PrescQIPP Community Interest Company

Understanding the role of the Medicines Safety Officer/Medical Devices Safety Officer in CCGs - Commissioning Guidelines

The White Paper: Liberating the NHS outlined the intention to focus on clinical outcomes. It stated that success would be measured, not through bureaucratic process targets, but against results that really matter to patients.[1] Measuring and publishing information on health outcomes helps drive improvements to the quality of care people receive.[2]

The NHS Outcomes Framework was developed in December 2010, following public consultation, and has been updated every year to ensure that the most appropriate measures are included. Over time, the Department of Health has been improving the framework, by refining existing measurement indicators and developing new indicators.[2] To reduce the incidence of medication errors causing serious harm was one of the improvement areas identified in the NHS Outcomes Framework 2014 – 2015.[3]

NHS England and The Medicines and Healthcare products Regulatory Agency (MHRA) are working together to simplify and increase reporting, improve data report quality, maximise learning and guide practice to minimise harm from medication errors and medical device incidents.[3] To achieve this they issued two patient safety alerts to help healthcare providers increase incident reporting for medication errors and medical device incidents on 20th March 2014.[4] This joint working is in response to a number of strategic drivers which includes recommendations by Sir Robert Francis QC; Professor Don Berwick on patient safety; and a review by Earl Howe into MHRA's handling of the PIP breast implant fraud. All recommended taking steps to maximise the quality and quantity of adverse incident reports from healthcare organisations.[4]

Recommendations from NHS England and MHRA alerts

The alerts set out several actions for implementation by 19th September 2014. The actions to take depend on the size or type of provider and are as follows:

- Large healthcare providers including NHS Trusts, community pharmacy multiples, home healthcare companies and those in the independent sector (including certain large organisations providing care homes, e.g. Care UK and Healthcare Management Trust) should:

1. Identify a board level director to have the responsibility to oversee medication error/medical device incident reporting and learning; and,
2. Identify a Medication Safety Officer (MSO)/Medical Devices Safety Officer (MDSO) and email their contact details to the Central Alerting System (CAS) team; and
3. Identify an existing or new multi-professional group to regularly review medication error/medical device incident reports, improve reporting and learning and take local action to improve medication safety/safety of medical devices.[5,6]

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

1. Continue to report medication error/incidents involving medical devices to the National Reporting and Learning Systems (NRLS) using the e-form on the NRLS website, or other methods and the MHRA's online reporting system for medical devices. Take action to improve reporting, learning (medication errors and medical devices incidents) and medication safety locally.[5,6]

- Healthcare commissioners including Area Teams and CCGs are invited to:

1. Identify a MSO/MDSO and email their contact details to the CAS team; and,
2. 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/safety of medical devices.[5,6]

Background

A 'patient safety incident' (PSI) is defined by the National Reporting and Learning Systems (NRLS) 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.[7] The NRLS is a central database of PSI reports from NHS organisations. These reports are analysed by NHS England to identify hazards, risks and opportunities to continuously improve the safety of patient care.[8] NRLS reports include many types of incidents such as falls, diagnosis, surgery, medication and medical devices.[9] When a pattern of similar patient safety incidents is identified, the NHS England Patient Safety team are able to quickly highlight those risks to healthcare providers by issuing a patient safety alert to ensure appropriate interventions and resources can be put in place to prevent harm.[8]

An 'Adverse drug reaction' (ADR) is defined as, '*a response to a medicinal product that is noxious and produces 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*', by the EU Directive 2010/84/EU.[7] An ADR as a result of medication error should be reported to the NRLS, however suspected ADR reports which are not the result of a medication error continue to be collected by the MHRA through the Yellow Card Scheme.[7] The Yellow Card Scheme now supports the reporting of all suspected problems or incidents of all healthcare products. This includes side effects of medicines, vaccines, herbal remedies, homeopathic remedies, defective medicines, fake and counterfeit medicines and medical devices and medical device adverse incidents.

The MHRA defines a reportable 'adverse incident' concerning a medical device as '*any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health*'.[9]

The definition of a medical device in European and UK law is, '*any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:*

- *Diagnosis, prevention, monitoring, treatment or alleviation of disease;*
- *Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;*
- *Investigation, replacement or modification of the anatomy or of a physiological process; and*
- *Control of conception,*

and which does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means'.[9]

National guidance for reporting PSI and ADRs/adverse incident for medicine errors and medical device incidents

Progress has been made over the last decade to detect, report and learn from patient safety incidents and medical device safety incidents, but further improvements are needed to increase the number of incident reports, improve data quality and enhance learning.[7,9]

To support this, NHS England and the MHRA issued the alerts 'Improving medication error incident reporting and learning' and 'Improving medical device incident reporting and learning'. These alerts recommend that smaller healthcare provider organisations should continue to report medication and

device incidents, take action to improve medication and device safety locally and work with local safety champions.[4] The alerts also recommend that large healthcare provider organisations across a range of healthcare sectors, along with healthcare commissioners, identify named leaders in both medication and medical device safety roles (MSOs and MDSOs). These leaders will be supported by two new national networks for medication and medical device safety. The National Medication Safety Network and the National Medical Devices Safety Network is intended to link and provide support for these new safety officers to enable improved feedback on incident reports, improved methods to identify new risks and for sharing safer practices.[3] The networks will improve communication and feedback on reported safety issues, and enable safer practice to be discussed and shared through webinars, online forums, conferences and workshops.[4]

In addition to reporting the incident, MSOs/MDSOs should consider engaging with the manufacturer of the medication or device involved. Companies may be able to support healthcare professionals by providing clinical and educational materials which may prevent incidents in the future.

Reporting PSIs and ADRs for medicine errors

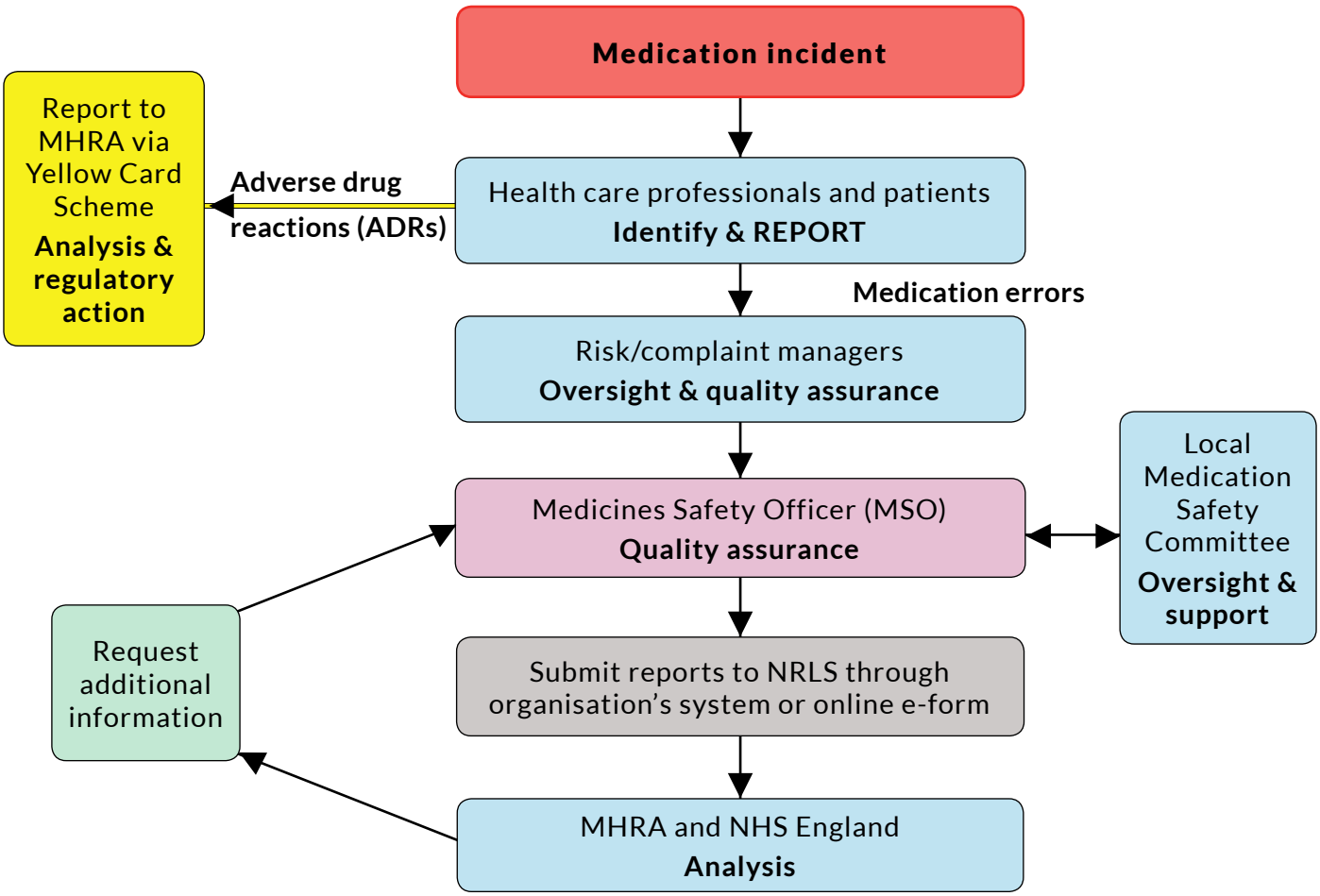
PSI involving medication errors in England are reported via the NRLS online at: http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/

Suspected ADRs not involving medication errors are reported via the MHRA through the Yellow Card Scheme online at: https://yellowcard.mhra.gov.uk/

It is good practice to share copies of submitted Yellow Card reports with the MSO for local learning and action.[7]

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

Figure 1: How medication error incidents and ADR should be reported - The flow of information[7]



Reporting PSIs and ADRs for medical devices

Incidents involving medical devices are reported via the NRLS, operated by NHS England and the MHRA. Not all types of medical devices incidents are of interest to both reporting systems. For example, incidents involving an unavailable device should be reported to NHS England but not to the MHRA. Incidents involving serious harm to members of staff or third parties should be reported to the MHRA but not NHS England.[9]

A new integrated NRLS route for reporting to NHS England and the MHRA is currently being developed and when it is operational, reporting to the MHRA will no longer be necessary.[9] This reporting route will be subject to thorough testing and healthcare organisations will be informed when it is operational.[9]

Serious patient incidents that have resulted in death or severe harm to a patient should be reported to the NRLS within two working days of the incident being identified. Moderate, low or no harm incidents should be reported to the NRLS in accordance with local procedures. Ideally, this should be each week.[9]

If a reportable adverse incident occurs these three basic reporting criteria should be reported to MHRA:

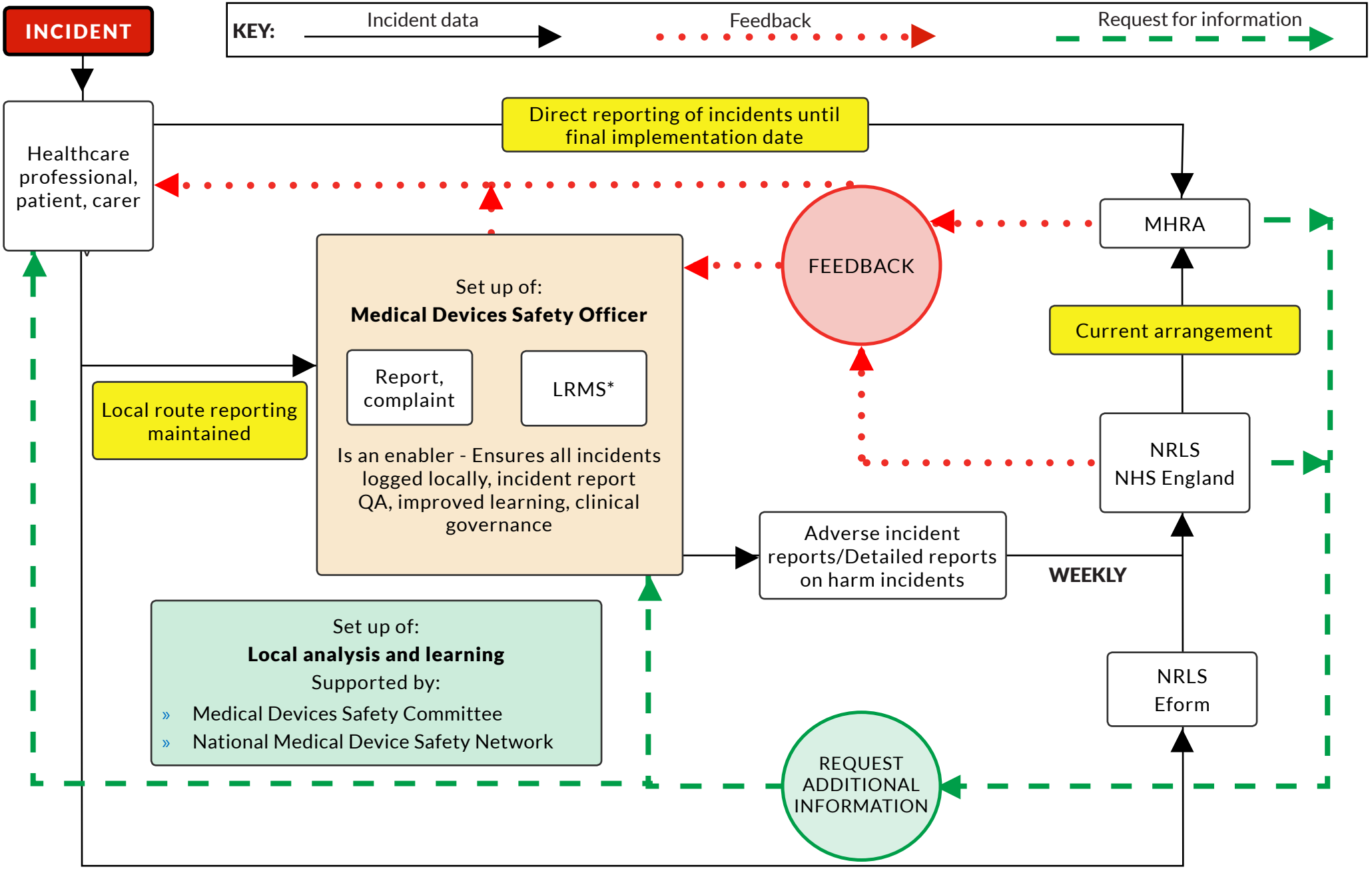
A. An event has occurred;

B. A medical device is suspected, or cannot be ruled out, as a contributory cause of the adverse incident; and,

C. The event led, or might have led, to one of the following outcomes;

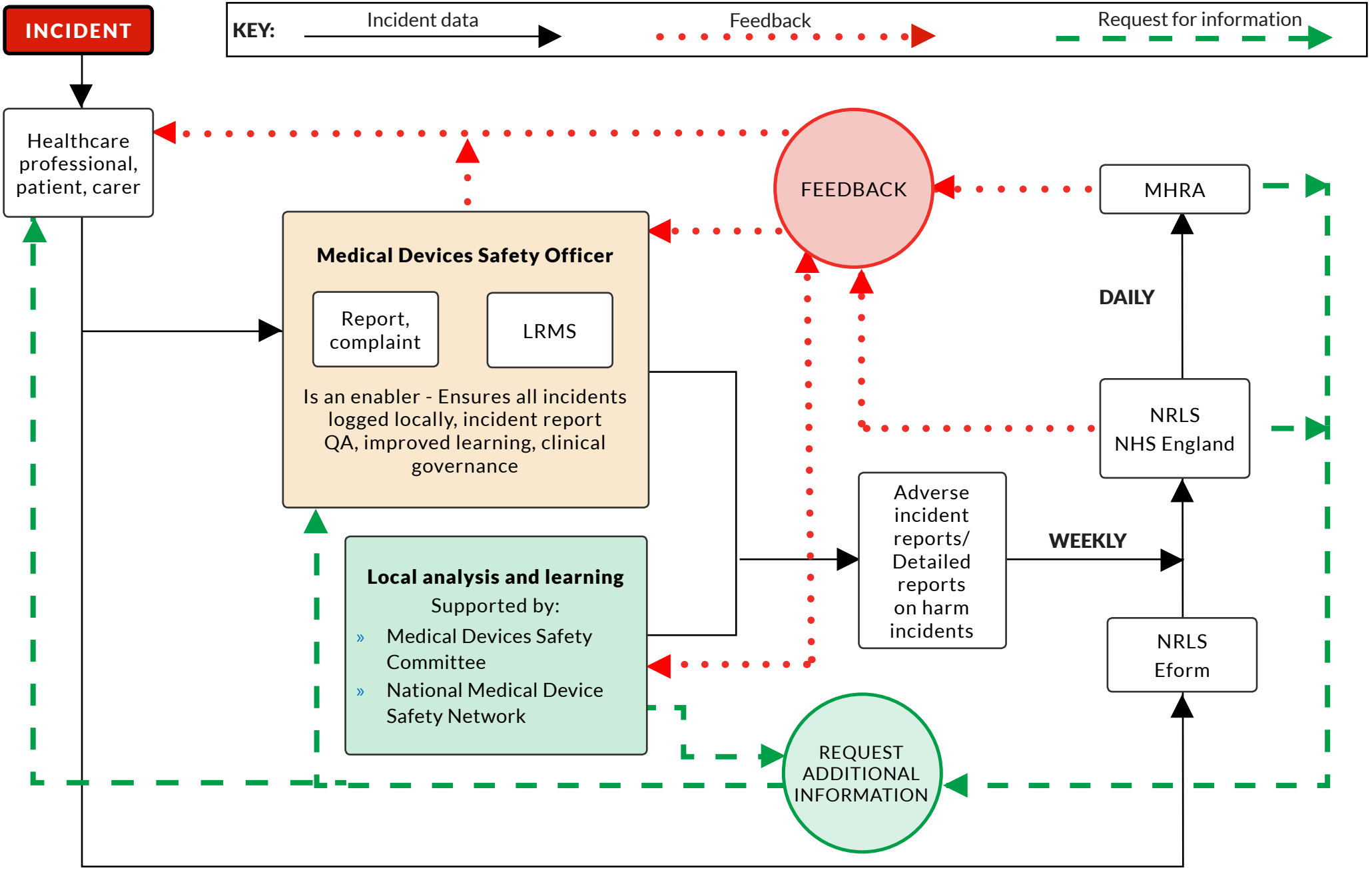
- Death of a patient, user or other person,
- Serious deterioration in state of health of a patient, user or other person.[9]

Figure 2: How medical device incidents should be reported until a new integrated NRLS reporting route is created[9]



*LRMS – Local Risk Management System

Figure 3: Reporting and feedback routes to and from MHRA and the NRLS/NHS England after the operational roll-out of the integrated NRLS reporting route[9]



Even after the systems are integrated it will still be possible for organisations not covered by this guidance to submit medical device incident reports directly to MHRA using the online device reporting system.[9]

Identifying, reporting and reviewing medicines-related problems in care homes

From 1 October 2010, all adult social care providers must notify the Care Quality Commission (CQC) under the Health and Social Care Act 2008 about specific incidents including medication errors and incidents. The notification must be made in writing and the CQC provide template forms to simplify the notification process. Further information and guidance is available on the 'Notifications' section of CQCs website www.cqc.org.uk[10]

As part of the CQC Essential Standards care homes are required to have *"arrangements for reporting adverse events, adverse drug reactions, incidents, errors and near misses. These should encourage local and, where applicable, national reporting, learning and promoting an open and fair culture of safety"*[10]

The National Institute for Health and Care Excellence (NICE) have produced a social care guideline on managing medicines in care homes.[11] This guidance makes the following recommendations for good practice relating to medicine-related problems and safeguarding:

- Commissioners and providers of health or social care services should ensure that a robust process is in place for identifying, reporting, reviewing and learning from medicines errors involving residents.
- Health and social care practitioners should consider working with all relevant stakeholders to develop a locally agreed action plan, in line with other local and national strategies and governance arrangements, for improving the safety of residents and reducing medication errors in care homes.
- Care home staff (registered nurses and social care practitioners working in care homes) should report all suspected adverse effects from medicines to the health professional who prescribed the medicine or another health professional as soon as possible; this would usually be the GP or out-of-hours service. Staff should record the details in the resident's care plan and tell the supplying pharmacy (if the resident agrees that this information can be shared).
- Commissioners and providers of health or social care services should all be aware of local arrangements for notifying suspected or confirmed medicines-related safeguarding incidents.
- Care home providers should have a clear process for reporting medicines-related safeguarding incidents under local safeguarding processes and to the Care Quality Commission (CQC) (or other appropriate regulator). The process should be recorded in the care home medicines policy and should clearly state:
  - When the CQC (or other appropriate regulator) should be notified.
  - Which medicines-related safeguarding incidents should be reported under local safeguarding processes and when.
  - Accurate details of any medicines-related safeguarding incidents are recorded as soon as possible so that the information is available for any investigation and reporting.
- Commissioners should ensure that reporting requirements are included in commissioning and contracting arrangements.[11]

NHS England Patient Safety Alerting System

In January 2014 the new National Patient Safety Alerting System (NPSAS) was launched to strengthen the rapid dissemination of urgent patient safety alerts to healthcare providers via the Central Alerting System (CAS).[12] The system builds on the strengths of the previous National Patient Safety Agency (NPSA) patient safety alerts and rapid response reports and is based on systems used in other high risk industries such as aviation.[12]

The NPSAS is a three-stage system and is used to disseminate patient safety information at different stages of development to NHS organisations providing care across all settings. It differs from the previous NPSA system by allowing more rapid dissemination of urgent information via the CAS, as well as encouraging information sharing between organisations and providing useful education and implementation resources to support providers in reducing risks to patients. Crucially it provides patients and their carers with greater confidence that the NHS is able to react quickly and rapidly to risks that are identified.[12] For primary care, relevant alerts will be cascaded via NHS England Area Teams.[12]

The three stages of NPSAS alerts are:

Stage One Alert: Warning

This stage 'warns' organisations of emerging risk. It can be issued very quickly once a new risk has been identified to allow rapid dissemination of information.[13]

Stage Two Alert: Resource

This alert may be issued some weeks or months after the stage one alert, and could consist of:

Sharing of relevant local information identified by providers following a stage one alert;

Sharing of examples of local good practice that mitigates the risk identified in the stage one alert;

Access to tools and resources that help providers implement solutions to the stage one alert;

Access to learning resources that are relevant to all healthcare workers and can be used as evidence of continued professional development.[13]

Stage Three Alert: Directive

When this stage of alert is issued, organisations will be required to confirm they have implemented specific solutions or actions to mitigate the risk. A checklist will be issued of required actions to be signed-off in a set timeframe. These actions will be tailored to the patient safety issue.[13]

The alerts "Improving medication error incident reporting and learning" and "Improving medical device incident reporting and learning" were both Stage Three Directives and therefore require confirmation of implementation.

Local implementation for the Medication Safety Officer (MSO) and Medical Devices Safety Officer (MDSO) role

For small healthcare providers

The alerts define small healthcare providers as GP practices, dental practices, community pharmacies (excluding large multiples) and those in the independent sector not defined in the supporting information as a large healthcare provider. They do not have to identify a MSO or a MDSO, however the alerts state that they should continue to report medication errors/medical device incidents to the NRLS and the MHRA as described above.

Local actions to improve reporting, learning and medication safety should be supported by medication/device safety champions in local professional committees, networks, multi-professional groups and commissioners. To help measure future improvements an assessment of the quality of reports of PSIs could be undertaken to use as a baseline.[14]

For large healthcare providers and healthcare commissioners

The alerts define large healthcare providers as NHS Trusts, community pharmacy multiples, home healthcare companies and those in the independent sector (including certain large organisations providing care homes, e.g. Care UK, Healthcare Management Trust). The supporting information for both alerts name companies and organisations specifically identified as large healthcare providers.[7,9] Healthcare commissioners are described as Area Teams and Clinical Commissioning Groups.

The recommendations in the alerts should be implemented by large healthcare providers; however healthcare commissioners are only invited to implement the actions. Considering the focus on clinical outcomes as stated in The White Paper: Liberating the NHS[1] and the NHS Outcomes Framework indicator to reduce the incidence of medication errors causing serious harm[2] it would be good practice and strongly advisable that Area Teams and CCGs also action the recommendations as commissioners are responsible for improving quality and safety in primary and secondary care.[7,9]

All large healthcare providers should identify a Board Level Director with the responsibility to oversee medication error/medical device incident reporting and learning.[5,6] This is not required of healthcare commissioners, but could be considered to be appropriate.

Both large healthcare providers and healthcare commissioners should identify a MSO/MDSO and consideration should be given to cover for that person during any planned and unplanned absence. A generic e-mail or group email that can be accessed by the covering person should be set up.[14] The CAS team should be notified of the MSO/MDSO's contact details and generic e-mail address.[5,6,14] CCGs may also like to ensure they have an effective system for receiving CAS Alerts. They can register with CAS to receive alerts directly.[7,9]

As part of their role the MSO/MDSO will be a member of the National Medication Safety Network/ National Medical Device Safety Network.[5,6] They should also work with regional or area networks, attend webinars organised by NHS England, look out for MSO/MDSO conferences and keep up to date with the content of the webinars and other information on http://www.patientsafetyfirst.nhs.uk[14]

The MSO/MDSO will support reporting and learning and take local actions to improve medication safety/medical devices safety.[5,6] To measure future improvements an assessment of the quality of the reports should be made to use as a baseline. Areas to assess could include how often fields are accurately completed, the number of times the reports are revisited to update information. The MSO should:

- Develop a system to aggregate Root Cause Analysis (RCA) and find out if they did actually lead to safer practice.
- Survey staff groups to determine their understanding of 'level of harm'. Investigate mechanisms locally for conveying to practitioners what has been done as a consequence of their reporting.
- Investigate the results of the Medicines Optimisation Dashboard and the Medication Safety Thermometer as independent surrogate measures of quality improvement.[14]

The MSO/MDSO should use learning to influence policy, planning and commissioning as part of clinical governance in the commissioning organisation.[5,6] Invited arrangements for improving reporting and learning from medication error/medical device incidents should be part of clinical governance structures in commissioning organisations. These structures should ensure that medication error/medical device incidents 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.[7,9] The MSO/ MDSO should consider how reporting is managed in their organisation, understand how serious incidents are reported, dealt with and ensure that these are also reported to the NRLS. They also need an understanding of how local reports are made and how these are transmitted to the NRLS. They should review all reports to ensure data quality for local and national learning and where necessary investigate and find additional information from reporters.[14]

They should 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/safety of medical devices.[5,6] The MSO/MDSO should also consider how reported incidents will be fed back[14] within their organisation and have procedures in place to allow effective feedback and learning. They should build relationships with existing organisation risk management or clinical governance team(s), obtain permissions to access NRLS 'live' so that amendments can be made, and investigate reports that are available locally from the NRLS data, e.g. the organisation's data compared to selected others. They should also make arrangements to regularly review and amend the quality of the reports for all identified serious and moderate incidents.[14]

The MSO/MDSO should work with medication safety champions/medical devices safety champions in local professional committees and networks, and with a new or existing multi-professional group.[5,6] They should check the representation of the group against Alert requirements and agree terms of reference with respect to reviewing incident reports, improving reporting and learning and taking local action to minimise harm to patients. They should clarify roles in the organisation with respect to incident reporting and agree mechanisms to feedback data on medication incidents to reporters.[14]

Summary

- The establishment of a MSO/MDSO role will help to improve medication error/medical device incident reporting and learning in the healthcare economy. A key role for the MSO/MDSO is to promote the safe use of medicines/medical devices and be the main expert in this area providing advice. In addition to improving reporting, the MSO/MDSO can serve as the essential link for the identification and implementation of (local and national) medication safety/medical devices safety initiatives.[7,9]
- Role responsibilities should include the following:
    1. Active membership of the National Medication Safety Network/National Medical Devices Safety Network.
    2. Improving reporting and learning from medication error/medical device incidents in the health economy.
    3. Receiving periodic summaries of medication error/medical device incidents reported from the NRLS to support learning.
    4. Analysing trends and issues and taking supportive action as appropriate.
    5. Working with the medication/medical devices safety committee to deliver responsibilities listed below.
    6. Using learning to influence policy, planning and commissioning.
    7. Working with medication safety/medical devices safety champions on local professional committees/networks such as the local pharmaceutical or medical committees and/or professional networks.
    8. Supporting the dissemination of medication/medical devices safety communications from NHS England and the MHRA.
- MDSO's also need to act as an additional senior point of contact for manufacturers supporting local actions on Field Safety Notices.[7,9]
- Responsibilities of the medication safety/medical devices safety committee
    1. Improving reporting and learning of medication/ medical device error incidents.
    2. Receiving summaries of NRLS incident data, audit and other data to identify, prioritise and address medication/ medical devices risks to minimise harm to patients.
    3. Identifying, developing and promoting best practice for medication/medical device 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/medical device errors occurring and reoccurring.
    4. Providing regular feedback and planning action to minimise these risks to healthcare providers.
    5. Using learning to influence policy planning and commissioning.
    6. Co-ordinating education and training support to improve the quality of medication/ medical device error incident reports and safe medication practices.
    7. Assisting in development and review of medication/medical devices use policies and procedures.[7,9]

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Contact info@prescqipp.info with any queries or comments related to the content of this document.