# 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

Contents

## 1. Introduction

The Patient Safety Alert on 'Improving medical devices incident reporting and learning' identified that progress has been made over the last decade to detect, report and learn from medical device safety incidents. Further improvements are needed to increase reporting, improve data quality, enhance learning and guide practice to minimise harm, from incidents involving medical devices.

The alert recommended changes to strengthen local clinical governance arrangements and the identification of Medical Devices Safety Officers (MDSOs) and multi-professional groups to review incidents and to improve the safety of medical devices. NHS England and the MHRA are working together to simplify reporting, improve learning and support practice to minimise harm from device-related errors. This initiative will be supported by the establishment of a national Medical Devices Safety Network intended to provide ongoing learning and identify and spread safety improvements across the health economy.

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

## 2. What are medical devices?

The term 'medical device' covers a broad range of products, used every day throughout the health economy to support the diagnosis, treatment and care of patients. The definition of a medical device in European and UK law[1] 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.'

## 3. What types of incidents should be reported?

There are currently two national reporting systems for incidents involving medical devices. One is operated by the Medicines and Healthcare Products Regulatory Agency (MHRA)[2] and the other, the National Reporting and Learning System (NRLS)[3], is operated by NHS England[4].

The NRLS defines a 'patient safety incident' as any unintended or unexpected incident, which could have or did lead to harm for one or more patients receiving NHS care[5]. NRLS reports include many types of incidents such as falls, diagnosis, surgery, medication and medical devices.

All serious 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 in accordance to the NHS Serious Incident Framework[6]. Other incidents reporting moderate, low or no harm should be reported to the NRLS in accordance with local procedures. Ideally, this should be each week.

The MHRA defines a reportable 'adverse incident' 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.'

Any event that meets 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.

 

For more detailed guidance on this see appendix A.

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.

As part of these initiatives a new, integrated NRLS route for reporting to NHS England and the MHRA will be developed. This reporting route will only become operational after thorough testing. NHS England and the MHRA will tell healthcare organisations when the new integrated NRLS reporting route has become operational at which point separate reporting to the MHRA will no longer be necessary.

**In the interim medical devices adverse incidents should continue to be reported to the MHRA and NRLS.**

## 4. National Reporting and Learning System

NHS England has the responsibility for the National Reporting and Learning System. Imperial College NHS Trust is commissioned to operate the NRLS. The system collects all types of patient safety incidents leading to any degree of harm, from all care settings and all specialities. All incident reports contain some categorical information and a free text description of what happened, why it happened and what is being done to prevent the incident from happening again. All serious incident reports are reviewed by clinical reviewers. Important new risks are shared with Clinical Expert Patient Safety Groups for further review and analysis.

Analysis of NRLS reports nationally has enabled new risks to be identified and communicated to the NHS through the use of Patient Safety Alerts, Rapid Response Reports and Signals by the National Patient Safety Agency in the past, and this function has been transferred to NHS England. Details of a new National Patient Safety Alerting System have recently been issued.

The NRLS was established as a voluntary national reporting system, however, in April 2010, when the Care Quality Commission (CQC) Registration Regulations 2009[7] came into force, it became mandatory for organisations registered to provide healthcare in England to report certain death and serious incidents to the CQC. NHS organisations fulfil their requirements under the regulations by reporting patient safety incidents to the NRLS and these reports are then being made available to CQC on a weekly basis.

In response to reporter feedback during 2013 and 2014, MHRA and NHS England are improving the NRLS reporting route to enable it to function as a medical device reporting route for MHRA, see below for further detail.

## 5. MHRA's medical devices reporting system

All medical device adverse incident reports submitted to MHRA are subject to a risk assessment and triage system carried out by medical device specialists and clinical advisers. This process, which takes between three and five days from receipt of a report to triage determination, allows MHRA to focus their specialist resources directly on those issues that present the greatest risk to patient safety, and where their active intervention will help to resolve the problem. As part of this process, not only are all incident reports recorded, risk assessed and reviewed, but investigations are supported by systems for identifying, analysing and acting on emerging incident signals, patterns and trends. These systems are regularly refined and updated based on experiences.

There are three ways in which MHRA acts on incident reports.

1. For incidents where MHRA needs to intervene directly, a medical device specialist will take personal responsibility for leading the investigation in conjunction with the clinical team. These specialist-led investigations may involve contact with the user of the device (via the Medical Device Safety Officer if necessary), the reporter and the manufacturer. Exceptionally, MHRA may also need to visit the site where the device was used and examine and analyse the device concerned.
2. MHRA pursue other incident reports directly with the manufacturer. The manufacturer is legally required to investigate the incident, which is done under the supervision of MHRA, and to report back as soon as possible so that MHRA can assess their findings and any proposed actions.
3. Some incident reports may not be investigated immediately but are recorded in detail on MHRA's adverse incident database as part of the continuing trending and surveillance process. This database covers all incident reports and is central to MHRA's strategy for handling adverse incidents. The continuous analysis of the collated adverse incident data not only gives important background data for triage and investigation processes, but also allows MHRA to initiate new investigations where those data have identified emerging problems and/or unexpected reporting trends.

 

This overall process ensures that every incident report not only contributes to MHRA's knowledge about medical devices and their use, but also that appropriate action is taken to prevent similar problems recurring.

Examples of the causes of adverse incidents are:

- design or manufacturing problems;
- poor user instructions or training (which may result in incorrect user practice);
- inadequate servicing and maintenance;
- inappropriate local modifications;
- unsuitable storage and use conditions;
- use of the wrong device for the intended purpose; and,
- inappropriate management procedures.

A summary of outcomes from investigations during 2012 can be found in appendix B.

It is important for reporters to realise that MHRA cannot ensure that manufacturers modify medical devices or labelling design on the basis of a single report, unless, as occasionally happens, it is clear from the initial report that the device or labelling is not functioning as intended. In the majority of cases, enough evidence needs to be gathered in the form of further reports or other scientific evidence before it can reasonably be argued that the device or labelling is not functioning as intended. For all device types, trigger levels for further investigation have been set. Therefore it is important for reporters to continue to report further adverse incidents when they happen, rather than assuming that nothing will come of these reports. When enough evidence is submitted, MHRA will act within the measures of the law. It is through these systems, coupled with the planned joint partnership working, that MHRA can play its full role and can help to protect the safety of patients and other medical devices users.

## 6. What is the burden of harm from medical devices?

Medical devices and technologies can contribute to effective patient care. However, most are also complex and their effective application relies on a complex interplay of factors. Thus, they can actually cause harm, if design flaws are not identified and rectified, equipment is not adequately maintained or prepared for use, or proper use procedures are not established and followed.

In 2012, 38,395 incidents relating to medical devices were reported to the NRLS from the NHS in England (see appendix C). There are key findings from the analysis of the 2012 data are.

- the majority of incidents are reported as resulting in no harm (83.7%) but a substantial number or reports were reported as resulting in moderate harm (n=1044), severe harm (n=82) and death (n=13);
- more than a third of reports were categorised as 'failure of device/ equipment' (37%) and more than a third were categorised as 'lack/unavailability of device/ equipment' (36.8%);
- the majority of incidents were reported from acute hospitals (88.6%) followed by community services (7.8%)

Similarly, of the 13,549 reports received by MHRA in 2012

- 2.2% were reported as resulting in death and 33.2% as serious injury; the remaining 64% were a combination of minor or no injury.
- healthcare organisation/ user responsibility were the causes of 25% of the incidents (e.g. training), 28% were manufacturer responsibility (eg quality assurance) and in 47% there was no established device or use link
- The majority of incidents were reported from manufacturers (53%), followed by the NHS (31%) - the full breakdown of all of these can be found in appendix B.

## 7. Why changes are needed to improve reporting and learning from medical device incidents

### 7.1. National safety reviews

Following serious problems with Poly Implant Prosthese (PIP) breast implants in 2011, the Department of Health issued a report in May 2012[8] which included the following recommendations:

 

- maximise reporting of adverse device incidents and for ensuring that reports are of high quality;
- MHRA should work with partners to explore the potential for strengthening the network of Medical Device Liaison Officers, and emphasising the importance of the role within healthcare providers;
- all parties, healthcare professionals, providers and patients, as well as industry, must be involved in the vigilance system as equal partners with the single aim of reducing the risk of harm to patients from medical device incidents; and,
- MHRA should therefore continuously review its activities to ensure that everything it does is consistent with this aim, and that it promotes this shared aim amongst all those involved in medical device vigilance.

In April 2013 the Department of Health issued a report on *The Regulation of Cosmetic Interventions*[9] that included the following recommendations:

- it is clear that the role and practice of the adverse event reporting system, and the duty on health professionals to report, needs to be better understood;
- the Director of Patient Safety for NHS England should develop a framework to encourage and support the reporting of suspected device failures to the MHRA;
- assessment of systems for reporting adverse events should be part of CQC's registration and assessment of providers. Adverse incident reporting should be a standard component of professional appraisals and revalidation; and,
- Medical Device Liaison Officers - members of staff designated in all NHS trusts and primary care trusts in England who are responsible for encouraging effective and comprehensive adverse incident reporting and action on medical device safety publications through encouragement and training of healthcare and support staff and medical device users.

In *'A Promise To Learn – A Commitment to Act. Improving The Safety Of Patients In England'*[10], it was recommended that the NHS develop systems devoted to:

- continual learning and improvement of patient care, top-to-bottom and end-to-end;
- sharing all data on quality and safety in a timely fashion, with all parties who require it; and,
- establish safety improvement collaboratives to identify and spread safety improvement approaches across the NHS.

## 7.2. Data quality in the NRLS and local and national learning from incidents

To improve learning at all levels in the NHS and facilitate vigilance responsibilities of the MHRA, there is an urgent requirement to improve the volume, timeliness and quality of reports concerning medical devices to the NRLS and MHRA.

Analysis of 38,395 medical devices incidents reported to the NRLS as occurring between 1 Jan – 31 Dec 2012 illustrates some of the data quality issues that required to be addressed in medical device incident reports from the NHS.

| Data quality issue | NRLS field name | Description | % of total |
|---|---|---|---|
| Delayed report | IN01 | Date of incident; Incident reported more than 4 weeks after the incident | 49.7% |
| Data not recorded | DE03 | Device/ product name | 65% |
| Data not recorded | DE07 | Manufacturer | 82.3% |
| Data miscoded | IN05 | Use of the term 'other' in the incident category level 2: | 14.5% |
| Data miscoded | DE01 | Use of the term 'other' in type of device | 32.4% |
| Data not recorded | IN10 | Action taken to prevent recurrence | 47.7% |
| Data not recorded | IN11 | Apparent causes | 68.1% |
| Data miscoded | PD09 | Clinical outcome codes indicating death or severe harm | 40% |

 

Incident reports are not always reviewed locally by NHS staff with medical device safety expertise as a quality check and to initiate action prior to submission to the NRLS.

Senior Managers in NHS 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 to communicate with individuals with the relevant technical knowledge to provide supplemental information concerning specific incidents.

## 8. MHRA and NHS England partnership to improve reporting and learning

MHRA and NHS England have formed a strategic partnership to improve reporting and learning in medical device safety. This partnership includes joint working on several strategic initiatives, as follows:

1. the NRLS as an integrated reporting route for medical device incidents;
2. developing enhanced governance systems including medical or nursing director oversight at board level, introduction of a Medical Device Safety Officer with an enhanced role (replacing the Medical Device Liaison Officer), strong links with a local multi-professional medical device safety committee;
3. developing a national medical device safety improvement network; and,
4. improving feedback.

### 8.1. Developing the NRLS as an integrated reporting route for medical device incidents

Until a new integrated NRLS reporting route is created, the reporting route and feedback systems will be as set out in Figure one below.

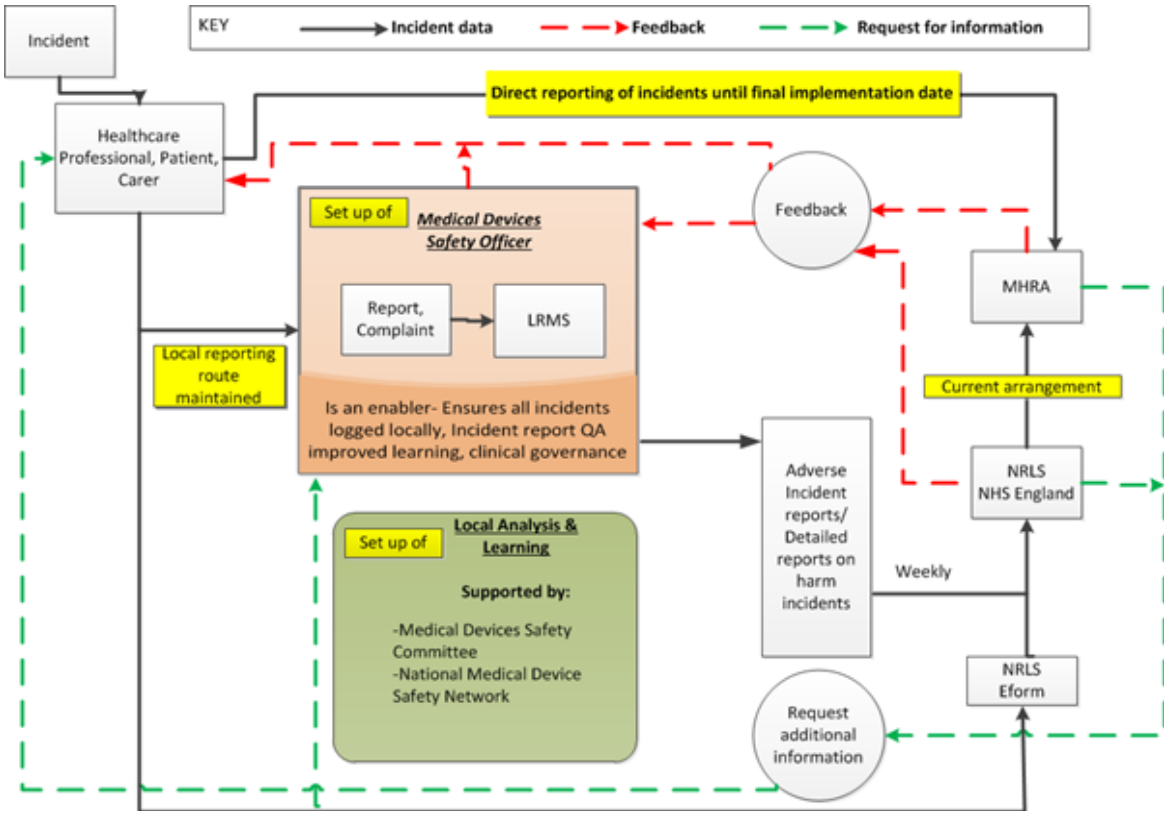


Figure one: Reporting and feedback routes to and from MHRA and the NRLS/NHS England before the operational roll-out of the integrated NRLS reporting route. Once the new integrated reporting route is operational the reporting routes and feedback systems will be as set out in Figure two.

 

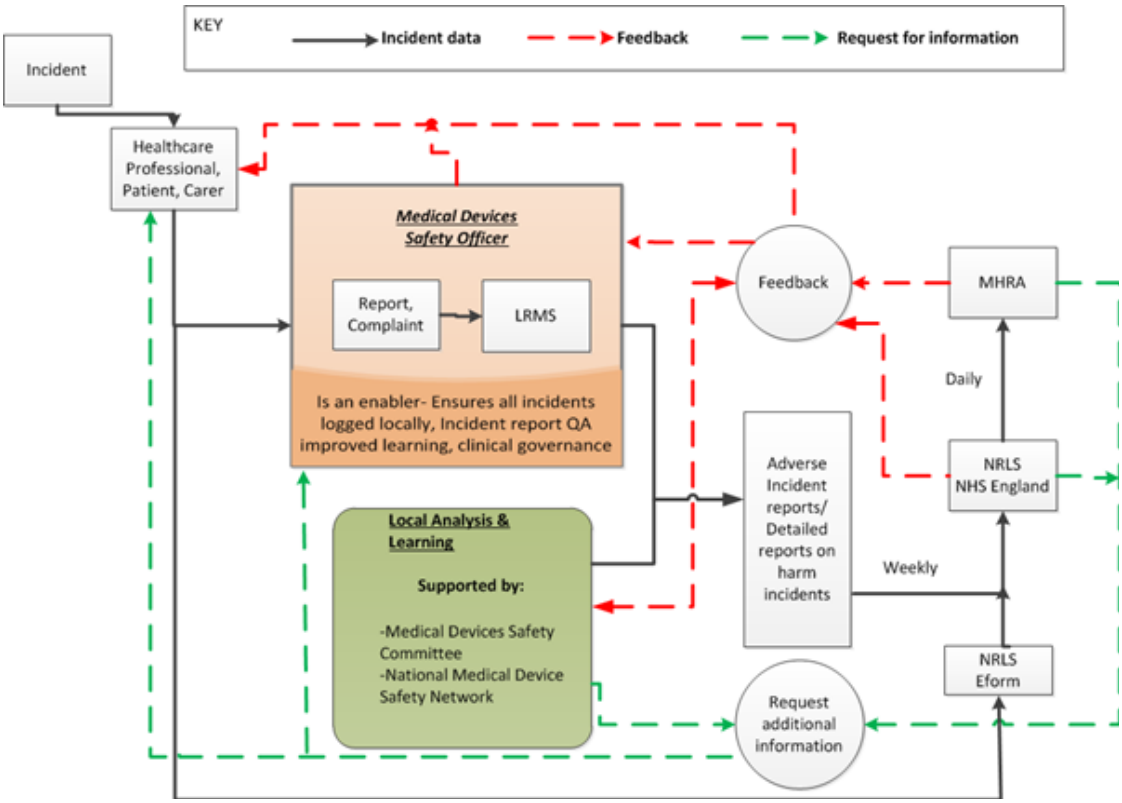


Figure two: Reporting and feedback routes to and from MHRA and the NRLS/NHS England after the operational roll-out of the integrated NRLS reporting route.

In order for the integrated reporting system to function as intended essential information about medical device incidents needs to be:

- gathered and included in the Local Risk Management System; and,
- sent **immediately** to the NRLS for MHRA.

This will mean changes to existing systems and practices.

Further information about completing medical device incident reports for the NRLS can be found at appendices D and E.

**Note**: 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. Actions

### 9.1. Actions for large healthcare provider organisations

#### 9.1.1.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.

 

### In community pharmacy

Community pharmacy 'multiples', 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
- W.R. Evans (Chemist) Ltd.

### Independent sector

The following independent sector 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
- Huntercomber 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

### Home healthcare companies

The following home healthcare companies:

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

 

### 9.1.2. The oversight role of the medical / nursing director

A board director (medical or nursing supported by a senior healthcare professional) or in community pharmacy or home healthcare a senior manager (for example a Superintendent Pharmacist), should have the responsibility to oversee medical devices incident reporting and learning systems.

In the independent sector, ensure that there is an auditable line of delegated authority from the board to the Medical Devices Safety Officer (MDSO) and that the board still oversees medical device incident reporting and learning.

The board director or senior manager should foster a safety culture and satisfy themselves that these 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.

An existing or new mult-professional group for medical devices safety should be identified, along with a MDSO.

These individuals should have relevant knowledge and experience, and their current role should cover appropriate responsibilities. The Central Alerting System team should be given the MDSO's contact details (see appendix F).

### 9.1.3. The role of the Medical Devices Safety Officer (MDSO)

The establishment of a MDSO role is integral to improving medical device incident reporting and learning within organisations. One of the MDSO's key roles is to promote the safe use of medical devices across their organisation and provide expert advice. As well as improving the quality of reporting, the MDSO will be the essential link between the identification and implementation of (local and national) medical devices safety initiatives and the daily operations to improve the safety of medical devices.

*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 a 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.

### 9.1.4. The role of the Medical Devices Safety Committee

An established or new multi-professional committee should be identified to support the safe use of medical devices in the organisation, made up of:

- medical staff;
- nursing staff;
- pharmacy staff;
- biomedical science/engineering staff;
- people working in risk management;
- general management; and,
- and patient representation is recommended to support the safe use of medical devices in the organisation.

 

*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.

## 9.2. Action for small organisations

### 9.2.1. Definition of a small organisation

Any healthcare provider organisation not defined in section 9.1 including general medical practices, dental practices, community pharmacies and small organisations in the independent sector.

### 9.2.2. Reporting and learning

Continue to report medical device error incidents 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 local reporting and medical devices safety.

### 9.2.3. Communication and support

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

### 9.2.4. Medical device safety champions

Medical device safety champions are individuals who take an active role in improving the safe use of medical devices. Champions can be from any discipline or setting including the voluntary sector. A safety champion should be someone who is already working to improve patient safety.

**Note**: It is not the intention of this alert to require the appointment of safety champions, however, where such champions are active, organisations should endeavour to capitalise on the contributions they can make.

## 9.3. Invited actions for healthcare commissioners

### 9.3.1. Definition of healthcare commissioners

Healthcare commissioning organisations buy 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 get support from Commissioning Support Units. Both types of commissioners have responsibilities to improve quality and safety in primary and secondary care.

### 9.3.2. The oversight role of clinical governance

Invited arrangements for improving reporting and learning for medical device incidents should be part of clinical governance structures in commissioning organisations. These structures should ensure that medical device incident 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.

Commissioners are invited to identify an existing or new multi-professional group for medical devices safety and a MDSO.

 

These individuals should have appropriate knowledge and experience, and their current work is likely to cover broadly similar responsibilities. NHS England and the MHRA should be given this person's contact details via the Central Alerting System (CAS), see appendix F. CCG's may also like to ensure they have an effective system for receiving CAS Alerts. They can register with CAS to receive Alerts directly.

### 9.3.3. The role of the Medical Devices Safety Officer

The establishment of a MDSO will help to improve medical devices incident reporting and learning within a healthcare economy. A key role for the MDSO is to promote the safe use of medical devices and to provide expert advice. In addition to improving reporting, the MDSO can serve as the essential link for the identification and implementation of (local and national) medical devices safety initiatives.

*Role responsibilities should include:*

i. active membership of the National Medical Devices Safety Network;
ii. improving reporting of and learning from medical device incidents in the health economy receiving periodic summaries of medical device incidents reported within the health economy from the NRLS to support learning;
iii. analysing trends and issues and taking appropriate supporting action;
iv. working as a member of the medical devices safety committee to deliver the responsibilities listed in 9.3.4;
v. using learning to influence policy planning and commissioning work with medical devices safety champions on local professional committees/networks such as the local pharmaceutical or medical committees and/or professional networks;
vi. supporting the dissemination of medical devices safety communications from NHS England and the MHRA; and,
vii. acting as an additional senior point of contact for manufacturers supporting local actions on Field Safety Notices.

### 9.3.4. The role of the medical devices safety committee

A new or existing multi-professional committee should be set up to support the safe use of medical devices. The group should be made up of:

- medical staff;
- nursing staff;
- pharmacy staff;
- biomedical science/engineering staff;
- people working in risk management;
- general management; and,
- patient representation which is recommended to support the safe use of medical devices in the health economy.

*Role responsibilities should include:*

i. improving reporting of and learning from medical device error receive summaries of NRLS incident data, audit and other data to identify, prioritise and address medical devices risks and minimise harm to patients;
ii. identifying, developing and promoting best practice for medical device 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 errors occurring or reoccurring;
iii. using learning to influence policy, planning and commissioning;
iv. coordinating education and training support to improve the quality of medical device error incident reports and safe medical devices practices; and,
v. assisting in the development and review of medical devices use policies and procedures.

## 10. The National Medical Devices Safety Network

The Patient Safety Domain at NHS England and the MHRA are planning additional support for Medical Devices Safety Officers. Once contact details of these safety officers have been communicated to the Central Alerting System (CAS), the network will be established.

Membership of the national network is expected to include representatives from national organisations with a role to play in medical device safety. Where necessary for particular safety issues, it may also draft in short-term specific expertise. The aim of the network is to:

 

- ensure effective dialogue between all partners in the collaborative;
- ensure effective reporting of medical device incidents, throughout the health system;
- share learning from reporting;
- disseminate relevant research and information about new risks and best practices; and,
- educate and train Medical Device Safety Officers in medical device safety science.

It is envisaged that Medical Devices Safety Officers will participate in regular online meetings (e.g. WebEx) and email discussion groups, and be given online information on local and national learning. These will include the identification of new risks and best practices to minimise these risks, implementing medical device safety guidance, and improving incident reporting quality and learning.

Initial specific improvement aims are:

- increased numbers of reports of medical device incidents;
- improved timeliness of when these reports are sent to the NRLS;
- improved quality of medical device incident reports,
    - NRLS data fields completed,
    - accuracy of use NRLS codes,
    - description of the incident – sufficient for learning,
    - development of use of international nomenclatures,
    - increased number of new safety issues detected,
- wider implementation of local actions to minimise harms from identified risks; and,
- measures for improvement to safer practice.

## 11. Improving feedback

### 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 medical devices incidents for each organisation is not provided as part of this summary.
It is available at: www.nrls.npsa.nhs.uk/patient-safety-data/organisation-patient-safety-incident-reports.

It is planned that all MDSOs will receive feedback on the data quality of medical device incident reports every six months to give an independent assessment on whether incident data provides enough information for local and national learning.

#### 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 the NRLS medical device 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/medical-device-equipment

NHS England published details of a new National Patient Safety Alerting System on 31st January 2014, details are available at: www.england.nhs.uk/ourwork/patientsafety/psa/national-psa-system/

### 11.2. Feedback from the MHRA

The MHRA provides routine feedback on the outcome of individual investigations. In addition, MHRA website users can sign up for email alerts on new topics in their areas of interest.

The MHRA will be progressively trialling and introducing new forms of summarised and grouped incident investigation feedback on incidents submitted from all report sources.

#### Medical Device Alerts and other safety warnings

Details of Medical Device Alerts (and earlier types of safety warnings) are available at:
www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/index.htm

 

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

Where the report gives incomplete or unclear information for learning or where more information is needed about actions taken locally to help mitigate similar incidents in the future, the Patient Safety Domain in NHS England or the MHRA may contact the MDSO for more information.

Healthcare organisations are responsible for notifying and updating the CAS team with contact details of MDSOs.

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

The NHS Constitution states that patients have the right to complain about their treatment, have the complaint dealt with efficiently, properly investigated and be given a full and prompt reply.

Patients should normally inform their service provider (such as 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 medical devices. It is important that learning from this information is not lost and relevant information in complaints from patients is shared with the NRLS by healthcare organisations
Relevant complaints about medical devices will also be sent to MHRA.

Medical Device Safety Officers should develop effective working links with complaints and risk managers in organisations, and arrange that, where appropriate, incident information in a complaint can be used for learning and communicated via the NRLS.

## 14. How should the Strategic Executive Information System (STEIS) reporting system be used alongside NRLS?

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

The use of the STEIS reporting system does not mean that medical device incidents do not need to be reported to the NRLS and MHRA. Information reported to the STEIS is not shared with NHS England's Patient Safety Domain or the MHRA for national learning. It is essential that serious incidents are reported to the NRLS and MHRA as well as through the STEIS to support national learning.

A serious incident framework for use by all NHS organisations in England was published in March 2013. The framework outlines the process for reporting information about serious incidents the STEIS, the NRLS and in the case of incidents involving medical devices to the MHRA.

 

## Appendix A: More information about the types of adverse incident that should be reported to the MHRA

Any event which meets all three basic reporting criteria **A – C** listed below is considered to be an adverse incident and should be reported to the MHRA.

### A: An event has occurred

This includes situations where testing performed on the device, examination of the information supplied with the device or any scientific information indicates some factor that could lead or has led to an event.

Typical events include, but are not limited to:

a. a malfunction or deterioration in the characteristics or performance. A malfunction or deterioration is a failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions;
b. for in vitro diagnostic devices (IVDs) where there is a risk that a wrong result would either,

    i. lead to a patient management decision resulting in an imminent life-threatening situation to the individual being tested, or to the individual's offspring, or
    ii. cause death or severe disability to the individual or fetus being tested, or to the individual's offspring, all false positive or false negative test results are considered as events. For all other IVDs, false positive or false negative results falling outside the manufacturer's declared performance of the test are considered as events;

c. unanticipated adverse reaction or unanticipated side effect;
d. interactions with other substances or products;
e. degradation/destruction of the device (eg fire);
f. inappropriate therapy; or,
g. an inaccuracy in the labelling, instructions for use and/or promotional materials.
h. Inaccuracies include omissions and deficiencies. Omissions do not include the absence of information that should generally be known by the intended users.

**Note:** see ISO TS 19218 adverse event type and cause/effect coding for further details on events.

### B: A medical device is suspected to be a contributory cause of the incident

In assessing the link between the device and the adverse incident the reporter should take account of:

- the opinion, based on available evidence, of those involved in the incident; healthcare professionals and those staff with a good knowledge of the medical device; or
- evidence of previous, similar adverse incidents.

This judgement may sometimes be difficult when there are multiple devices and drugs involved. In complex situations, it should be assumed that the device may have caused or contributed to the adverse incident and the reporter should err on the side of caution and submit a report.

### C: The event led, or might have led, to one of the following outcomes:

- death of a patient, user or other person; or,
- serious deterioration in state of health of a patient, user or other person.

A serious deterioration in state of health can include:

a. life-threatening illness;
b. permanent impairment of a body function or permanent damage to a body structure;
c. condition requiring medical or surgical intervention to prevent a or b:
    - examples include a clinically-relevant increase in the duration of a surgical procedure
    - or a condition that requires hospitalisation or significantly longer hospitalisation;

 

d. any indirect harm (see definition in Appendix G ) as a consequence of an incorrect diagnostic or IVD test result or as a consequence of the use of an IVF/ART device when used within the manufacturer's instructions for use (use errors should also be reported); or,
e. foetal distress, foetal death or any congenital abnormality or birth defects.

**Note:** not all adverse incidents lead to death or serious deterioration in health. The non-occurrence of such a result might have been due to other fortunate circumstances or to the intervention of healthcare personnel.

## Appendix B: An analysis of medical device incident reports submitted to MHRA

Figure 1: Total number of reports received

| 2008 | 2009 | 2010 | 2011 | 2012 |
|---|---|---|---|---|
| 8,910 | 9,906 | 10,282 | 10,967 | 13,549 |

Figure 2: Adverse Incident report sources

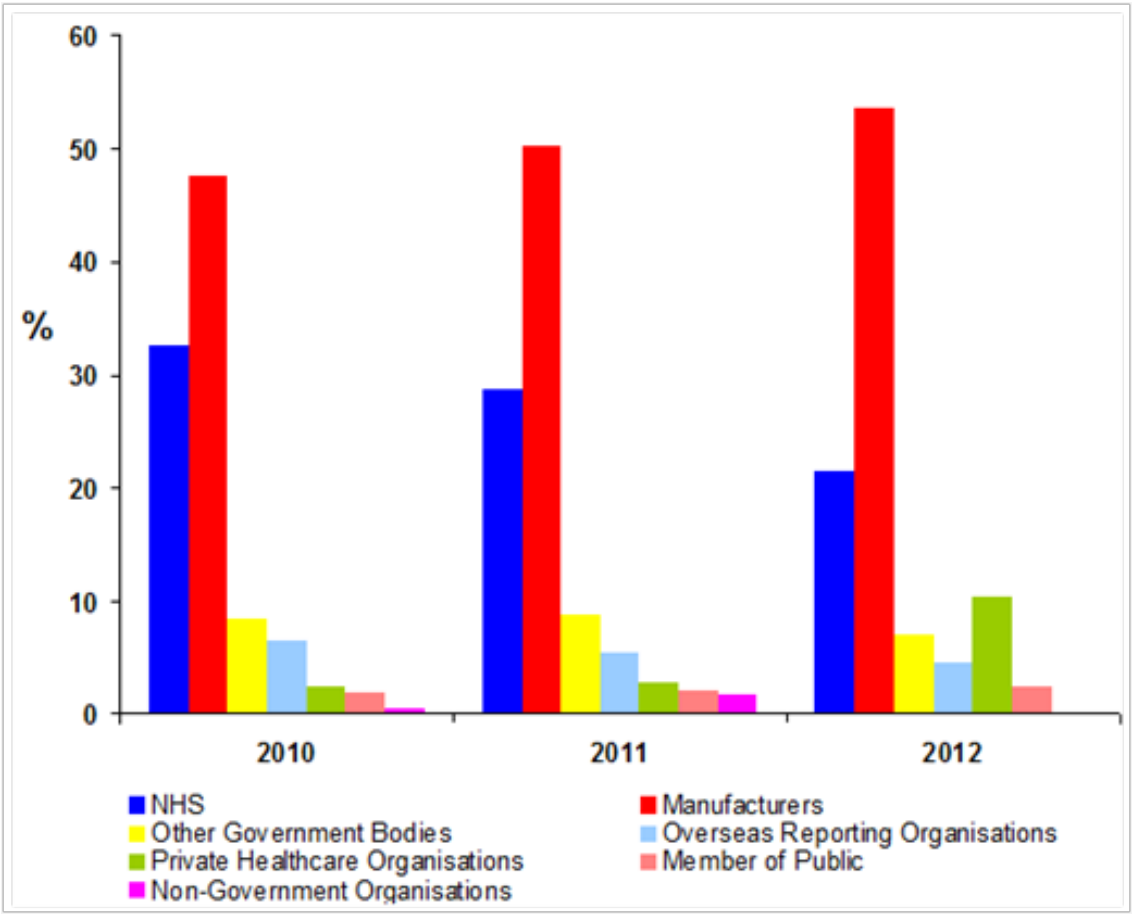


 

Figure 3: Comparative data 2010-2012

| Description of reports or action taken | 2010 | | 2011 | | 2012 | |
|---|---|---|---|---|---|---|
| | No. of reports | % | No. of reports | % | No. of reports | % |
| Reported as involving a fatality | 301 | 2.9% | 294 | 2.7% | 303 | 2.2% |
| Reported as involving a serious injury *(including implant or pacemaker revision)* | 2,382 | 23.2% | 2,941 | 26.8% | 4,495 | 33.2% |
| Prompted MHRA led investigations | 2,227 | 21.7% | 1,598 | 14.5% | 2,001 | 14.8% |
| Investigated by manufacturers under MHRA supervision | 4,256 | 41.4% | 3,648 | 33.2% | 4,694 | 34.6% |
| Not requiring immediate MHRA action. Recorded on database for trend monitoring and pattern detection | 2,064 | 20.1% | 4,158 | 37.9% | 5,704 | 42.1% |
| Reports of incidents similar to those already received by the MHRA | 796 | 7.7% | 662 | 6.0% | 625 | 4.6% |
| Reports from secondary sources, duplicating existing reports | 676 | 6.6% | 704 | 6.4% | 696 | 5.1% |
| Reports not relating to medical devices | 110 | 1.1% | 148 | 1.3% | 185 | 1.4% |
| Reports investigated by other organisations and their conclusion made available to the MHRA | 103 | 1.0% | 45 | 0.4% | 58 | 0.4% |

Figure 4: Causes of adverse incidents

The MHRA's Adverse Incident Tracking System (AITS) incorporates many levels of categorised, contributory causal factors that are used in the record of each incident investigation. The first level has three options.

*Healthcare establishment/user responsibility*

After delivery, eg maintenance failures and degradation due to storage outside specification.

*Manufacturer responsibility*

Before delivery, eg design, manufacture, quality control and packaging.

*No established device/use link*

Where either the device was subsequently found to work as intended (possibly due to an intermittent fault, tampering or use error, or where the report was made on a precautionary basis) or where the device involved was not available for investigation.

The data below have been taken from adverse incident investigations that have been finished. We can only draw tentative conclusions from any apparent changes as they may simply reflect the continued pattern of change in numbers of reports received from medical device users and from manufacturers. A further influencing factor is that the device is not available for examination and testing as, despite clear MHRA advice, the device is often thrown away by the user before any investigation can take place.

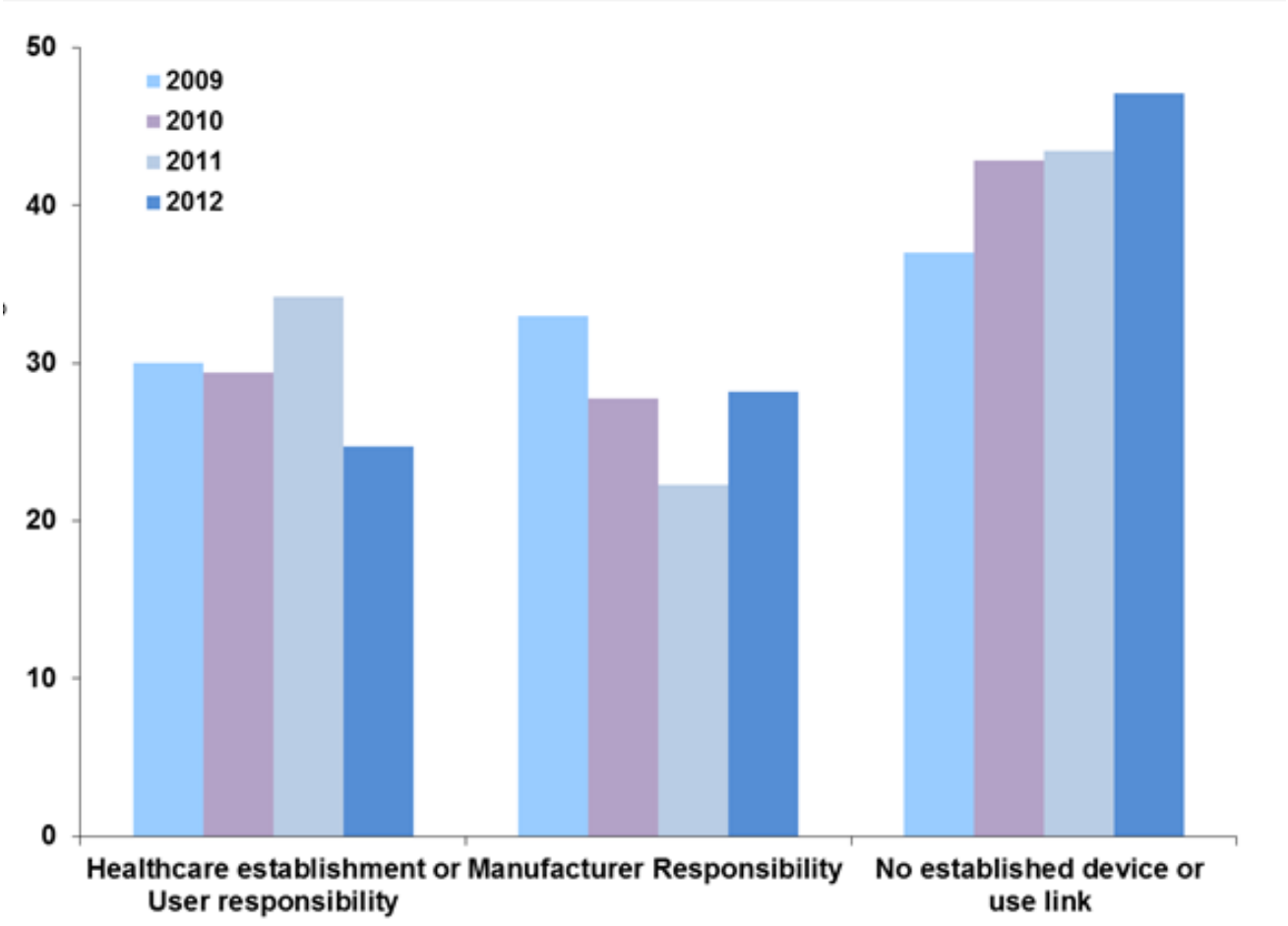


 

Figure 5: Safety Warnings issued

| | 2011 | 2012 | 2013 (up to 01/08/13) |
|---|---|---|---|
| **MDA action** | 113 | 83 | 60 |
| **CA to CA notification (National Competent Authority Report)** | 157 | 255 | 147 |

Figure 6: Safety warnings issued 1st January 2011- 1 August 2013, in relation to report source

| | |
|---|---|
| **Competent authority (CA)** | 17 |
| **Devolved administration** | 3 |
| **Manufacturer** | 166 |
| **MHRA** | 8 |
| **Others** | 5 |
| **Professional user** | 61 |
| **Grand Total** | **260** |

| | |
|---|---|
| **NHS TRUST** | 53 |
| **PRIVATE** | 4 |
| **SOCIAL CARE** | 3 |
| **OTHER** | 1 |

(Other is the United Kingdom National External Quality Assessment Service (UK NEQAS) for Microbiology)

 

## Appendix C: An analysis of NRLS medical devices incident reports in England in 2012[1]

Table 1: Degree of harm

| Degree of harm | Number of reports | Percentage |
|---|---|---|
| No Harm | 32,142 | 84 |
| Low | 5,114 | 13 |
| Moderate | 1,044 | 3 |
| Severe | 82 | <1 |
| Death | 13 | <1 |
| **Total** | **38,395** | **100** |

Table 2: Incident sub-category

| Incident sub category | Number of reports | Percentage |
|---|---|---|
| Failure of device / equipment | 14,218 | 37 |
| Lack / unavailability of device / equipment | 14,121 | 37 |
| Other | 5,582 | 15 |
| User error | 3,496 | 9 |
| Wrong device / equipment used | 971 | 2 |
| Blank | 7 | 0 |
| **Total** | **38,395** | **100** |

Table 3: Care setting

| Care setting | Number of reports | Percentage |
|---|---|---|
| Acute / general hospital | 34,042 | 89 |
| Community nursing, medical and therapy service (incl. community hospital) | 2,983 | 8 |
| Ambulance service | 960 | 2 |
| Mental health service | 250 | 1 |
| Community and general dental service | 60 | 0 |
| General practice | 49 | 0 |
| Learning disabilities service | 40 | 0 |
| Community pharmacy | 11 | 0 |
| **Total** | **38,395** | **100** |

[1]Search strategy: incident category level 1, medical device/ equipment, Incident date, 1 January and 31 December 2012, extracted on 20 March 2013

## Appendix D: Criteria for sharing NRLS medical device incidents with the MHRA

The following NRLS fields need to have been completed:

| NRLS field name | NRLS field description | Criteria |
|---|---|---|
| IN01 | Date | Is completed, and |
| IN05 | Incident category | 'Medical device' , and |
| INO5 | Incident category level 2 | 'Failure of device/ equipment' or 'User error' or 'Wrong device/ equipment used' or Or 'other And |
| DE07 | Manufacturer | Is completed, or |
| DE08 | Supplier | Is completed, and |
| DE03 | Product name | Is completed, or |
| DE04 | Model | Is completed, or |
| DE05 | Catalogue number | Is completed, or |
| DE06 | Serial number | Is completed, or |
| DE09 | Batch number | Is completed, and |
| PD09 | Clinical outcome | 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, and |
| RP06 | Trust Name | Is completed, and |
| RP01 | Unique ID | Is completed, and |
| RP05 | Local reference ID | Is completed |

The following fields should also be included in the incident data shared with the MHRA. Healthcare organisations should be able record this information in their local incident reports and transfer them to the NRLS.

| Reference code | Description |
|---|---|
| ST01 | Staff type reporting incident |
| IN06 | Contributing Factors |
| IN10 | Reoccurrence Prevention |
| IN11 | Underlying Causes |
| PD11 | Patient ethnicity |
| PD13 | Preventative actions taken |
| PD14 | Action taken to minimise the impact |
| PD15 | Describe the actions taken |

## Appendix E: An example of how a medical device report should be completed

| NRLS Code | Field name | Entry |
|---|---|---|
| INO1 | Date of incident | 15.07.13 |
| INO3 | Location | General/acute hospital, support services, radiology |
| IN05 | Incident category | Medical Device/equipment, failure of devices/equipment |
| PD01 | Patient Age | 76 years |
| PD02 | Patient Gender | Male |
| PD05 | Specialty | Radiology |
| RP02 | Care setting | Hospital |
| RP07 | Organisation Code | 1234 |
| RP01 | Unique ID | 5678 |
| RP05 | Local reference ID | 91011 |
| ST01 | Staff type reporting incident | Consultant cardiologist |
| DE01 | Type of device | Implants – cardiovascular |
| DE03 | Name of device | Abcd |
| DE04 | Model | ef1234 |
| DE05 | Catalogue number | 56789 |
| DE06 | Serial number | 34567 |
| DE07 | Manufacturer | Xcvbnm |
| DE08 | Supplier | Ghjklmi |
| DE09 | Batch Number | 876576 |
| IN06 | Contributing factors | *Failure of device* |
| IN07 | Description of incident | I was placing a stent graft in the left carotid artery for false aneurysm. The stent was well sited and deployment started normally. The deployment jammed after 3cm of the 8cm stent was deployed. Further pulling to continue deployment resulted in the delivery catheter snapping. The whole system was dragged out of the carotid artery and down to the sheath in the groin. At this point the delivery catheter slid off the remainder of the stent and the stent was finally deployed in the right external iliac artery from the 10F sheath. Patient will need to return for further treatment Stent delivery system retained for company evaluation . |
| IN10 | Recurrence prevention | Use alternative stent graft model until satisfactory response from manufacturer |
| IN11 | Underlying causes | Failure of device |
| PD16 | Was the patient harmed | Yes |
| PD09 | Clinical outcome | Moderate harm |

 

## Appendix F: Medical Device 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 emailed to the Central Alerting Systems at: safetyalerts@dh.gsi.gov.uk

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

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

 

## Appendix G: Definitions

ABNORMAL USE
Act or omission of an act by the operator or user of a medical device as a result of conduct which is beyond any means of risk control by the manufacturer.

ADVERSE INCIDENT
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.

FIELD SAFETY CORRECTIVE ACTION (FSCA)
A field safety corrective action is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. Such actions, whether associated with direct or indirect harm, should be reported to the relevant Competent Authorities and should be notified via a field safety notice.

Note 1: The FSCA may include:

- the return of a medical device to the supplier;
- device modification;
- device exchange;
- device destruction;
- retrofit by purchaser of manufacturer's modification or design change; and,
- advice given by manufacturer regarding the use of the device and/or the follow up of patients, users or others (eg where the device is no longer on the market or has been withdrawn but could still possibly be in use e.g. implants or change in analytical sensitivity or specificity for diagnostic devices).

FIELD SAFETY NOTICE (FSN)
A communication to customers and/or users sent out by a manufacturer or its representative in relation to a field safety corrective action.

HARM
Physical injury or damage to the health of people, or damage to property or the environment.

IMMEDIATELY
For purposes of this guideline, immediately means without any delay that could not be justified.

INDIRECT HARM
In the majority of cases, diagnostic devices IVDs and IVF/ART medical devices will, due to their intended use, not directly lead to physical injury or damage to health of people ( harm). These devices are more likely to lead to indirect harm rather than to direct harm. Harm may occur as a consequence of the medical decision, action taken/not taken on the basis of information or result(s) provided by the device or as a consequence of the treatment of cells (eg gametes and embryos in the case of IVF/ART devices) or organs outside of the human body that will later be transferred to a patient.

Examples of indirect harm include:

- misdiagnosis;
- delayed diagnosis;
- delayed treatment;
- inappropriate treatment;
- absence of treatment; and,
- transfusion of inappropriate materials.

 

Indirect harm may be caused by:

- imprecise results;
- inadequate quality controls;
- inadequate calibration;
- false positive; or,
- false negative results.

For self-testing devices, a medical decision may be made by the user of the device who is also the patient.

INTENDED PURPOSE
The use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

MANUFACTURER
The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

MEDICAL DEVICE
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
- control of conception

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

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)
The Medicines and Healthcare Products Regulatory Agency (MHRA) is the executive agency of the Department of Health charged with protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and that they are used safely. The MHRA is also the designated UK competent authority for the Blood Safety and Quality Regulations.

OPERATOR
Person handling equipment.

SERIOUS DETERIORATION IN STATE OF HEALTH
A serious deterioration in state of health can include:

a. life-threatening illness;
b. permanent impairment of a body function or permanent damage to a body structure;
c. a condition necessitating medical or surgical intervention to prevent a or b;
   Examples,
   - clinically relevant increase in the duration of a surgical procedure,
   - a condition that requires hospitalisation or significant prolongation of existing hospitalisation;
d. any indirect harm (see definition in Appendix G) as a consequence of an incorrect diagnostic or IVD test result or as a consequence of the use of an IVF/ART device when used within manufacturer´s instructions for use (use errors must also be reported); and,
e. foetal distress, foetal death or any congenital abnormality or birth defects.

USE ERROR
Act or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator of the medical device.

USER
The healthcare institution, professional, carer or patient using or maintaining medical device.

 

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