Safeguarding public health

MHRA

Device Bulletin

Reporting adverse incidents and disseminating medical device alerts

DB2011(01)
March 2011
website only

DH Department of Health

Contents

1 Introduction

1.1 Medicines and Healthcare products Regulatory Agency

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.

One way in which we aim to achieve this is by investigating reports of adverse incidents involving medical devices and, where appropriate, instigating corrective actions to reduce the risk of recurrence.

The Adverse Incident Centre (AIC) is the MHRA's focal point for the reporting of adverse incidents involving medical devices. Where the result of investigations of those incident reports (or any other information received) has implications for patients or users, the Agency will issue a Medical Device Alert (MDA) warning of hazardous products, potential safety issues or unsafe procedures, and providing relevant advice.

1.2 Guidance documents

This Device Bulletin provides guidance on the MHRA's adverse incident reporting system for medical devices. It encourages users to report incidents to us and provides information on the dissemination of Medical Device Alerts. We update this guidance annually and alert all MHRA medical device liaison officers (MDLOs) when it is published on the MHRA website. The online reporting system and printable adverse incident report forms are available on the MHRA website along with further, regularly updated, supporting information.

Also available on the MHRA website is our publication 'Managing medical devices' DB 2006(05). This document is intended primarily for people in hospital and community based organisations (including social services) that are responsible for the management of medical devices, to help them set up systems that minimise risks associated with the use of those medical devices. The purpose of this document is to outline a systematic approach to the purchasing, deployment, maintenance, repair and disposal of medical devices.

1.3 First Medical Device Alert of the year

Each year the first Medical Device Alert published by the MHRA provides an important general message for all MDLOs and other medical device users.

This year Medical Device Alert MDA/2011/001 encouraged MDLOs to:

- Work with the MHRA to ensure that comprehensive and effective systems are in place for the reporting of medical device related adverse incidents to the MHRA, and that these systems are regularly reviewed and maintained;
- Encourage staff and other medical device users to report medical device related adverse incidents in accordance with published MHRA guidance, and to use the MHRA's online adverse incident reporting system;
- Continue to promote the reporting of all medical device related adverse incidents to the MHRA in accordance with the latest guidance.

2 What is a medical device?

2.1 Examples of medical devices

Anaesthetic equipment
Blood warming cabinets
Catheters (e.g. urinary, cardiac)
Chiropody equipment
Dental equipment and materials
Dressings
Endoscopes
Examination gloves
Hospital beds
Implants – powered (e.g. implantable defibrillators, pacemakers) and non-powered (e.g. heart valves, orthopaedic implants, bone cements)
Incontinence products
IV administration sets and pumps
Ophthalmic equipment
Patient monitoring equipment (e.g. cardiac monitors)
Physiotherapy equipment
Radiotherapy equipment (brachytherapy, external beam)
Sphygmomanometers
Surgical instruments and equipment
Syringes and needles
Thermometers
Urine drainage systems
Vaginal specula
X-ray systems, ultrasound imagers and CT/MR scanners

For patient transportation or moving (but **not** including ambulance vehicles):
Carry chairs
Hoists and slings
Portering chairs
Slider boards and standing aids
Stretchers and trolleys

For critical care:
Defibrillators
Resuscitators
Ventilators

For people with reduced mobility or physical impairment:
Communication aids
Environmental controls
Hearing aids
Orthotics
Prosthetic limbs
Pressure relief mattresses, cushions or pads
Supportive seating
Walking aids
Wheelchairs (powered and non-powered)

For daily living:
Bathing and showering equipment
Commodes
Incontinence products
Prescribable footwear
Special chairs
Urine drainage systems

In vitro diagnostic medical devices and their accessories:
Blood gas analysers
Blood glucose meters
Hepatitis and HIV test kits
Pregnancy test kits
Specimen collection tubes
Urine test strips

Also included are:
Condoms
Contact lenses and care products
Intra-uterine devices (IUDs)

We are also interested in products which, whilst not themselves medical devices, are used closely in conjunction with these devices. For example:
Benchtop sterilizers
Blood and tissue storage systems
Disinfecting and sterilizing equipment
Chemical and biological indicators used in sterilization processes

3 What is an adverse incident and when should I report it?

3.1 Definition

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons.

The non-availability of a device, whether through the failure of procurement arrangements or through the inadequacy of local stock replacement systems, does not constitute a medical device related adverse incident reportable to us. Such events may, however, be reportable to your local system, to the National Patient Safety Agency (NPSA) and may be helpful for CQC compliance assessment.

3.2 Possible causes and outcomes

Causes of adverse incidents involving devices may include:

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

Conditions of use may also give rise to adverse incidents:

- environmental conditions (e.g. electromagnetic interference)
- location (e.g. devices designed for hospitals may not be suitable for a community or ambulance setting).

Please remember that the MHRA is concerned with preventing the occurrence of adverse incidents, not with assigning blame or liability.

3.3 Who should report?

Anyone may submit an adverse incident report to the MHRA – clinicians, healthcare workers, carers, patients and members of the public.

Reporters should, however, familiarise themselves with their organisation's local incident reporting procedures and risk management systems, as these may require reports to be submitted via, or copied to, medical device liaison officers and/or patient safety managers.

3.4 What should I report?

Any adverse incident involving a device or its instructions for use (including user/device interface problems) should be reported to the MHRA, especially if the incident has led to or, were it to occur again, could lead to:

- death, life-threatening illness or injury
- deterioration in health or permanent impairment of body structure or function
- the necessity for medical or surgical intervention (including implant revision)
- hospitalisation or prolongation of existing hospitalisation
- unreliable test results and associated risk of mis-diagnosis or inappropriate treatment
- fetal distress, fetal death, congenital abnormality or birth defect
- ongoing faults that successive service/maintenance visits have failed to rectify.

This includes the reporting of potential problems. Do not wait until identified risks are manifested in actual incidents before reporting a problem.

Subject to the above, specific advice on reporting incidents involving coronary stents, hip and knee joints, and breast implants should be followed. This advice is available on the MHRA website, along with a range of other product-specific information (www.mhra.gov.uk > Safety information > General safety information and advice > Product-specific information and advice).

Other minor safety or quality problems should also be reported as these can help demonstrate trends or highlight inadequate manufacturing or supply systems.

Reports of adverse incidents that appear to be caused by human error should also be reported because:

- the error may be partly (or wholly) due to deficiencies in the design of the device or instructions for use
- they may prompt promulgation of advice or device design improvements that will help prevent repetition of mistakes.

3.5 When should I report?

Incidents should be reported as soon as possible, usually within 24 hours. Serious incidents should be reported to us by the fastest means available, **preferably online**, or by fax or email and should be confirmed with a telephone call. Where the first report is by telephone, a written report (email or fax – but preferably online) should follow as soon as possible.

The initial report of an incident should contain as much relevant detail as is immediately available, but should not be delayed for the sake of gathering additional information.

4 Why should I report an adverse incident?

4.1 Safeguarding public health

Our principal aim is to safeguard the public's health. We do this by making sure that medical devices (and medicines) work properly and are acceptably safe. We respond promptly when new concerns come to light, and ensure that sound evidence underpins all our decisions. Whilst no product is completely free of risk, we can work constructively with medical device manufacturers and device users to ensure that these risks are minimised. In most circumstances we work with manufacturers to address device problems. However, if the issue cannot be resolved, regulatory action may be required.

The MHRA greatly values the significant and positive efforts made by medical device liaison officers (MDLOs) and all other health and social care professionals to ensure that medical device related adverse incidents are reported promptly to our Adverse Incident Centre. This has ensured that a number of important public health issues have been identified early and dealt with appropriately.

4.2 Early identification and action on incident reporting patterns and trends

MHRA is reviewing our own adverse incident report handling strategy. This will include the development and introduction of a number of significant changes designed to ensure that we are able to focus our specialist resources directly upon those issues which present the greatest risk to patient safety, and where our active intervention will make a positive difference to the resolution of the problem.

As part of this process not only will all incident reports continue to be recorded, risk assessed and reviewed in as much detail as possible, but our investigative activity will be supported by an expanded and developed system for identifying, analysing and acting upon emerging incident signals, patterns and trends.

4.3 Care Quality Commission – essential standards of quality and safety

The **CQC essential standards of quality and safety** comprise a number of regulations and associated outcomes that are set out in legislation. When the CQC checks providers' compliance with these essential standards, it focuses on the regulations that most directly relate to the quality and safety of care. Providers must have evidence that they meet the specified outcomes. **Regulation 16** and associated **Outcome 11** concern the **safety, availability and suitability of equipment.** Specifically, these demand that where equipment is used, it must be safe, available, comfortable and suitable for people's needs.

The CQC Regulations are clear:
(a) 'equipment' includes a medical device; and
(b) 'medical device' has the same meaning as in the Medical Devices Regulations.

In order to ensure that health and social care staff, patients and other members of the public are not at risk of harm from unsafe or unsuitable equipment, providers must ensure that their equipment is properly maintained and is used correctly and safely and in accordance with published guidance.

5 How do I report an incident?

5.1 Online reporting

Online reports may be submitted securely via the MHRA website at any time of any day. We strongly recommend that, where possible, online reporting is used. Approximately 80% of reports from medical device users are now submitted through the online system.

Successful use of this route provides the reporter with immediate confirmation of receipt, a unique incident reference number and, where requested, an emailed copy of the submitted report in pdf format. Copies of the report may also be sent to any other specified email address.

5.2 Proposed further online developments for MDLOs

We have previously identified two areas for possible development of our online systems:

Electronic links between the MHRA and local risk management systems
Implementing an automated report data transfer system to allow electronic movement of adverse incident reports from local risk management systems directly to the MHRA.

A medical device liaison officer interface
In addition to links to local risk management systems, this would provide a secure sign-on area with a list of all reports from a specific MDLO's organisation; provide latest investigation progress information; and facilitate online updates from the reporter.

Future work on these and other projects is subject to review and prioritisation in light of an ongoing assessment of resources.

5.3 Telephone reports

Telephone reports must always be followed up by a written (online or email) confirmation.

In urgent cases outside of normal office hours, and where it is not possible to use the online reporting facility, an answering machine at the Adverse Incident Centre carries a message giving the contact telephone number for the duty officer in the MHRA's Communications team. The duty officer is able to contact senior MHRA staff.

Alternatively, telephone messages may be left on the answering machine for the next working day.

5.4 Reporting by email or post

Forms for reporting incidents may be downloaded from the MHRA website and then completed electronically and emailed as a .doc or .pdf file. They may also be printed and sent by post.

Copies of forms are also available from:

MHRA Adverse Incident Centre
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7080
Email: aic@mhra.gsi.gov.uk

6 What do I do with devices that have been involved in incidents?

6.1 Traceability of devices

Good medical device traceability records are essential. This is of particular importance when you may be required to identify and locate devices for urgent maintenance or modification, or when devices have to be withdrawn from service quickly, e.g. following an adverse incident, publication of a medical device alert, or for a manufacturer's field safety corrective action.

In this respect all health and social care providers should be alert to the potential liability implications if they are unable to locate a faulty medical device, especially if the subsequent use and failure of that device leads to an adverse incident.

Record keeping forms an important part of the general information on managing medical devices that is provided by MHRA in Device Bulletin DB2006(05).

6.2 Quarantine, labelling and storage

Medical devices that have been involved in an incident **should** be **quarantined**.

Until the MHRA has been given the opportunity to carry out an investigation, they **should not** be:

- discarded
- repaired
- returned to the manufacturer.

All material evidence, i.e. devices/parts removed, replaced or withdrawn from use following an incident, instructions for use, records of use, repair and maintenance records, packaging materials, or other means of batch identification **must** be:

- clearly identified and labelled
- stored securely.

Evidence should not be interfered with in any way except for safety reasons or to prevent its loss. Where appropriate, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eyewitness reports.

If you think an urgent examination of the device (and/or related items) is needed, contact the MHRA Adverse Incident Centre. An MHRA device specialist will decide whether to inspect the item urgently on site (or at other appropriate facilities), or may request that the device be sent to the MHRA.

Important: **If you are in any doubt about what to do with a device, contact the MHRA.**

6.3 Dealing with the manufacturer/supplier

The manufacturer or supplier should be informed promptly of incidents and, if accompanied by an appropriate person, may be allowed to inspect the items. To facilitate an investigation, it may be possible to provide the manufacturer with a sample of unused stock from a large batch. However, until advised to the contrary by the MHRA, the manufacturer must not be allowed to exchange, interfere with, or remove any part of the product implicated in the incident as this might prejudice our investigations, or those of other official bodies.

6.4 Devices required for continued use

In exceptional circumstances, where a device cannot be removed from use because there is no alternative available, and where patient health would otherwise suffer, the MHRA should be contacted for confirmation that the device may continue to be used or be repaired and put back into use. If it is not possible to withdraw or repair the device, users must be made aware of the need for increased caution in using it.

7.5 Returning devices to the manufacturer/supplier

Once the MHRA has indicated that an item may be returned to the manufacturer, the manufacturer should be contacted to ensure that correct forms of documentation and carriage are arranged. In particular, a manufacturer's returns authorisation reference number may be required. The MHRA reference number should be quoted in all circumstances.

6.6 Submitting devices to the MHRA

Important: Do not send medical devices to the MHRA unless we have specifically requested you to do so.

If responding to such a request, you must ensure that the device has been appropriately decontaminated, securely packaged, and clearly labelled (including the MHRA reference number).

Address the package to:

MHRA (Devices)
241 Bristol Avenue
Bispham
Blackpool
FY2 0BR

Tel: 01253 596 000
Fax: 01253 596 177
Email: bav@mhra.gsi.gov.uk

Important: It is illegal to send contaminated items through the post

6.7 Contaminated items

Our publication 'Managing Medical Devices' DB 2006(05) contains advice on decontaminating healthcare equipment. Our device specialists can provide additional advice, particularly if the item requires examination prior to any decontamination.

Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective containment, labelled and placed in quarantine. The MHRA and the manufacturer/supplier should be contacted for advice prior to any further action being taken.

7 What does the MHRA do when it receives a report?

7.1 Review of MHRA adverse incident handling strategy

We are undertaking a review of our adverse incident report handling strategy. This includes the development and introduction of a number of significant changes designed to ensure that we are able to focus our specialist resources directly on those issues that present the greatest risk to patient safety, and where our active intervention will make a positive difference to the resolution of the problem. As part of this process not only will all incident reports continue to be recorded, risk assessed and reviewed in as much detail as possible, but our investigative activity will be supported by an expanded and developed system for identifying, analysing and acting upon emerging incident signals, patterns and trends.

The outcome of this review will necessitate a number of changes to our existing processes, described below.

7.2 Adverse Incident Tracking System (AITS)

Upon receipt, each report is acknowledged, recorded on our database (the Adverse Incident Tracking System – AITS) and assigned a unique reference number. Adverse Incident Centre staff are available to provide an update on the progress of an investigation, or to put an incident reporter in contact with the device specialist responsible for that investigation.

7.3 Risk assessment and investigation levels

A medical device specialist then carries out a risk assessment to determine whether an investigation is to be led by the MHRA or if we should ask the manufacturer to investigate under MHRA supervision. If an incident involved a death or serious injury, or had a high potential to do so, the MHRA will usually lead the investigation. In the course of this type of investigation MHRA staff may:

- talk with the user and the manufacturer
- visit the site of the incident
- review evidence (including the device itself)

- issue safety advice (e.g. Medical Device Alert, One Liner, poster, leaflet)
- liaise with other authorities (e.g. HSE, NPSA).

For the majority of reported incidents, we will ask the manufacturer to help with the initial investigations. In these investigations we provide the manufacturer with core information about the report received (the location, the device, what happened) and ask them to investigate particular aspects of the incident and to report back to us as soon as possible. At this stage we will also let you know if we are content for you to make the device (or samples from the same batch) available to the manufacturer as part of the investigation. We closely monitor progress of the manufacturer's investigation and critically assess their responses and their final report.

For other incidents, details are recorded for trend analysis and ongoing surveillance. In all cases the reporter is informed of our assessment and the outcome.

If at any later stage new information is brought to light, previously concluded investigations are re-appraised. Additionally, outcomes of investigations routinely undergo trend analysis with the aim of identifying patterns or clusters of incidents that may require further investigation.

7.4 Keeping in touch

After initial acknowledgement, reporters are routinely kept informed of the progress of the incident investigation. At the end of an investigation we also provide the reporter with a summary of the incident investigation conclusions.

The MHRA sends these progress updates to the person named on the report form. If the liaison officer submits the report it is important that they ensure that all MHRA updates are passed on to the originator of the report, e.g. the healthcare worker using the device at the time of the incident.

Wider contact is also welcome – reporters are always free to contact the Adverse Incident Centre with any general or specific enquiries and comments.

7.5 Confidentiality, data protection and the provision of information to third parties

Unless notified to the contrary, the submission of a report to the MHRA provides us with the authority to use the information it contains as we consider appropriate in the interest of safeguarding public health.

The MHRA does not normally require patient names or other identifying information in order to carry out an investigation. Healthcare staff reporting incidents should, therefore, ensure that such details are deleted or redacted from their reports, from accompanying attachments and from any subsequent correspondence.

The details that we do require are clearly specified on the MHRA report forms. The reporter's full contact details (name, post held etc.) are essential, as this allows us to contact you to acknowledge receipt of your report or message and to request any further information that may be needed.

Where the reporter is also the patient, these contact details are still required. However, it is standard MHRA practice to have a medical device specialist consult directly with the patient before disclosing any personal identifying information to a third party such as the device manufacturer.

Technical and scientific information relevant to our investigations may be shared with bodies such as the Department of Health, the Health & Safety Executive and the National Patient Safety Agency (NPSA), as well as with the supplier or manufacturer of the device concerned.

In addition, existing legislation may also require disclosure of certain information to other statutory bodies. For example, we may provide information and expert advice to the police and/or to a coroner. This may include the provision of verbal or written evidence to a coroner's inquest.

8 How long does MHRA risk assessment and investigation take?

8.1 Time taken for risk assessments and investigations

In most cases adverse incident report details are recorded on the MHRA database within one or two working days of receipt of an incident report. This is followed by a full risk assessment by MHRA medical device specialists. For the most serious incidents (e.g. those involving a death or serious injury), these processes can be completed within hours.

Of the approximetaly10,300 adverse incident reports received by the MHRA in 2010, around 40% were risk assessed as requiring Standard investigations and over 20% as requiring In depth investigations. The remainder of those incidents correctly reported to the MHRA were recorded as part of our ongoing trend analyses. Further information on MHRA investigation levels may be found below in Section 8.2.

The length of time taken for completion of an investigation will vary according to a number of factors. These include:

- the complexity of the research and analysis undertaken
- the range of people that we need to contact
- the number of devices involved in the incident, and their location
- testing of the device by the manufacturer or by independent experts
- police or coroner involvement, or other legal action.

Our database shows that in 2010, approximately 50% of Standard investigations were concluded within 18 weeks and 50% of In depth investigations within 31 weeks.

Further information on the time taken for completion of adverse incident investigations will be published in the medical device adverse incident annual report.

8.2 Satisfaction survey

Each year we send a feedback survey to 20% of reporters following the conclusion of our investigation of the incident they had reported. Although in 2009 only a small number of forms were completed and returned, the responses show a continued high levels of satisfaction with our performance.

One of the key areas that is routinely assessed is the speed of the investigation. In 2009**,** the level of satisfaction with the speed of the MHRA investigation rose from 77% to 82% for 'In depth' investigations and from 83% to 85% for 'Standard' investigations.

Further details of survey responses are available in our publication 'Adverse Incident Reports 2009', – DB2010(03) – available from our website www.mhra.gov.uk.
The report covering activity in 2010 will be published by the end of March 2011.

9 Disseminating Medical Device Alerts and the role of the MDLO

9.1 Medical Device Alerts

Medical Device Alerts (MDAs) are the MHRA's prime means of communicating safety information to medical device users in health and social care. MDAs may also be used to provide updated information. Each Medical Device Alert is given one of the following categories:

- Immediate action
- Immediate action update
- Action
- Action update

MDAs are reviewed on a regular basis and updated or deleted. Our website provides lists of MDAs that are still in force. If a notice is not listed, it has been superseded or withdrawn.

9.2 Central Alerting System (CAS) and the role of the CAS liaison officer

The Central Alerting System (CAS) is a web-based system for distributing alerts and urgent guidance on patient safety on behalf of the MHRA, the Department of Health and the National Patient Safety Agency. The MHRA distributes drug alerts, medicines 'Dear Doctor' letters, and Medical Device Alerts (MDAs) via CAS.

Alerts are disseminated to CAS liaison officers in NHS trusts and primary care trusts through CAS. Each alert has deadlines for getting action underway and completed. The CAS liaison officer ensures onward distribution of the alerts and responds to alerts using the drop-down menu in CAS. Queries on specific alerts can also be raised via CAS.

Guidance for CAS liaison officers can be found in the CAS Help section, including guidance for primary care trusts when they split. This is available to CAS users after they have logged in via the CAS homepage

Changes in CAS contact details should be notified to the CAS helpdesk by telephone (020 7972 1500) or email (safetyalerts@dh.gsi.gov.uk)

9.3 Role of medical device liaison officers in NHS trusts and primary care trusts

NHS trusts and primary care trusts in England have all designated a member of staff as their medical device liaison officer (MDLO). The primary role of the MDLO is to encourage effective and comprehensive adverse incident reporting through encouragement and training of healthcare and support staff and medical device users.

In many organisations the MDLO and the CAS contact is the same person. They will encourage, promote and coordinate adverse incident reporting, manage the dissemination of medical device alerts and provide feedback. In organisations where these posts are separate, both contacts will work closely together.

A wide range of publications that may help liaison officers in fulfilling their role is also available on the MHRA website under: Safety information > General safety information and advice > Medical Device Liaison Officer information

Additional support is available from us on 020 3080 7272 or email dts@mhra.gsi.gov.uk

9.4 Role of medical device liaison officers in social services departments

Medical device liaison officers (MDLOs) in social services departments encourage and train staff and users to report adverse incidents and disseminate MDAs to all relevant staff that fall within their area of responsibility.

Although all care homes and independent social care providers have been requested to register for CAS alerts, the majority have not yet done so. The MHRA is working with the Care Quality Commission and the CAS team to try to address this. MDLOs in social services departments are requested to check that care homes and independent healthcare providers in their areas have registered to receive CAS alerts. To register for alerts, please email the CAS helpdesk on safetyalerts@dh.gsi.gov.uk.

If you need to inform the MHRA about a change of MDLO, please ring 020 3080 7272 or email dts@mhra.gsi.gov.uk with the name, title, organisation, address, telephone number, fax number and email address of the new MDLO.

9.5 MDLO conferences

The MHRA hosts conferences for medical device liaison officers from both the healthcare and social services sectors. Details of the conference programme, venue and booking arrangements are made available on the MHRA website: www.mhra.gov.uk > Conferences and Learning Centre

9.6 MDLO focus group

The MHRA's MDLO focus group is designed to be representative of the community it serves. It currently comprises liaison officers from NHS trusts, primary care trusts and social services departments. The group meets at least annually to share experiences, exchange ideas, discuss best practice and comment on MHRA issues and training for liaison officers.

Further information can be found on the MHRA liaison officer webpages. If you would like to be considered as a member of the Focus Group or would like to receive any further information please call 020 3080 7272 or email dts@mhra.gsi.gov.uk

9.7 Local procedures

Local procedures for all MDLOs should ensure that:

- the appointed MDLO has the necessary authority to take responsibility for the reporting of medical device related adverse incidents
- all medical device related incidents are reported to the MHRA

Note: As highlighted in Section 11.2, this currently cannot be achieved by using local risk management systems to report to the National Reporting and Learning System. Although the NPSA now passes medical device related reports to the MHRA, these are significantly delayed and very rarely contain sufficient detail to allow us to investigate without requests for further information.

- the appointed MDLO personally reports all medical device adverse incidents to the MHRA (and sends on MHRA responses to the originator of the report)

  OR

  other reporters within the trust provide the MDLO with copies of their reports to the MHRA, and all subsequent related correspondence

- the MHRA is informed promptly of changes to MDLO contact details
- a deputy MDLO, who can carry out all of the duties allocated to the MDLO, is appointed
- regular reviews are undertaken to ensure that local procedures are effective and are being followed.

It is important to ensure that local reporting and risk management systems are not used to filter out medical device related adverse incident reports that would otherwise have been sent directly to the MHRA Adverse Incident Centre. If a relevant incident report is submitted to another body (such as the Health and Safety Executive or the National Reporting and Learning System), it is essential that a separate report is also sent to the MHRA.

9.8 Targeting of MDAs

All MDAs are distributed electronically to the registered CAS liaison officer in NHS trusts and PCTs and the MDLOs in social services departments. This provides each liaison officer with the opportunity to assess the relevance of each alert to their own organisation.

Each MDA has a suggested, tailored distribution list but we strongly recommend that the MDLO checks the relevance of this list to their organisation before beginning distribution.

10 Field Safety Notices and Field Safety Corrective Actions

10.1 What are FSNs and FSCAs?

The EU Medical Devices Directives require manufacturers to monitor the safety of their products and, where necessary, carry out corrective actions on medical devices that have been distributed to customers (i.e. that are 'in the field'). Field Safety Notices (FSNs) are used by manufacturers to inform medical device users about Field Safety Corrective Actions (FSCAs) taken by them (the manufacturer) to reduce the risk of death or serious deterioration in state of health during the use of the device. FSCAs are usually, but not exclusively, prompted by investigations of adverse incidents reported by medical device users. They relate particularly to investigations made by the MHRA and/or manufacturer that have revealed the need to:

- change the design of the device
- remove or replace devices in the field
- make device modifications in the field or amend instructions for use.

The same Directives oblige manufacturers to alert the MHRA, as the UK Competent Authority, about any corrective actions affecting their products that have been distributed within the UK. The MHRA has monitored manufacturer Field Safety Corrective Actions since the transposition of the European Medical Devices Directives into UK law.

The MHRA carries out an assessment of each FSCA to determine whether the manufacturer's proposed action is relevant to the UK and whether it is sufficient to protect public health. On most occasions it is, and the MHRA monitors progress to ensure that the action is completed. This approach helps to minimise the need for the MHRA to issue Medical Device Alerts.

FSNs are frequently accompanied by confirmation receipts to be completed by the medical device user and returned to the manufacturer.

It is important that the actions advised in the FSN are taken, and that receipt of the FSN is acknowledged by your organisation. This receipt provides the manufacturer, and subsequently the MHRA, with the means to monitor the progress of Field Safety Corrective Actions. It also minimises the need for the MHRA to issue Medical Device Alerts, which otherwise place an additional burden on the health service because of the broadcast nature of the MDA and the extra administrative work required.

Manufacturers generally send Field Safety Notices directly to healthcare organisations and these may be addressed to specific individuals or departments. Although the MHRA checks that the manufacturer's distribution lists for FSCAs are credible and likely to achieve a satisfactory result we cannot check for 100% accuracy – this is the manufacturer's responsibility. If a FSN is targeted wrongly (e.g. out-of-date information on staff and equipment locations), crucial information may not be acted upon or documented.

All healthcare staff should be aware that if they receive a manufacturer's FSN they should notify the appropriate member of staff who can arrange for the requested action to be undertaken. This may involve wider distribution and activation of formal risk management procedures within the healthcare organisation.

10.2 FSNs on the MHRA website

In response to requests from some medical device liaison officers and CAS liaison officers, and in order to provide transparency concerning Field Safety Corrective Actions in the UK, the MHRA places Field Safety Notices that are relevant to the UK on our website. They are placed on the website for information and will not normally require further action unless your organisation has been contacted directly by the manufacturer or if the MHRA has issued supplementary advice.

Once reviewed and placed on our website we assess each manufacturer's FSN and the associated Field Safety Corrective Action and determine whether we need to issue supplementary advice or if the manufacturer's action is sufficient. There is the option on our website to register to receive email alerts for new FSNs.

Medical device liaison officers and CAS liaison officers are not expected to treat FSNs placed on the MHRA's website in the same way as Medical Device Alerts. Additional action or direct feedback will usually only be required when a Medical Device Alert has been issued.

11 Other reporting systems

11.1 Local reporting and risk management systems

It is important to ensure that local reporting and risk management systems are not used to filter out medical device related adverse incident reports that should be sent directly to the MHRA Adverse Incident Centre. If a relevant incident report is submitted to another body (such as the Health & Safety Executive or the National Patient Safety Agency), it is essential that a separate report is also sent to the MHRA.

11.2 National Patient Safety Agency (NPSA)

Following the planned abolition of the NPSA by March 2012, the patient safety function will transfer to the new NHS Commissioning Board and there will continue to be a requirement to report patient safety incidents via the National Reporting and Learning System.

The MHRA and the NPSA have worked collaboratively to ensure coordinated development of our reporting systems, with the common goal of maximising our effectiveness in preventing harm arising from the use of medical devices.

Although the NPSA alerts the MHRA about specific device issues, the confidential reporting allowed under the NPSA system can prevent the MHRA from investigating those incidents in full.

The NPSA therefore actively encourages reporting of all medical device failures directly to the MHRA.

Reports of non-medical device related adverse incidents affecting patient safety should continue to be made to the NPSA using your trust's local risk management system.

11.3 Medicines

Incidents involving defective medicines should be reported to the MHRA's Defective Medicines Report Centre via our website (www.mhra.gov.uk) or by post/fax/telephone/email:

MHRA Defective Medicines Report Centre
151 Buckingham Palace Road
Victoria
London
SW1W 9SZ

Monday to Friday 08:45 -16:45
Tel: 020 3080 6574

Urgent calls outside of these hours, or weekends and public holidays
Tel: 020 3080 3000

Email: dmrc@mhra.gsi.gov.uk

Suspected adverse drug reactions (ADRs) not thought to be a consequence of a defective product should be reported to the MHRA using the Yellow Card Scheme. For further details on how and what to report see the website at www.mhra.gov.uk

11.4 RIDDOR

In addition to reporting medical device related incidents to the MHRA, incidents involving certain types of injury, occupational disease or dangerous occurrence, whether involving medical devices or not, should also be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR '95) to the relevant enforcing authority for the premises at which the incident occurred. For healthcare premises, this will usually be the local office of the Health and Safety Executive (HSE) but for some it may be the local authority. All notifications under RIDDOR should be sent to:

Incident Contact Centre
Caerphilly Business Park
Caerphilly
CF83 3GG

Tel: 0845 300 9923
Fax: 0845 300 9924
Email: riddor@connaught.plc.uk
Website: www.hse.gov.uk/riddor/

Online reporting and copies of report forms are available via their website.

11.5 DH Estates & Facilities

Mandatory reporting of defects and failures incidents, involving non-medical equipment, engineering plant, installed services and the building fabric should be reported using the NHS Information Centre efm-information system at http://www.efm.ic.nhs.uk/

The system is intended to be used by healthcare providers in England.

For all queries regarding passwords and access to this system please contact 0845 3006016. For further guidance on estates and facilities alerts reporting go to guidance DH(2008)01 at www.dh.gov.uk

DH Estates & Facilities
Department of Health
Quarry House
Quarry Hill
Leeds LS2 7UE

Tel: 0113 254 5531
Fax: 0113 254 5793
Email: ian.rowlan@dh.gsi.gov.uk
Website: www.dh.gov.uk

11.6 Devolved administrations

This Device Bulletin is relevant to incidents occurring in England only. Separate guidance is available on the reporting of incidents that have occurred within the territory of a devolved administration – see contact details below.

Northern Ireland Ref: MDEA(NI)2010/01

Northern Ireland Adverse Incident Centre (NIAIC)
DHSS & PS
Annex 6
Castle Buildings
Stormont Estate
Dundonald
BT4 3SQ

Tel: 028 9052 3868
Fax: 028 9052 3900
Email: niaic@dhsspsni.gov.uk
Website: www.dhsspsni.gov.uk/niaic

Scotland Ref: CEL 43 (2009)
Incident Reporting & Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722
Email: nss.iric@nhs.net

www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales Ref: MDA/2004/054

Welsh Assembly Government
Department for Public Health & Health Professionals
4th Floor, East Wing
Cathays Park
Cardiff
CF10 3NQ

Tel: 029 2082 3922
Fax: 029 2082 3982
Email: haz-aic@wales.gsi.gov.uk
Website: www.wales.gov.uk

All hazardous medical device related incidents occurring in Wales should be reported direct to the MHRA.

11.7 SABRE (reporting blood safety and quality incidents)

The MHRA Adverse Incident Centre, as the UK Competent Authority for Blood Safety & Quality, also receives reports made under the EU Blood Safety and Traceability Directives and the UK Blood Safety and Quality Regulations (SI 2005 No.50, as amended).

These regulations require the reporting of serious adverse reactions and serious adverse events relating to the collection, testing, processing, storage and distribution of blood and blood components for transfusion. Reports must be made to the designated competent authority which in the UK is the MHRA.

Reports under these regulations are submitted to the MHRA using the dedicated online reporting system, SABRE (Serious Adverse Blood Reactions & Events). SABRE is accessible via the MHRA website (www.mhra.gov.uk). The system also prompts reporting to SHOT (Serious Hazards Of Transfusion http://www.shotuk.org/).

Enquiries concerning the reporting of blood safety incidents should be directed to:

MHRA
Email: sabre@mhra.gsi.gov.uk
Tel: 020 3080 7336

SHOT
Email: shot@nhsbt.nhs.uk
Tel: 0161 423 4208 Fax: 0161 423 4395

Quick reference guide

What is a medical device?
Medical devices and equipment are items used for the diagnosis and/or treatment of disease, for monitoring patients, and as assistive technology. This does not include general workshop equipment such as power or machine tools, or general purpose laboratory equipment.

How long does MHRA risk assessment and investigation take?
In most cases, a full risk assessment is completed within one or two days of receipt of an incident report. For more serious incidents, however, this can take place within hours. In 2010 approximately 50% of **Standard** investigations were concluded within 18 weeks and 50% of **In depth** investigations within 31 weeks.

What is an adverse incident?
An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons. Causes may include: design; poor user instructions or training; inappropriate modifications; inadequate maintenance; and unsuitable storage and use conditions.

Who should report?
Anyone may submit an adverse incident report to the MHRA – clinicians, healthcare workers, carers, patients and members of the public. Reports may also need to be submitted via or copied to medical device liaison officers and/or patient safety managers.

What should be reported?
Any adverse incident involving a medical device should be reported to the MHRA. Some apparently minor incidents may have greater significance when aggregated with other similar reports.

When should an incident report be made?
All incidents should be reported to the MHRA as soon as possible. Serious cases should be reported by the fastest means possible. Initial incident reports should contain as much relevant detail as is immediately available, but should not be delayed for the sake of gathering additional information.

How do I report an incident?
Electronic reporting using the online form on the MHRA website is the preferred method. Reports may, however, also be sent by email or post. Report forms may be downloaded/printed from the website.

What do I do with devices that have been involved in incidents?
All items should be quarantined and not repaired, returned to the manufacturer, or discarded until the MHRA has been given the opportunity to carry out its own investigation. The MHRA will advise you when it is necessary to submit a device for examination. If asked to send an item to the MHRA or to the manufacturer for investigation, remember that it is illegal to send contaminated items through the post.

What does the MHRA do when it receives a report?
Report details are recorded on a database and risk assessments are completed by device specialists. That assessment determines whether an investigation is undertaken directly by the MHRA or by the manufacturer on the Agency's behalf. Other incidents are recorded for information and trend analysis only. Reports are acknowledged and reporters advised of the nature and outcome of the investigation.

Medical Device Alerts (MDAs)
MDAs are the MHRA's prime means of communicating safety information to medical device users in health and social care. Each MDA is designated as for 'Immediate action' or 'Action'. Where appropriate, additional safety information is published in an 'Immediate action update or 'Action update'.

The Central Alerting System (CAS) and the role of medical device liaison officers (MDLOs)
The Central Alerting System is the medium through which MDAs are issued to the NHS.
Each NHS trust and social services department has an MDLO. Their key roles are to co-ordinate the effective reporting of adverse incidents involving medical devices, and the dissemination of Medical Device Alerts.

Reporting to other organisations
Depending on the nature of the adverse incident, other central reporting bodies may also require notification.

Organisation	telephone	website	email
NPSA	020 7927 9500	npsa.nhs.uk	enquiries@npsa.nhs.uk
MHRA Defective Medicines Report Centre	020 3080 6574	mhra.gov.uk	dmrc@mhra.gsi.gov.uk
MHRA SABRE helpdesk	020 3080 7336	mhra.gov.uk	sabre@mhra.gsi.gov.uk
RIDDOR	0845 300 9923	www.hse.gov.uk/riddor/	riddor@connaught.plc.uk
DH Estates & Facilities	0113 254 5531	dh.gov.uk	Ian.rowlan@dh.gsi.gov.uk
Northern Ireland	028 9052 3868	dhsspsni.gov.uk/niaic	niaic@dhsspsni.gov.uk
Scotland	0131 275 7575	www.hfs.scot.nhs.uk	nss.iric@nhs.net
Wales	029 2082 3922	wales.gov.uk	haz-aic@wales.gsi.gov.uk

Contacts

Enquiries concerning the content of this Device Bulletin should be addressed to:
Mr Roy Saunders email: roy.saunders@mhra.gsi.gov.uk

Tel: 020 3080 7080

Enquiries about the medical device liaison officer focus group and conferences or about the dissemination of medical device alerts should be sent to
email: dts@mhra.gsi.gov.uk

Tel: 020 3080 7272

Medicines and Healthcare products Regulatory Agency
An executive agency of the Department of Health
ISBN 978-1 90-073173-8