Patient Safety Alert

Stage Three: Directive
Improving medication error incident reporting and learning
20 March 2014

Supporting information

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

Alert stage: Three - Directive

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

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1. Introduction

Progress has been made over the last decade to detect, report and learn from patient safety incidents, but further improvements are needed to increase the number of incident reports, improve data quality and maximise what is learned from medication errors.

The alert 'Improving medication error incident reporting and learning' recommends changes to strengthen clinical governance arrangements, and the identification of medication safety officers (MSOs) and multi-professional groups to review medication error incidents and improve medication safety locally.

NHS England and the MHRA are working together to simplify reporting, improve learning and guide practice to minimise harm from medication errors. To support this initiative, a National Medication Safety Network will be created which will give continual learning and identify and spread medication safety improvements across the health economy.

This supporting information gives additional information and clarification on the thinking behind this Patient Safety Alert and its recommended actions.

2. What are medication errors and patient safety incidents?

The National Reporting and Learning Systems (NRLS) defines a 'patient safety incident' (PSI) as, 'any unintended or unexpected incident, which could have or did lead to harm for one or more patients receiving NHS care.'

Medication errors are any PSIs where there has been an error in the process of prescribing, preparing, dispensing, administering, monitoring or providing advice on medicines. These PSIs can be divided into two categories; errors of commission or errors of omission. The former include, for example, wrong medicine or wrong dose. The latter include, for example, omitted dose or a failure to monitor, such as international normalised ratio for anticoagulant therapy.

Analysis of NRLS reports nationally has allowed new risks to be identified and communicated through the use of Patient Safety Alerts, Rapid Response Reports and Signals by the former National Patient Safety Agency. NHS England now carries out this work. Details of a new National Patient Safety Alerting System have recently been issued.

3. What are adverse drug reactions?

Under the new EU Directive 2010/84/EU[1] that came into force in July 2012, the term 'adverse drug reaction' (ADR) is defined as, 'a response to a medicinal product that is 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, off-label use and abuse of the medicinal product.'

In the UK, the MHRA must operate a pharmacovigilance system to monitor the use of medicines in everyday practice. The NRLS is being developed as an integrated reporting route for medication error incidents in England by NHS England and the MHRA.

Other types of suspected ADR reports which are not the result of a medication error continue to be collected by the MHRA through the Yellow Card Scheme. The Yellow Card Scheme helps the MHRA to identify previously unrecognised suspected adverse drug reactions. It also provides valuable information on recognised ADRs, allowing risks that may affect patients to be identified and understood.

The value of the scheme has been demonstrated many times and it has helped identify many important safety issues. It collects reports of suspected ADRs from across the United Kingdom and covers all medicines, including prescription medicines, over-the-counter medicines or general retail sales. Reports are also received for herbal, homeopathic and unlicensed medicines.

The MHRA asks for Yellow Cards for all suspected ADRs to medicines and vaccines under additional monitoring (marked with an inverted black triangle symbol (▼)). Reports of all serious ADRs are requested for established medicines and vaccines. Serious reactions include those that are:

- fatal;
- life-threatening;
- disabling;
- incapacitating;
- result in congenital abnormalities; and,
- result in or prolong hospitalisation.

They should be reported even if the effect is well recognised.

The MHRA is also particularly interested in receiving, through the Yellow Card Scheme, reports of suspected ADRs:
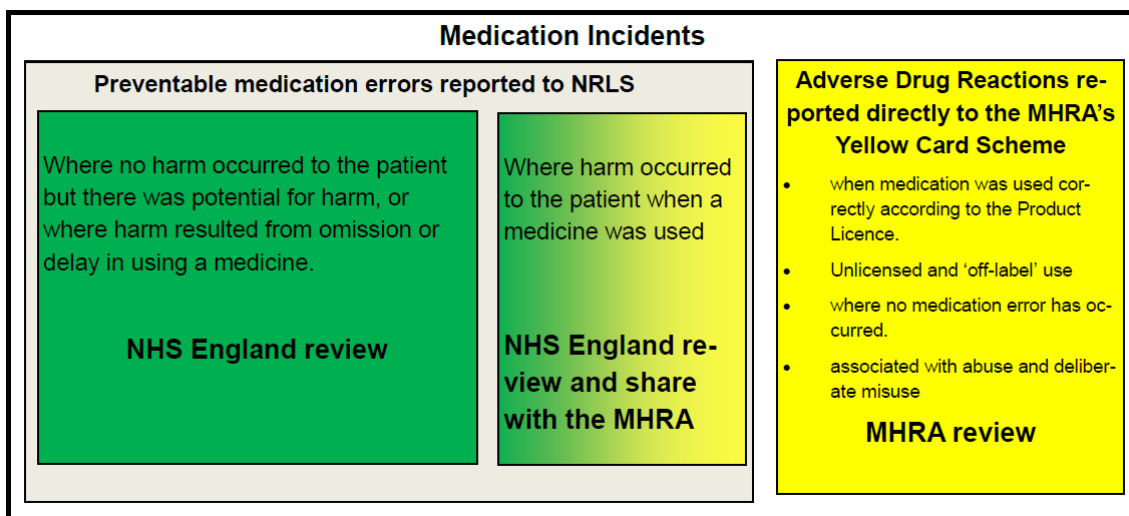
- in children;
- in patients that are over 65;
- to biological medicines;
- associated with delayed drug effects and interactions; and,
- complimentary therapies such as homeopathic and herbal remedies.

Causality does not have to be proved in order to report a suspected ADR, a suspicion is enough.

A summary of the different sources and volumes of suspected ADR reports received by the MHRA is shown in Annex D, page 17.

The new pattern for reporting medication incidents is described in figure one.

Figure one: Medication incidents and reporting

Medication Incidents

Preventable medication errors reported to NRLS		Adverse Drug Reactions reported directly to the MHRA's Yellow Card Scheme
Where no harm occurred to the patient but there was potential for harm, or where harm resulted from omission or delay in using a medicine. **NHS England review**	Where harm occurred to the patient when a medicine was used **NHS England review and share with the MHRA**	• when medication was used correctly according to the Product Licence. • Unlicensed and 'off-label' use • where no medication error has occurred. • associated with abuse and deliberate misuse **MHRA review**

4. The cost of medication errors

Research evidence indicates the following medication error rates in the medicine use process:

- prescribing error rate in hospital, 7% of prescription items[2];
- prescribing errors rate in general practic, 5% of prescriptions of which 0.18% were severe errors[3]: With a billion prescription items prescribed in primary care in the NHS in England annually. This research predicts 1.8 million serious prescribing errors each year;
- dispensing error rate in hospitals, 0.02 – 2.7% of dispensed medicines[4];
- dispensing error rates in community pharmacies, 0.01 – 3.32% dispensed medicines[4]; and,
- medicine administration errors in hospital, 3 – 8%[5].

There is limited research to quantify actual harm arising from medication errors.

A study was conducted in two large hospitals in Merseyside to determine the current burden of ADRs in the NHS[6]. The study found that of 18,820 patients aged over 16 years admitted to hospital over a six-month period, there were 1,225 admissions judged to be related to an ADR, giving a prevalence of 6.5%. Of these 1,225, the ADR was judged to have led directly to the admission in 80% of cases. The majority (72%) of ADR-related admissions were judged as avoidable, including medication errors. The median bed stay was eight days, accounting for 4% of the hospital bed capacity. The projected annual cost of such admissions to the NHS was £466 million.

In a review of medication error incidents reported to the NRLS over six years between 2005 to 2010 there were 525,186 incidents reported. Of these, 86,821 (16%) of medication incidents reported actual patient harm, 822 (0.9%) resulted in death or severe harm[7].

## 5. How should medication error incidents and ADRs be reported in the future?

The system for reporting medication error incidents in England is the NRLS.

The MHRA and NHS England are working together to improve the quality and extent of reporting, and the resulting learning, in the field of medication errors. As part of this partnership, the NRLS will be an integrated reporting route for medication error incidents, see figure two below.

Suspected ADRs not involving medication errors reported via the NRLS should continue to be sent directly to the MHRA through the Yellow Card Scheme. It is good practice to share copies of submitted Yellow Card reports with the MSO for local learning and action.

Near-miss incidents that have not caused harm but have the potential to do so and those involving errors of omission will stay in the NRLS and be used by the Patient Safety Domain in NHS England for national learning.

Figure two: The flow of information
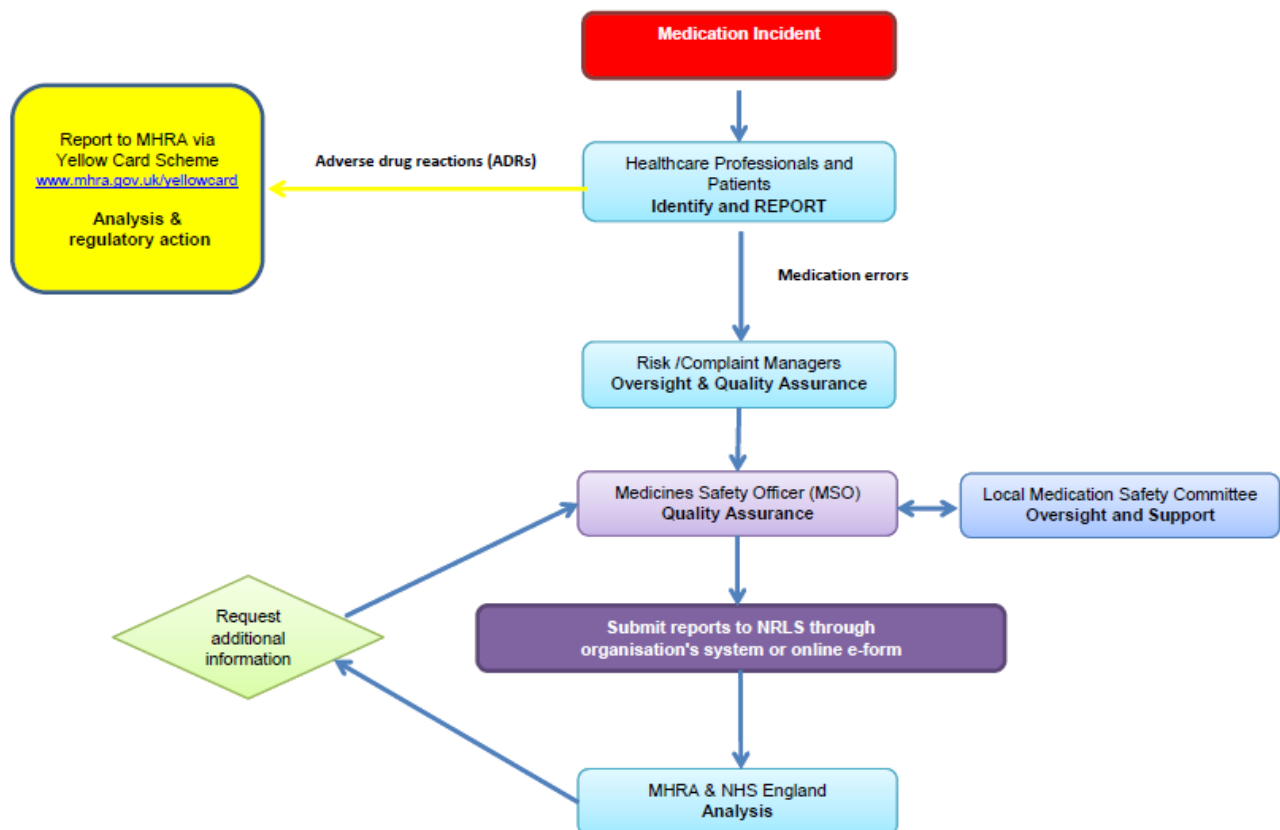
Medication error PSI reports where the error has caused harm and include enough information for analysis will be shared with the MHRA.

In order for the MHRA to evaluate and investigate ADRs there is a minimum of four pieces of information needed. These are:

1. an identifiable patient from information on, for example, age and gender;
2. an identifiable reporter (typically the organisation);
3. a suspected medicine (brand/generic name or active ingredient); and,
4. a suspected reaction.

The specific criteria for extracting data from the NRLS to be sent to the MHRA is in Appendix A (page 13). Medication incident data reported to the NRLS that meets these criteria will be shared with the MHRA, initially on a weekly basis.

For an example of how a medication error report should be completed see Appendix B (pages 14 and 15).

6. Why does the quality of medication incident reports need to be improved?

Analysis of NRLS reports nationally has allowed new risks to be identified and communicated to healthcare providers. The success of this system depends on the quality of reporting.

Some fatal, serious incidents and never events involving medication errors may not be reported to the NRLS. Essential information to allow understanding of medication error incidents, both locally and nationally, may not be included in reports. Incident information may be miscoded and incident reports may be delayed in reaching the NRLS.

Correct and completed data fields will improve the data quality of medication incidents reported to the NRLS. This will allow more detailed assessment, support national analysis of potential safety concerns resulting in regulatory action (if necessary) and enable feedback to healthcare professionals which will support local learning. This will lead to the safer use of medicines and greater protection of public health.

Analysis of the 12,355 medication error incidents reported to the NRLS in March 2013 illustrates some of the data quality issues that needed to be addressed (see table one below).

Table one: Data quality of NRLS medication incidents

Data quality issue	NRLS field name	Description	% of total
Delayed report	IN01	Date of incident. Incident reported more than four weeks after the incident	53%
Data not recorded	MD05	Medicine name	32%
Data not recorded	MD06	Proprietary name	99%
Data not recorded	MD10	Manufacturer	99.9%
Data miscoded	MD01	Use of the term 'other' in the medication process field. Options include: prescribing/preparation/dispensing, administration, monitoring etc	12%
Data miscoded	MD02	Use of the term 'other' in type of medication error. Options include: wrong patient, medicine, route, dose frequency, quantity, omitted etc	25%
Data not recorded	ST01	Staff type reporting the incident. Options include doctor, nurse pharmacist etc	71%
Quality of data	IN07	Review of free text description of what happened, death or severe harm reports.	7% of incidents stated very little meaningful information to aid learning. 18% did not report the reaction to the error that led to harm.
Data not recorded	IN010	Actions taken to prevent recurrence	49%
Data not recorded	IN11	Apparent causes	69%
Data miscoded	PD09	Clinical outcome codes indicating death or severe harm	44%

7. Why changes are needed to improve the clinical governance of medication error reporting and learning

Incident reports are not always reviewed locally by staff with medication safety expertise to check quality and to initiate action before being submitted to the NRLS.

Senior managers in healthcare organisations are not always aware of important patient safety issues, or the quality of the reporting and learning systems that operate in their organisations.

It can also be difficult for NHS England or the MHRA to communicate with individuals with the relevant technical knowledge to get more information about specific incidents.

To improve learning at all levels and facilitate vigilance responsibilities of the MHRA, the governance procedures concerning reporting of medication error incidents to the NRLS need to be improved urgently.

Figure three below gives an overview of the governance structure to be implemented to improve feedback and learning from medication error incidents reported though the NRLS.

Figure three: Feedback and learning from medication incidents.
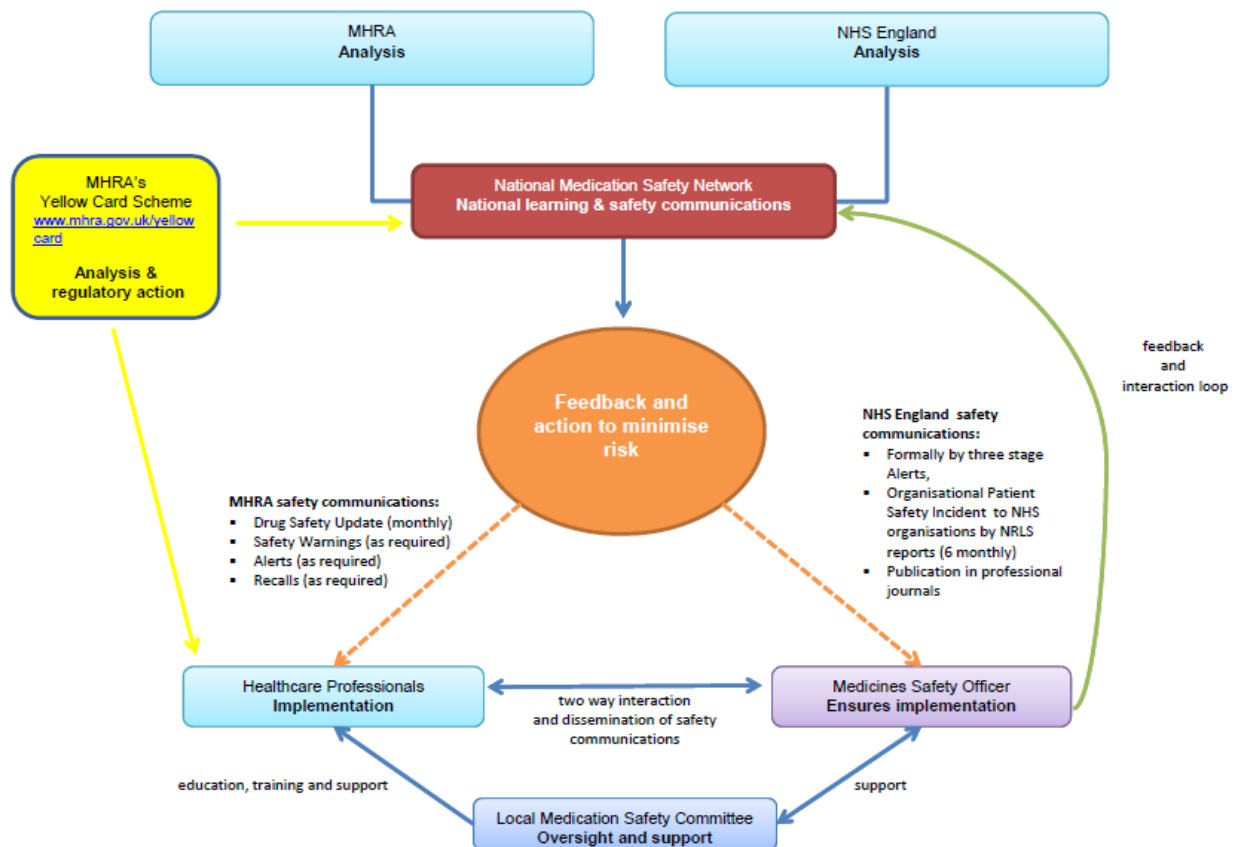
7.1. Actions for large healthcare provider organisations

7.1.1. Definition of a large healthcare provider organisation

All NHS trusts
Including acute, ambulance, care community, foundation, learning disability, mental health, partnership, social care and specialist trusts.

Independent Sector

The following independent sector companies have been identified as large organisations:

- Aspen Healthcare
- Benenden Hospital
- BMI Healthcare
- Bridgewater Hospital
- Bupa Cromwell Hospital
- Care UK
- Fairfield Hospital
- HCA International
- Healthcare Management Trust
- Horder Healthcare
- Hospital Of St John and St. Elizabeth
- Huntercombe Group
- King Edwards VII Hospital
- Marie Stopes International
- New Victoria Hospital
- Nuffield Health
- Ramsay Health Care
- Serco
- Spencer Private Hospitals
- Spire Healthcare
- The Hospital Group
- The London Clinic
- Transform

Community pharmacy

Community pharmacy companies with 50 or more community pharmacies registered with the General Pharmaceutical Council at the end of 2013 are specifically identified as large organisations.

- Asda Stores Ltd
- Boots UK Limited
- Co-operative Group Healthcare Ltd
- Day Lewis Plc
- Day Lewis Chemists Ltd
- Dudley Taylor Pharmacies Ltd
- Gorgemead Ltd
- H.I. Weldrick Ltd
- Lloyds Pharmacy Ltd
- L Rowland & Co (Retail) Ltd
- National Co-operative Chemists Ltd
- National Pharmaceutical Association
- Paydens Ltd
- PCT Healthcare Limited
- Sainsbury's Supermarkets Ltd
- Superdrug Stores Plc
- Tesco Stores Ltd
- Wm Morrison Supermarkets Plc.

Home healthcare companies

Specific home healthcare companies have been identified as large organisations:

- Alcura UK Ltd
- Baxter Healthcare Ltd
- B Braun Medical Limited
- BUPA Home Healthcare Limited
- Calea UK Ltd
- Evolution Homecare Services Ltd
- Healthcare at Home Ltd
- Polar Speed Distribution.

7.1.2. The oversight role of the medical / nursing director or superintendent pharmacist

A board director (medical or nursing supported by the chief pharmacist) or superintendent pharmacist in a community pharmacy or home healthcare company, should have oversight responsibilities and oversee medication error incident reporting and learning systems.

In the independent sector, ensure that there is an auditable line of delegated authority from the board to the medication safety officer and that the board retains the oversight responsibilities and oversees medication safety incident reporting and learning.

The board director or superintendent pharmacist should foster a safety culture and satisfy themselves that; these systems are operating effectively, the quality of incident reports supports learning, important patient safety issues identified by these systems are adequately addressed locally and incident reports are submitted in a timely fashion for national learning.

Arrangements should be made to identify an existing or new multi-professional group for medication safety and a MSO.

These individuals should have relevant knowledge and experience, and their current role should cover appropriate responsibilities. The Central Alerting System (CAS) team should be sent the contact details of the MSO (see Appendix C, page 16).

7.1.3. The role of the medication safety officer

The establishment of a MSO is integral to improving medication error incident reporting and learning within healthcare provider organisations. One of the MSOs' key roles is to promote the safe use of medicines across their organisations and be the main experts in this area. In addition to improving the quality of reporting, the MSO will serve as the essential link between the identification and implementation of (local and national) medication safety initiatives and the daily operations to improve patient safety with the use of medicines.

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 Doman 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.

7.1.4. The role of the medication safety committee

An existing or new multi-professional committee should be identified to support the safe use of medicines in the organisation. It should be made up of:

- medical staff;
- nursing staff;
- pharmacy staff;
- those in risk management and general management; and,
- a patient representative.

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.

7.2. Action for small healthcare provider organisations

7.2.1. Definition of a small healthcare provider organisation

Any healthcare organisations not defined in section 7.1 including general medical practices, dental practices, community pharmacies, small organisations in the independent sector.

7.2.2. Reporting and learning

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.

7.2.3. Communication and support

Receive support for reporting and learning from medication safety officers in healthcare commissioning organisations and medication safety champions who are members of local professional committees and multi-professional committees.

7.2.2. Medication safety champions

Medication safety champions are individuals who have chosen to take an active role in improving the safe use of medicines. Champions can be in any discipline or setting including the voluntary sector. A safety champion will be someone who is already working to improve patient safety. Safety champions do not need to be appointed, however where champions are active organisations should try to capitalise on the contributions they can make.

7.3. Invited action for healthcare commissioners

7.3.1. Definition of healthcare commissioners

Healthcare commissioning organisations purchase healthcare services. NHS England Area Teams are responsible for commissioning primary healthcare. Clinical Commissioning Groups are responsible for commissioning secondary care and, depending on local arrangement, they may receive support from Commissioning Support Units. Both types of commissioners are responsible for improving quality and safety in primary and secondary care.

7.3.2. The oversight role of clinical governance

Invited arrangements for improving reporting and learning for medication error incidents should be part of clinical governance structures in commissioning organisations. These structures should ensure that medication error reporting systems are operating effectively, that the quality of incident reports supports learning, that important patient safety issues identified by these systems are adequately addressed locally and that incident reports are submitted in a timely fashion for national learning.

It is essential that serious incidents are reported to the NRLS for national learning in addition to the Strategic Executive Information System (STEIS) – see section 10.

Commissioners are invited to identify an existing or new multi-professional group for medication safety and a MSO.

These individuals should have appropriate knowledge and experience and their current work is likely to cover broadly similar responsibilities. The Central Alerting System (CAS) team should be sent the contact details of this person, see appendix C. CCGs may also like to ensure they have an effective system for receiving CAS Alerts. They can register with CAS to receive Alerts directly.

7.3.3. The role of the medication safety officer

The establishment of a MSO role will help to improve medication error incident reporting and learning in the healthcare economy. A key role for the MSO is to promote the safe use of medicines and be the main expert in this area. In addition to improving reporting, the MSO can serve as the essential link for the identification and implementation of (local and national) medication safety initiatives.

Responsibilities should include the following:

i.   active membership of the National Medication Safety Network;
ii.   improving reporting and learning of medication error incidents;
iii. receiving a periodic summary of medication error incidents reported from the NRLS to assist learning;
iv.   analysing trends and issues and taking supportive action as appropriate;
v.   working with the medication safety committee to deliver responsibilities listed in 7.3.4;
vi.   using learning to influence policy, planning and commissioning;
vii. working with medication safety champions or local professional committees/networks such as the local pharmaceutical or medical committees and/or professional networks; and,
viii. supporting the dissemination of medication safety communications from NHS England and the MHRA.

7.3.4. The role of the medication safety committee

An existing or new multi-professional committee can help to support the safe use of medicines in the organisation. It should be made up of:

- medical staff;
- nursing staff;
- pharmacy staff;
- those in risk management and general management; and,
- a patient representative.

Responsibilities should include the following:

i.   improving reporting and learning of medication error incidents;
ii. receiving summaries of NRLS 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 reoccurring;
iv. providing regular feedback and planning action to minimise these risks to healthcare providers;
v.   using learning to influence policy planning and commissioning;
vi. coordinating education and training support to improve the quality of medication error incident reports and safe medication practices; and,
vii. assisting in development and review of medication-use policies and procedures.

8. How do you include reports and complaints from patients and carers?

The NHS Constitution outlines that patients have the right to complain about their treatment, have complaints dealt with efficiently, and have complaints properly investigated and be given a full and prompt reply. Patients should normally inform their service provider, for example, their GP, dentist, pharmacist or hospital of their complaint. Alternatively the patient may send their complaint to NHS England or Clinical Commissioning Groups. Some patient complaints may contain information about incidents involving medication errors. It is important that learning from this information is not lost and the information in complaints is shared with the NRLS by healthcare organisations.

Medication safety officers should develop effective working links with those managing complaints processes and risk managers in organisations and arrange that, where appropriate, incident information in complaints can be used for learning and communicated through the NRLS.

Patients should also be told that they are able to report suspected adverse drug reactions or side effects directly to the MHRA using the Yellow Card Scheme.

9. How will NHS England and the MHRA request additional information?

Where a medication incident report provides incomplete or unclear information for learning, or where more information is needed concerning actions taken locally to help mitigate similar incidents in the future, the Patient Safety Domain in NHS England or the MHRA may contact the MSO to request more information.

Organisations are responsible for notifying and updating contact details of MSOs to the Central Alerting System. See Appendix C for the contact detail form.

10. How should the STEIS reporting system be used alongside NRLS?

The Serious Incident (SI) system is one of the modules of the Strategic Executive Information System (STEIS). The SI system enables electronic logging, tracking and reporting of Serious Incidents Requiring Investigation (SIRI).

The use of STEIS does not replace the need to report the early details of patient safety incidents to the NRLS. The detailed information following investigations is not usually shared with the NHS England Patient Safety Domain or the MHRA. It is essential that serious incidents are reported to the NRLS in addition to STEIS for national learning.

A serious incident framework was published by The NHS Commissioning Board in March 2013.[8]

11. What feedback will medication safety officers receive on incident reports?

11.1 Feedback from the NRLS and NHS England

The NRLS provides Organisation Patient Safety Incident Report Workbooks every six months. This information provides an overview of all types of patient safety incidents reported to the NRLS. The overall number of medication incidents for each organisation is provided as part of this summary.

Available at: www.nrls.npsa.nhs.uk/patient-safety-data/organisation-patient-safety-incident-reports

It is planned that MSOs will receive data quality reports every six months to provide an independent assessment of whether incident data provides sufficient information for local and national learning.

Publication in professional journals

From time to time publications will be submitted to professional journals to describe patient safety issues involving risks with the use of medicines identified from analysis of patient safety incident reports submitted to the NRLS. Some example publications are shown below:

Cousins D, Gerrett D, Warner B. A review of Controlled Drug incidents reported to the National Reporting and Learning System (NRLS) over seven years (2005 – 2011); implications for safer practice. Pharm J 2013; 391: 647.

Cousins D, Gerrett D, Warner B .Reporting and Learning System in England and Wales over six years (2005 – 2010) Br J Clin Pharmacol. 2012.74:597-604

Cousins D, Rosario C, Scarpello J. Insulin, hospitals and harm: a review of patient safety incidents reported to the National Patient Safety Agency. Clin Med. 2011; 11:28-30.

Patient Safety Guidance

New patient safety alerts will be issued via the Central Alerting System by the Patient Safety Domain in NHS England and will also be available at: www.england.nhs.uk/patientsafety/psa

In the past information from NRLS medication incident reports has been used by the National Patient Safety Agency to develop patient safety guidance in the form of Patient Safety Alerts, Rapid Response Reports, Signals and Design for Patient Safety Materials. Available at: www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/

NHS England published details of a new National Patient Safety Alerting System on 31st January 2014.

Available at: www.england.nhs.uk/ourwork/patientsafety/psa/national-psa-system/

11.2. Feedback from the MHRA

Drug Safety Update

Drug Safety Update is the monthly electronic bulletin from the MHRA and Commission on Human Medicines.
Drug Safety Update is essential reading for all healthcare professionals, bringing them the very latest information and advice to support the safer use of medicines.

Available at: www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm

Safety Warnings, Alerts and Recalls

- Drug alerts on defective medicines
- Letters to healthcare professionals. Communications via the Central Alerting System
- Safety warnings and messages about medicines

Available at: www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/index.htm

Drug Analysis Prints

All reports made to the MHRA on suspected reactions (including medication errors) are listed in Drug Analysis Prints (DAPs). Drug Analysis Prints (DAPs) contain complete listings of all suspected adverse drug reactions or side effects, which have been reported to the MHRA using the Yellow Card Scheme for a particular drug substance. This includes all reports received from healthcare professionals, members of the public and pharmaceutical companies.

Available at: www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme/YellowCarddata/Druganalysisprints/index.htm

12. The National Medication Safety Network

The Patient Safety Domain at NHS England and the MHRA are planning additional support for MSOs in the form of the National Medication Safety Network.

The objectives for the network are to:

- improve reporting and learning of medication incidents by educating and training Medication Safety Officers in patient safety science; and,
- disseminate relevant research and information concerning new risks and best practice.

Specific improvements include to:

- increase the number of reports of medication incidents;
- improve the timeliness of report submission;
- improve the quality of reports,
    - NRLS data fields completed;
    - accuracy of use of NRLS codes;
    - description of the incident – to be sufficient for learning;
- increase the number of new safety issues detected;
- implement local actions to minimise harm from identified risks; and,
- measure improvements to safer practice.

Medication safety officers will be invited to conferences/workshops, regular online Webex meetings, email discussion groups and online information forums to discuss topics identified at local and national level. These will include the identification of new risks and best practice to minimise these risks, implementing patient safety guidance and improving incident reporting quality and learning.

13. References

1. European Union Directive 2010/84/EU. Pharmacovigilance. Official Journal of the European Union 31.12.2010. Available at: www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:348:0074:0099:EN:PDF
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7. Cousins DH, Gerrett D, Warner B. A review of medication incidents reported to the National Reporting and Learning System in England and Wales over 6 years (2005–2010). Br J Clin Pharmacol 2012;74(4):597–604
8. National Health Service Commissioning Board (NHS England). Serious incident framework: An update to the 2010 National Framework for Reporting and Learning from Serious Incidents Requiring Investigation. 2013;(March). Available at www.england.nhs.uk/wp-content/uploads/2013/03/sif-guide.pdf

Appendix A. Specific criteria for extraction of data from the NRLS for transmission to the MHRA

Medication incident data reported to the NRLS and fulfilling the following specified criteria below will be shared with the MHRA, initially on a weekly basis.

Data quality issue	NRLS field name	Description
IN01	Date of incident	Is completed, and
IN05	Incident category	'Medication' , and
PD16	Was the patient actually harmed?	'Yes'
PD09	Clinical outcome	Is completed, and
MD01	Stage or medication process	Is completed, and
MD02	Medication error description	Is completed, and
MD05 or MD30	Approved medicine name	Is completed, or
MD06 or MD31	Proprietary medicine name	Is completed, and
IN07	Free text description of the incident	Is completed, and
PD01	Patient age	Is completed, or
PD02	Patient Gender	Is completed, or
PD19	Patient weight	Is completed , and
PD05	Specialty	Is completed, and
RP02	Care Setting	Is completed, and
RP07	Trust organisation code	Is completed, or
RP06	Trust Name	Is completed , and
ST01	Staff type	Is completed, and
RP01	Unique ID	Is completed, and
RP05	Local reference ID	Is completed

The following data fields are also to be included in the incident data shared with the MHRA.
Healthcare organisations should have a means to record this information in their local incident reports and have the information transferred to the NRLS.

Reference Code	Description
IN06	Contributing factors
IN10	Reoccurrence prevention
IN11	Underlying causes
MD03	Other important factors
MD04	In this incident, this was the right/wrong medicine
MD06	Proprietary (trade) name
MD07	Form
MD08	Dose/strength
MD10	Manufacturer
MD11	Batch number
MD12	Is the medicine a manufactured special?
MD13	Medicine registered EU importer
MD16	Route
PD11	Patient ethnicity
PD13	Preventative actions taken
PD14	Action taken to minimise the impact
PD15	Describe the actions taken

Appendix B: An example of how a medication error incident report should be completed

The primary purpose of any incident report is for learning and as a means to improve patient safety. Enough information is needed to describe patient demographics, the medicine(s) name, medicine process, staff involved, a short description of what happened, the underlying causes and whether the incident caused actual harm and the level of resulting harm

NRLS Code	Field name	Entry
INO1	Date of incident	15.07.13
INO3	Location	General/acute hospital, inpatient area, ward
IN05	Incident category	Medication
PD01	Patient age	82 years
PD02	Patient gender	Female
PD05	Specialty	Medical Specialties, respiratory ward
RP02	Care setting	Hospital
RP07	Organisation code	1234
RP01	Unique ID	5678
RP05	Local reference ID	91011
ST01	Staff type reporting incident	Nurse
MD01	Stage of medication process	Administration / supply of a medicine from a clinical area
MD02	Medication error category	Wrong / unclear dose or strength
IN06	Contributing factors	*Inadequate check and double check of the strength of oxycodone oral liquid prior to administration*
IN07	Description of incident	*Patient noted to have apnoeic episode following morning medications. Patient requires many regular medicines including opioid analgesia. Drug chart and controlled drugs record cross checked and found that the patient had received 500mgs of oxycodone instead of 50mgs oxycodone as prescribed. The patient's own supply of medication used was a concentration of 10mg / ml compared with the ward supply which has a concentration of 1mg / ml.*
IN10	Recurrence prevention	*Modified medicine reconciliation protocol to ensure that warnings concerning the use of high strength oxycodone are included on the prescription sheet and on the bottle.*
IN11	Underlying causes	*Ward staff unaware that there were two strengths of oxycodone oral liquid.* *Medicines reconciliation process did not document that the patient was using the high strength product.* *Look-alike labelling and packaging of the two oxycodone liquid strengths*
MD05	Approved names of medicine	*Oxycodone*
MD07	Form	*Oral liquid*
MD08	Dose/strength	*10mg/ml*
MD10	Manufacturer	*Abcdefg*
MD16	Route	Oral
PD16	Was the patient harmed?	Yes
PD09	Clinical outcome	Moderate harm

Appendix C: Medication safety officer contact form

Name of organisation	
Address	
City	
Postcode	
Full Name of officer	
Group email address – see note*	
Qualifications	
Other current role(s) in organisation	
Department in which the post is based	
Telephone number	
Name of director or senior manager authorising the role	
Personal email address	

When completed this form should be sent to the Central Alerting System team,

Safetyalerts@dh.gsi.gov.uk

*Group email address
Healthcare organisations should set up a generic email address for their medication safety officer. This should include the organisation name and the abbreviated term 'mso'. For example, for a NHS mail account, the format of this generic email address will be organisation-name.mso@nhs.net.uk

Depending on the type of generic email type selected, emails to the generic address can be automatically forwarded to one or more individual accounts. Generic accounts can be user by more than one person, to maintain continuity of service. Access to the generic account can also be transferred when post holders change to minimise the risk of delays in communication.

Appendix D: A Summary of suspected ADR reports received by the MHRA

Reports of suspected Adverse Drug Reactions (ADRs) to medicinal products and vaccines are submitted to the Yellow Card Scheme that is run jointly by the Commission on Human Medicines (CHM) and the MHRA. Reporting is voluntary for healthcare professionals and since 2005 members of the public can also report a Yellow Card. Pharmaceutical companies legally must report suspected ADRs for their products to the MHRA. The Yellow Card Scheme is an important way of monitoring drug safety in clinical practice, acting as an early warning system for the identification of previously unrecognised adverse reactions and increasing knowledge of known ADRs.

Table 1 below shows the overall number of UK spontaneous suspected ADR reports received per year for the past five years

Table 1: Number of UK spontaneous ADR reports received for the past five years

Total number of ADR reports	2008	2009	2010	2011	2012
	25,012	25,454	23,305	25,135	26,073

Figure 1 provides a breakdown of the overall number of ADR reports received per year for the past five years with the reporting source ie patients, healthcare professionals or industry.

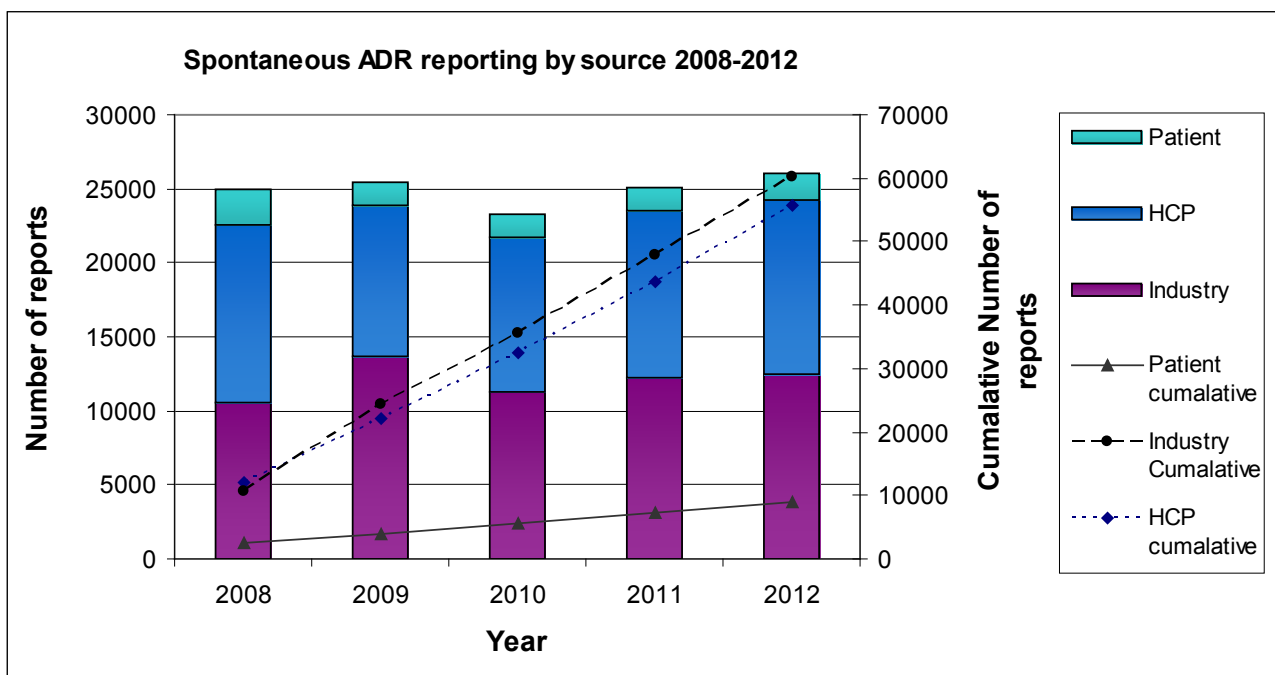Figure 1: UK spontaneous ADR reports received by the MHRA over the past five years

Figure 2 below shows the number of reports received directly from healthcare professionals over the past 5 years and how these volumes have changed as a result of a number of Yellow Card strategy initiatives the MHRA have carried out to strengthen and encourage the reporting of suspected ADRs.

Figure 2: Yellow Card reports received directly from healthcare professionals over the last five years

Yellow Card reports received directly from healthcare professionals: 2008 - 2012
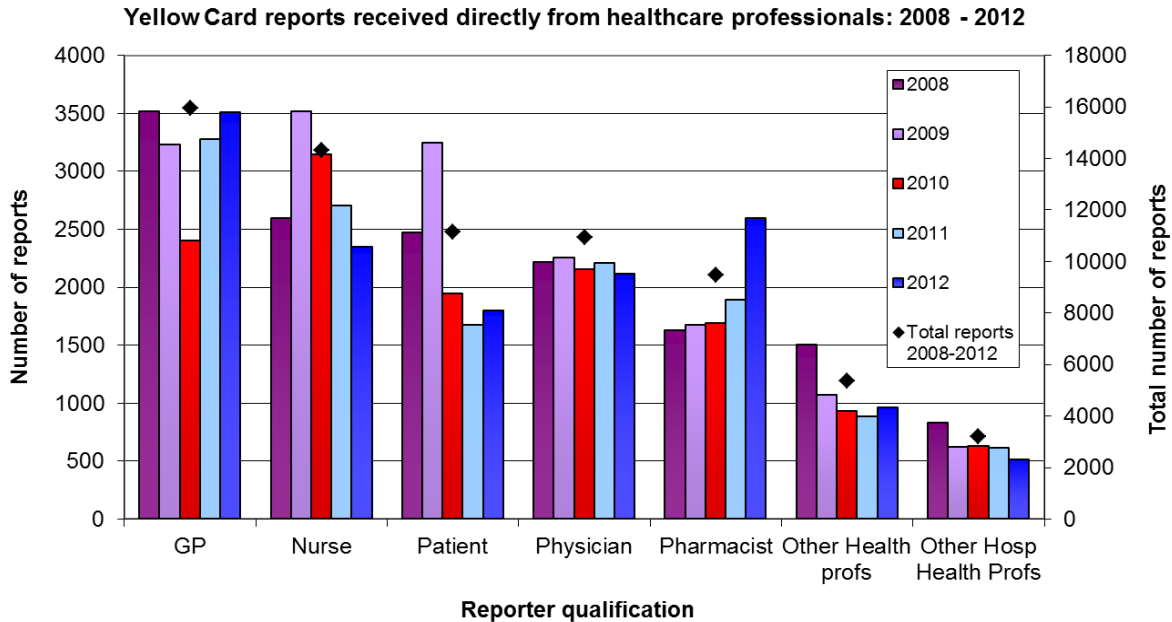
The number of suspected ADR reports received through the Yellow Card Scheme that describe reactions occurring as a result of a medication error is relatively low but has been increasing over the past four years (figure 3). With the new integrated reporting of medication errors through the NRLS the MHRA aims to significantly increase the quality and number of reports, supporting safety issues being detected more quickly. This ultimately leads to the safer use of medicines and greater protection of public health.

Figure 3: Total medication error ADR reports received by the MHRA for the past five years

ADR reports of medication errors received
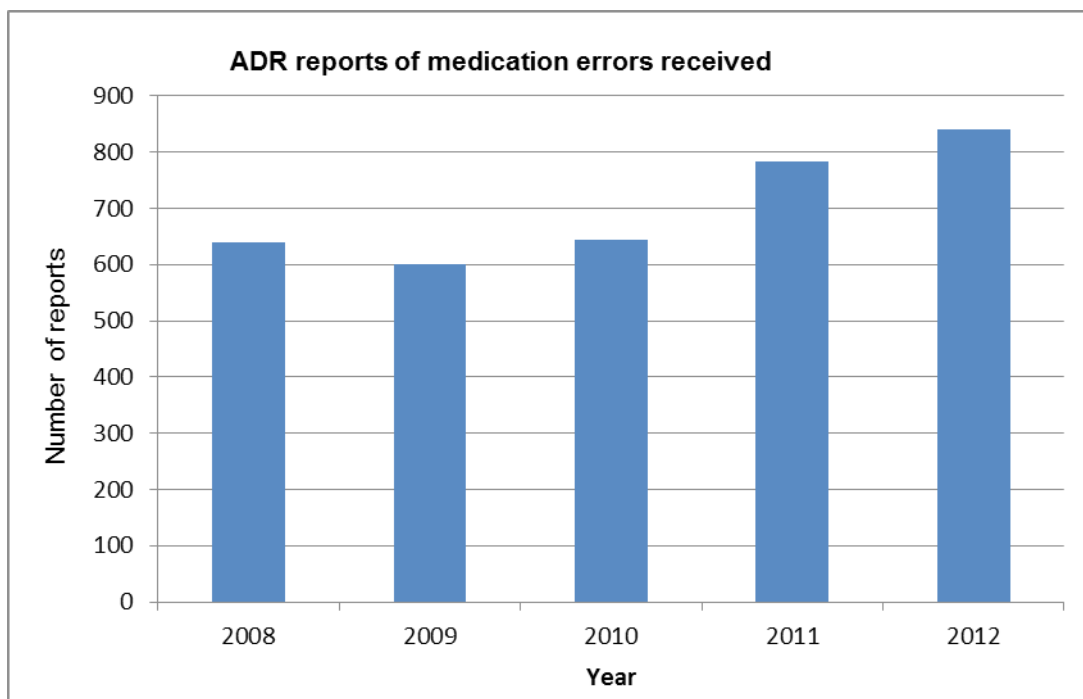
Further details about the MHRA's Yellow Card Scheme and ADR reporting statistics are available on the MHRA website: www.mhra.gov.uk