compliant with these resources within cycles of continuous improvement including consideration of teamwork and training, human factors and cultural aspects of compliance.
- Share locally developed resources and local learning via the Medication Safety Officers network or by emailing: England.medication-safety@nhs.net

These resources emphasise that there should be no conflict between the needs of patients with drug misuse and dependence who overdose, and those with chronic pain or in end of life care; the safety of all patients depends on staff who understand that doses that can be life-saving for one patient group and set of circumstances, can be life-threatening for another patient group.

Whilst these resources focus primarily on the circumstances where naloxone use is - or is not - appropriate, and dosing schedules for different patient groups, healthcare organisations should use these resources in the wider context of the whole patient pathway. This includes consideration of steps that can be taken to avoid the need for naloxone, and recognition that frontline staff need easy access to local protocols and local expertise for managing withdrawal, lost pain control, or other effects.





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Publications Gateway Reference: 04267

Patient Safety | Domain 5
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Contact us: patientsafety.enquiries@nhs.net

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-  Bring this Alert and linked resources to the attention of those in the organisation with responsibilities for local training, procedures and protocols for naloxone use
-  Use the resources in this Alert and any other relevant local or national resources to review, and if necessary revise, local training, procedures and protocols for naloxone use
-  Commence implementation of procedures and practice compliant with these resources within cycles of continuous improvement including consideration of teamwork and training, human factors and cultural aspects of compliance.
-  Share locally developed resources and local learning via the Medication Safety Officers network or by emailing: England.medication-safety@nhs.net

New style Patient Safety Alerts (PSAs)



Patient Safety Alert

Stage One: Warning

Risk of death or serious harm from accidental ingestion of potassium permanganate preparations

22 December 2014

Alert reference number: NHS/PSA/M/2014/18

Alert stage: One - Warning

Potassium permanganate is used in wound care because of its antiseptic and antimicrobial properties. It is available as a solution for further dilution and as a tablet preparation, which is dissolved in water and further diluted to a specified concentration. It is for external use only and can be fatal if ingested orally due to local inflammatory reactions that block the airways or cause perforations of the gastrointestinal tract. It can also cause death through toxicity and organ failure[1,2]. NHS England has been informed of an incident where a patient died after ingesting potassium permanganate. Whilst this death remains under investigation, analysis of the National Reporting and Learning System (NRLS) has identified 43 incidents in the past three and a half years where potassium permanganate tablets have been ingested orally by patients. Although none of these incidents were reported as causing severe harm or death, any later effect on the patient was not always clearly described.

An example incident reads:

Patient prescribed potassium permanganate for soaking of legs, tablet was diluted, but I did not communicate to my fellow colleague that it was not for oral consumption. Patient drank approximately 120-150mls of diluted preparation.

Although packaging clearly states potassium permanganate should not be swallowed, it is very unusual for a topical preparation to come in a tablet form, and therefore some staff, patients and carers may accidentally treat it as an oral preparation. The risk of error appears to increase when the term 'potassium permanganate tablets' is used rather than a term such as 'potassium permanganate soak'. The risk of accidental ingestion also increased where receptacles that implied oral ingestion were used, such as plastic cups or jugs. Other incidents involved potassium permanganate being directly dispensed to vulnerable patients in their own homes and the patient misunderstanding that the tablets were not for oral ingestion. Where accidental ingestion had occurred, staff did not always appear aware of the need to treat this as a medical emergency.

Analysis of the NRLS reports suggested that arrangements for supply, storage and preparation varied greatly among healthcare providers. Barriers expected for a product subject to Control of Substances Hazardous to Health[3] include; separate storage, additional hazard labelling, and issue only to staff and patients who have been educated to understand its safe use.

Actions

Who: All providers of NHS funded care

When: To commence immediately and be completed by 22 January 2015

- 1 Identify if potassium permanganate preparations are used in your organisation, and if accidental ingestion has or could occur.
- 2 Consider if immediate action needs to be taken locally, and ensure that an action plan is underway if required, to reduce the risk of further incidents occurring.
- 3 Circulate this alert to all relevant medical, nursing, pharmacy and other staff.
- 4 Share any learning from local investigations or locally developed good practice resources by emailing patientsafety.enquiries@nhs.net.

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Identify if potassium permanganate preparations are used in your organisation, and if accidental ingestion has or could occur.



Consider if immediate action needs to be taken locally, and ensure that an action plan is underway if required, to reduce the risk of further incidents occurring.



Circulate this alert to all relevant medical, nursing, pharmacy and other staff.



Share any learning from local investigations or locally developed good practice resources by emailing patientsafety.enquiries@nhs.net.

New style Patient Safety Alerts (PSAs)



Patient Safety Alert

Stage One: Warning

Risk of death from asphyxiation by accidental ingestion of fluid/food thickening powder

05 February 2015

Alert reference number: NHS/PSA/N/2015/002

Alert stage: One - Warning

Dysphagia (swallowing problems) occurs in all care settings¹ and although the true incidence and prevalence are unknown, it is estimated the condition can occur in up to 30% of people aged over 65 years of age². Stroke, neurodegenerative diseases and learning disabilities can be the cause of some cases of dysphagia, and may also result in cognitive or intellectual impairment, as well as visual impairment.

The modification of liquid thickness and food texture is common practice in dysphagia management to avoid aspiration of material into the airway whilst maintaining adequate hydration and nutrition. Thickening agents are available in a range of preparations, the most common being a powdered form, supplied in tubs and commonly kept in a place that is accessible such as at the bedside.

NHS England has received details of an incident where a care home resident died following the accidental ingestion of the thickening powder that had been left within their reach. Whilst this death remains under investigation, it appears the powder formed a solid mass and caused fatal airway obstruction. Analysis of the National Reporting and Learning System has identified one other similar incident that occurred in hospital:

'HCA alerted by another patient that the patient was choking. Found to have taken the lid off a tub of thickening powder and attempted to tip it back to 'drink'. The patient is partially sighted and his condition fluctuates re conscious / alert levels. Thickener was a fresh tub today as trial re his poor swallow.....'

Feedback from frontline staff indicates that the potential consequences of trying to swallow dry thickening powder appear under-recognised therefore there may be significant under reporting.

Whilst it is important that products remain accessible, all relevant staff need to be aware of potential risks to patient safety. Appropriate storage and administration of thickening powder needs to be embedded within the wider context of protocols, bedside documentation, training programmes and access to expert advice required to safely manage all aspects of the care of individuals with dysphagia. Individualised risk assessment and care planning is required to ensure that vulnerable people are identified and protected.

Actions

Who: All providers of NHS funded care where thickening agents are prescribed, dispensed or administered

When: To commence immediately and be completed by no later than 19 March 2015

- 1 Identify if the accidental ingestion of dry thickening powder has occurred, or could occur, in your organisation
- 2 Consider if immediate action needs to be taken locally, and ensure that an action plan is underway if required, to reduce the risk of further incidents occurring.
- 3 Distribute this alert to all relevant staff who care for children or adults in primary care, emergency care, and inpatient care settings, including mental health and learning disability units.
- 4 Share any learning from local investigations or locally developed good practice resources by emailing patientsafety.enquiries@nhs.net

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Publications Gateway Reference 02979

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Identify if the accidental ingestion of dry thickening powder has occurred, or could occur, in your organisation



Consider if immediate action needs to be taken locally, and ensure that an action plan is underway if required, to reduce the risk of further incidents occurring.



Distribute this alert to all relevant staff who care for children or adults in primary care, emergency care, and inpatient care settings, including mental health and learning disability units.



Share any learning from local investigations or locally developed good practice resources by emailing patientsafety.enquiries@nhs.net

New style Patient Safety Alerts (PSAs)



Patient Safety Alert

Stage Two: Resources

Resources to support the prompt recognition of sepsis and the rapid initiation of treatment

2 September 2014

Alert reference number: NHS/PSA/R/2014/015

Alert stage: Two - Resources

This patient safety alert applies to all patient age groups

Sepsis is a time-critical medical emergency, which can occur as part of the body's response to infection. The resulting inflammatory response adversely affects tissues and organs. Unless treated quickly, sepsis can progress to severe sepsis, multi-organ failure, septic shock and ultimately death. Septic shock has a 50% mortality rate¹.

Sepsis is almost unique among acute conditions in that it affects all age groups and can present in any clinical area and health sector. Over 70% of cases arise in the community². However, sepsis can be easily treated through timely intervention and basic, cost-effective therapies.

Recent epidemiological studies^{3,4} and data from the Intensive Care National Audit and Research Centre (ICNARC)⁵, estimate that 35,000 people die from sepsis in England each year. We are lacking in recent data, especially in the UK, but the mortality rate for sepsis in children is estimated to be 10 – 15%. Key to reducing these figures are:

- Timely recognition and diagnosis of sepsis
- Fast administration of intravenous antibiotics
- Quick involvement of experts including intensive care specialists

It is estimated that the reliable delivery of basic elements of sepsis care could save 11,000 lives a year and £150 million annually⁶. This equates to 100 lives and £1.25 million in bed days for an average district general hospital each year. Furthermore, in 2010 the Centre for Maternal & Child Enquiries (CMACE) published the UK Confidential Enquiry into Maternal Deaths for the period 2006 – 2008 that found sepsis to be the commonest cause of direct maternal death⁷.

This stage 2 alert has been issued to continue to raise awareness of sepsis and to signpost clinicians in the ambulance service, primary and community services and secondary care to a set of resources developed by the UK Sepsis Trust, and others, to support the prompt recognition and initiation of treatments for all patients suspected of having sepsis. These resources include the Sepsis 6, a care bundle whose use is associated with significant numbers of lives saved and reduced length of hospital stays⁸.

The resources are available from here: [UK Sepsis Trust's clinical toolkits](#)

Actions

Who: Chief Executives of NHS Trusts, Foundation Trusts, Ambulance Trusts & General Practitioners

When: To commence immediately and by no later than 31 October 2014 have a robust action plan developed to achieve compliance

1 Ensure staff have access to both adult, paediatric and infant sepsis screening and action tools that can be used for patients presenting on first attendance, or developing suspected infection as an in-patient. Examples of such tools can be found at the resource links given in this alert.

2 By either circulating this alert or through local alternatives (such as newsletters, local awareness campaigns, etc.) ensure that all relevant staff are aware of the key messages and the linked resources (or local equivalents) so they can be introduced into clinical practice; in particular the administration of antibiotics within one hour of suspicion of sepsis and early escalation to senior medical management.

3 Share local good practice or further locally developed resources relating to sepsis via the deterioration page of the Patient Safety First website.



Ensure staff have access to both adult, paediatric and infant sepsis screening and action tools that can be used for patients presenting on first attendance, or developing suspected infection as an in-patient. Examples of such tools can be found at the resource links given in this alert.



By either circulating this alert or through local alternatives (such as newsletters, local awareness campaigns, etc.) ensure that all relevant staff are aware of the key messages and the linked resources (or local equivalents) so they can be introduced into clinical practice; in particular the administration of antibiotics within one hour of suspicion of sepsis and early escalation to senior medical management.



Share local good practice or further locally developed resources relating to sepsis via the deterioration page of the Patient Safety First website.



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Contact us: patientsafety.enquiries@nhs.net

Publications Gateway Reference: 02165

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New style Patient Safety Alerts (PSAs)



Patient Safety Alert

Stage One: Warning
Risks arising from breakdown and failure to act on communication during handover at the time of discharge from secondary care
29 August 2014

Alert reference number: NHS/PSA/W/2014/014
Alert stage: One - Warning

Between October 2012 and September 2013 there were around 10,000 reports to the National Reporting and Learning System (NRLS) of patient safety incidents related to discharge. The handover of patients when discharged from secondary to primary, community and social care is a complicated and multifactorial process.

Communication at handover is identified as a particular area of risk and accounted for approximately 33% of the 10,000 incidents reported to the NRLS. Review of these incidents identified that patients are sometimes discharged without adequate and timely communication of essential information at point of handover to all relevant staff and teams in primary and social care, including out of hours, and that information is not always acted on in a timely manner. This can result in avoidable death and serious harm to patients due to a failure in continuity of care as well as avoidable readmission to secondary care. An example incident states:

'Continuing Care Team (CCT) received hospital discharge fax to provide daily wound care for a patient who was being discharged after a long inpatient stay with a right groin biopsy wound. Patient[was however being] discharged after long inpatient stay with end stage fibrocystic lung disease. There was no mention on the fax that the patient was for end of life care. There was very poor communication from the ward and medical team to the GP and CCT at time of discharge and no end of life drugs, DNACPR or referral for community end of life care.'

NHS England is leading a national programme of work to support organisations in improving the communication and management of information at handover by building on successful local and national initiatives already in place. This Stage 1 Alert is asking organisations to help form a national picture by informing us of their current practice and challenges and by sharing examples of what they have done to improve the quality and timeliness of communication with primary and social care on discharge. This includes GPs, community nurses, social care, voluntary sector and medicines reconciliation; and initiatives may include system design, policy, strategy and handover tools. To collect the required information local sector specific questionnaires and a best practice template have been developed.

Information received through the questionnaires and best practice template will be used to inform a subsequent Stage 2 Alert (Resource), which will provide a range of resources and recommendations to support organisations in improving safety of handover at discharge at a local level.

NHS England will also build a web-based best practice resource and are collaborating with local and national experts and enthusiasts in the field to provide series of webinars to facilitate system wide learning on this subject. Staff can sign up for these webinars at the [Patient Safety First website](#).

Actions

Who: All NHS organisations, other providers of NHS funded care and social care sector

When: To commence immediately and be completed by 13 October 2014

- 1 Identify any work that your organisation is undertaking or has undertaken to ensure that communication during handover at time of discharge is safe and timely, including medicine reconciliation, which could benefit other organisations and share via the [online template](#).
- 2 Identify a person within your organisation to be the link with NHS England on this programme of work and email their contact details to patientsafety.enquiries@nhs.net. They will be contacted about forthcoming discharge webinars
- 3 Complete the anonymous online questionnaire(s) relevant to your sector to inform the identification of national priorities for safety improvement relating to communication during handover at time of discharge [here](#).
- 4 Share this alert with the main voluntary sector organisations that you work in partnership with on discharge and invite them to access the resources accessible on the [Patient Safety First website](#).

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- 1 Identify any work that your organisation is undertaking or has undertaken to ensure that communication during handover at time of discharge is safe and timely, including medicine reconciliation, which could benefit other organisations and share via the [online template](#).
- 2 Identify a person within your organisation to be the link with NHS England on this programme of work and email their contact details to patientsafety.enquiries@nhs.net. They will be contacted about forthcoming discharge webinars
- 3 Complete the anonymous online questionnaire(s) relevant to your sector to inform the identification of national priorities for safety improvement relating to communication during handover at time of discharge [here](#).
- 4 Share this alert with the main voluntary sector organisations that you work in partnership with on discharge and invite them to access the resources accessible on the [Patient Safety First website](#).

Agenda

1. Scene setting
2. MSO and MDSO responsibilities
3. Making it safer in the NHS
4. How are MSO and MDSO affecting patient safety?

MSOs/MDSOs local and national focus

Essential focus

1. Local learning from PSIs
2. Taking National messages and implementing [Alerts] locally
3. Frequency and quality of reporting
4. Identifying and disseminating best practice
5. **Conduit between NHS England/MHRA and practice**

Hello David,

I hope that this email finds you well.

Please find attached the following items of info from Derby Hospitals, as requested via the MSO network & following on from your email prompt to us this week:

- 1) Paracetamol dosing info
- 2) **Critical medicines list - please note that we are currently updating ours to also include Desmopressin following on from a recent incident.**

I hope that this information is useful to you and your team.

Look forward to seeing you guys at the MSO conference in Birmingham next week.

Kind regards,

Jazz.


Lead to a topic presentation on a MSO event


Other hospitals saying it was an issue

A NRLS scope

Presentation to MSOs by a consultant directly involved in fatal incidents

Dissemination of previous information (*sure***MED**)



King's College Hospital


NHS Foundation Trust

ALERT

SureMED alerts are published to raise awareness of risks with medicines. Their aim is to minimise harm to patients by promoting safe use of medicines and reducing the risk of medication errors.

DRUG: **Desmopressin**

ERROR TYPE: **Omission**

POTENTIAL FOR ERROR

Omission of desmopressin in patients who regularly take the medication can cause serious patient harm or death.

Desmopressin (DDAVP) is a hormone which is used to treat diabetes insipidus, a condition where the pituitary gland produces insufficient antidiuretic hormone (ADH). The kidney is unable to conserve water and large volumes of urine are produced. The same symptoms of polyuria and polydipsia occur following surgical removal of the pituitary gland.

The usual dose of desmopressin orally is 100mcg 2 - 3 times a day and for maintenance 100 - 200 mcg taken 2-3 times a day.

If patients do not receive desmopressin when it is prescribed they are at risk of serious harm due to polyuria and hypernatraemia

DO NOT OMIT unless advised by a DOCTOR!


Therefore if a patient has been prescribed Desmopressin orally, all necessary steps must be taken to obtain the medication for administration at the right time.

If patients do not receive **desmopressin** when it is prescribed they are at risk of serious harm due to polyuria and hypernatraemia

DO NOT OMIT unless advised by a DOCTOR!

- NEVER omit oral desmopressin unless advised by a DOCTOR
- CONTACT the medical team if the patient is unable to take medicines by the oral route
- PRESCRIBE desmopressin by an alternative route if the oral route is not available
- OBTAIN stock out of hours by contacting the on-call pharmacist via switchboard or obtain the drug from the Emergency Drug Cupboard
- AVOID omissions. Desmopressin (and other medicines) are available 24 hours a day

King's College Hospital - sureMED Alert - July 2015


KING'S HEALTH PARTNERS

An Academic Health Sciences Centre for London

Pioneering better health for all

Agenda

1. Scene setting
2. MSO and MDSO responsibilities
3. Making it safer in the NHS
4. How are MSO and MDSO affecting patient safety?

Key messages MSOs and MDSOs

1.are formally recognised healthcare practitioners working for the improvement of patient safety across the landscape of healthcare
2.are a conduit between front-line practice and NHS England
3.have a role to improve the quality and frequency of medication and/or device incident reporting and to promote local learning from such adverse incidents
4. How are they affecting patient safety....they are improving it every day, in their own way!