Medical Device ALERT

03 August 2004
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Caerdydd CF1 3NQ

REPORTING ADVERSE INCIDENTS - GUIDANCE ON NEW ARRANGEMENTS FOR NHS WALES ORGANISATIONS

Sent to:

NHS Wales Business Service Centres
Directors of Public Health,
NHS Wales Business Service Centres
Chief Executives, NHS Trusts
Chief Executives, LHB’s
Medical Directors, NHS Trusts
NHS Direct
CSIW
All NHS Staff who use Medical Devices
A list of people who need to have early sight of this information is given in the Notice.

This Notice has been endorsed by the Welsh Assembly Government as being relevant to NHS Wales.

Points of particular importance in Wales:

Please ensure that all Medical staff has access to this guidance

Contact points in Wales:

Jeff Lewis: 029 2082 3987
Christopher Morgan: 029 2082 3373
Health Enabling Technologies
Welsh Assembly Government
Reporting Adverse Incidents – Guidance on new arrangements for NHS Wales organisations

1. To avoid duplication and reduce unnecessary bureaucracy the way in which adverse incidents are reported in Wales will change from 09 August 2004.

2. Previous advice on reporting of adverse incidents in Wales was issued in 1997 by the Welsh Office under circular WHC (97) 28. All hazardous defects should now be reported directly to the Medicines and Healthcare products Regulatory Agency (MHRA) with a copy of the report going to the Surgical Materials Testing Laboratory (SMTL). All items that have been involved in incidents should initially be quarantined where possible and should not be repaired (either in-house or by a third party), or returned to the manufacturer/supplier (unless otherwise agreed with MHRA/SMTL) or discarded before MHRA/SMTL have been given the opportunity to carry out an investigation.

3. Guidance on how incidents are reported directly to the MHRA is given on page 9 and has been extracted from MHRA Medical Device Alert MDA/2004/001 that was recently issued to the NHS in England.

4. From 09 August 2004 Adverse Incident Reports should not be sent to the Welsh Assembly Government.

5. Please note that hazardous defects are those which led to or might have led to, the death, serious injury, illness or serious deterioration in health of a patient, user or other person and where there is a potential for repetition. For the purpose of this guidance we refer to ‘Hazardous reports/defects and non-hazardous reports/defects.

6. All non-hazardous reports/defects should be reported directly to the Defects Section, SMTL using the defect reporting form and sent to:

   The Defects Section
   Surgical Materials Testing Laboratory (SMTL)
   Princess of Wales Hospital
   Coity Road
   Bridgend CF31 1RQ
   Tel: 01656 752820 Fax: 01656 752830
   E Mail:

7. A list of the types of devices dealt with by SMTL is available on the SMTL website at - www.smtl.co.uk/defects/ where you will also find the SMTL reporting form. Advice on decontamination and methods of sending the devices to SMTL are also available on the SMTL site.

8. Any non-hazardous samples must be sent to SMTL. If you are unable to decide on whether the incident is potentially hazardous, ring SMTL and ask to speak to one of the defect investigation officers.
9. SMTL will liaise with the MHRA as necessary. SMTL send copies of all final reports to the MHRA, the Welsh Assembly Government, the manufacturer and the reporting Trust. SMTL also distributes the results of the manufacturer’s responses to interested parties.

10. MHRA Reports relating to non-medical equipment, plant, services and fabrics (see relevant product categories below) will also need to be copied to Welsh Health Estates at the following address:

Welsh Health Estates
Bevan House
Lambourne Crescent
Llanishen
Cardiff CF14 5GS

Product categories:

a. engineering plant and services of all types, for example boilers, generators, heating, ventilating, water, drainage, electrical installations and any other fixed plant (but not fixed medical equipment);
b. fire protection installations and equipment;
c. piped medical gas and vacuum installations, vacuum insulated evaporators (VIEs) and anaesthetic gas scavenging systems;

11. This new way of working means that adverse incident reports do not now have to be sent to the Welsh Assembly Government, who currently in turn copy them to MHRA. We are aware that some organisations are currently reporting directly to both the MHRA and the Welsh Assembly Government.
REPORTING ADVERSE INCIDENTS TO THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)

QUICK REFERENCE GUIDE

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

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 patients, device users or other persons. Causes may include: design; user instructions; training and practice; maintenance; storage and use conditions.

What should be reported?
Any adverse incident involving a medical device should be reported to the MHRA. The MHRA publishes specific advice for incidents involving certain types of devices. 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. Telephone reports should be followed up with a written report as soon as 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 on-line form on the MHRA website is the preferred method. Reports may, however, also be sent by e-mail, fax or post. Report forms may also be downloaded or printed from the website.

What do I do with devices that have been involved in incidents?
All items should be quarantined and not be repaired, returned to the manufacturer, or discarded until the MHRA has been given the opportunity to carry out its own investigation. When sending an item to the MHRA or to the manufacturer for investigation, remember that it is illegal to send contaminated items through the post.
1. As an adverse incident, this item may have already been sent to SMTL as part of a non-hazardous report/defect on a consumable item.
2. Correspondence should state location, where defective item is being stored
What does MHRA do when it receives a report?

After recording incident details onto their database, a risk assessment is undertaken by medical device specialists. That assessment determines whether an investigation is undertaken directly by the MHRA or by the manufacturer on the Agency’s behalf, or whether the incident is recorded for information and trend analysis only. Reports are acknowledged and reporters advised of the nature and outcome of the investigation.

Reporting to other organisations

Depending on the nature of the adverse incident, other central reporting bodies – such as the Health & Safety Executive, NHS Estates and the National Patient Safety Agency – may require notification. Where an incident report made to the MHRA clearly indicates that the problem relates to the use of the device rather than the manufacture, maintenance or function of the device itself, details of the incident will be forwarded, in an anonymous format, to the National Patient Safety Agency (NPSA).

The Medicines and Healthcare products Regulatory Agency and Adverse Incident Centre
The Medicines and Healthcare products Regulatory Agency is an executive agency of the Department of Health. The Adverse Incident Centre (AIC) is the focal point for the reporting of incidents involving medical devices.

Their role is to take all reasonable steps to protect the public health and safeguard the interests of patients and users by ensuring that medical devices:

- meet appropriate standards of safety, quality and performance;
- comply with relevant Directives of the European Union;
- are used safely.

One way the MHRA 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. Where the result of investigations, or other information received, has implications for patients or users, MHRA issue a Medical Device Alert advising of hazardous products or unsafe procedures.

**What is a medical device?**

Equipment used for the diagnosis or treatment of disease, or for monitoring of patients. Some examples are given below (this is not an exhaustive list):

- Anaesthetic equipment
- Blood warming cabinets
- Catheters (e.g. urinary, cardiac)
- Chiropody equipment
- Dental equipment and materials
- Dressings
- Endoscopes
- Examination gloves
- Implants – powered and non-powered (e.g. implantable defibrillators, pacemakers, heart valves, orthopaedic prostheses, bone cements)
- 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
- Vaginal specula
- X-ray systems, ultrasound imagers and CT/MR scanners

**For critical care:**
- Defibrillators
- Resuscitators
- Ventilators

**For people with a disability:**
- Communication aids
- Environmental controls
- Orthotic and prosthetic appliances
- Patient hoists
- Pressure relief equipment
- Walking aids
- Wheelchairs and special support seating

**For patient transportation or moving (but not including ambulance vehicles themselves):**
- Carry chairs
- Lifting aids
- Stretchers and trolleys
For daily living:
- Bathing and showering equipment
- Commodes
- Hearing aids
- Incontinence products
- Prescribable footwear
- Special chairs
- Urine drainage systems

Medical devices and equipment also include the following in vitro diagnostic medical devices and their accessories:
- Blood gas analysers
- Devices for blood glucose measurement
- 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)

MHRA are also interested in products which, whilst not themselves medical devices, are used closely in conjunction with these devices:
- Bench top sterilizers
- Blood and tissue storage systems
- Chemical and biological indicators used in sterilization processes
- Disinfecting and sterilizing equipment

What is not a medical device?
Medical devices do not include ambulances, general workshop equipment such as power or machine tools, or general-purpose laboratory equipment. Pre-filled devices e.g. drug inhalers, syringes and certain other drug/device combinations also fall into this category. MHRA Adverse Incident Centre staff will be happy to provide advice in any cases of doubt.

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 patients, users or other persons.
Adverse incidents in medical devices may arise due to:

- shortcoming in the design or manufacture of the device itself;
- inadequate instructions for use;
- inadequate servicing and maintenance;
- locally initiated modifications or adjustments;
- inappropriate user practices (which may in turn result from inadequate training);
- inappropriate management procedures;
- the environment in which a device is used or stored;
- selection of the incorrect device for the purpose.

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 use in the community or ambulances).

What should be reported?
Any adverse incident involving a device or its instructions for use should be reported to 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);
- inpatient hospitalisation or prolongation of existing hospitalisation;
- unreliable test results leading to inappropriate diagnosis or therapy;
- fetal distress, fetal death or a congenital abnormality or birth defect.

Subject to the above, specific published MHRA 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.

MHRA should also be informed of:

- any other device-related adverse incidents;
- minor faults and discrepancies.

These may take on a greater significance when aggregated with other similar events as they may help demonstrate trends or may indicate inadequate quality assurance on the part of the manufacturer or supplier.

Reports of adverse incidents that appear to be caused by human error are also helpful as:

- the error may be partly (or wholly) due to deficiencies in the design of the device or instructions for use;
- they will help prevent repetition of mistakes, possibly by promulgation of advice or through improvements to the design of future devices.

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

When should an incident report be made?
All incidents should be reported as soon as possible, usually within 24 hours. Serious cases should be reported to us by the fastest means available, preferably on-line, fax or e-mail followed up by a confirmatory telephone call. Telephone reports should be followed up as soon as possible by a written report.

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.

How do I report an incident?
On-line reporting is now available through the MHRA website or via their site on the NHSNet. MHRA strongly recommend that, where possible, on-line reporting be used.
Successful use of this route will provide the reporter with immediate confirmation of receipt and a unique incident reference number.

Paper forms for reporting incidents may be downloaded from the MHRA website and then either completed electronically and e-mailed or printed and sent by mail or fax. However, the preferred method of reporting is on-line via the website.

Copies of forms are also available from

MHRA Adverse Incident Centre  Tel:  020 7972 8080
Hannibal House  Fax:  020 7972 8109
Elephant and Castle  E-mail:  aic@mhra.gsi.gov.uk
London SE1 6TQ

In cases of urgency outside normal office hours, incidents may be reported using the on-line reporting facility on the MHRA website (www.mhra.gov.uk). Alternatively, an answering machine at the MHRA's Adverse Incident Centre carries a message giving the telephone number of the Department of Health's Duty Officer. The Duty Officer is able to contact senior MHRA officials. Telephone messages may be left on the machine for response on the next working day, but we would prefer that reporters use the 24-hour on-line reporting option.

IMPORTANT:
- Full contact details (name, post held, telephone numbers etc.) should always be included on your forms and in your telephone messages. This will allow MHRA to contact you to acknowledge receipt of your report or message and to request any further information that may be needed;
- Reporters should ensure that local medical device liaison officers, patient safety managers and risk managers are aware of all incidents reported to MHRA by the trust. Reporters should use the e-mail forwarding facilities incorporated in the on-line reporting system.

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

All items that have been involved in incidents should initially be quarantined where possible (see Local Procedures below) and should not be repaired (either in-house or by a third party), or returned to the manufacturer/supplier (unless otherwise agreed with MHRA) or discarded before MHRA has been given the opportunity to carry out an investigation. The manufacturer or supplier should be informed promptly, and allowed to inspect the items if accompanied by an appropriate person. 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.

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.
In exceptional circumstances, where devices 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 vigilance and extra caution.

Any parts of devices removed and replaced in these circumstances, and any devices withdrawn from use, must be clearly identified, quarantined and stored securely pending investigation.

**Contaminated items**

Advice on procedures to be followed if healthcare equipment is contaminated and constitutes a biohazard is contained in MHRA DB2003 (05) Management of Medical Devices Prior to Repair, Service or Investigation, (available only on the MHRA website). MHRA device specialists can provide advice where necessary, particularly on whether arrangements should be made for the item to be examined prior to any decontamination.

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

**IMPORTANT: IT IS ILLEGAL TO SEND CONTAMINATED ITEMS THROUGH THE POST**

**Evidence**

All material evidence should be labelled and kept secure. This includes the products themselves, their instructions for use, records of use, repair and maintenance records, and where appropriate, packaging material or other means of batch identification. The evidence should not be interfered with in any way except for safety reasons or to prevent its loss. If necessary, 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 it is believed that an urgent examination of the defective item (and/or related items) is needed, the reporter should contact the MHRA Adverse Incident Centre (AIC). An MHRA device specialist will then decide whether to inspect the item urgently on site (or at other appropriate facilities), or may agree that the device should be submitted to the AIC.

**What does MHRA do when it receives a report?**

**When the MHRA’s Adverse Incident Centre receives a report:**

- it is logged on to the MHRA database;
- an acknowledgement is sent to the reporter (this will contain a unique reference number); and
- if a fatality or serious injury is involved, senior management and the relevant MHRA specialist technical unit is immediately alerted.

The report is then passed on to a MHRA device specialist to review the report and determine the most appropriate method of further investigation.
If an incident involves a death or serious injury, or if there is a high potential for further similar incidents to do so, the MHRA will lead the investigation itself. In the course of this type of investigation, MHRA staff may:

- talk with the user and manufacturer;
- when necessary, visit the site of the incident;
- review evidence (including the device itself); and
- if appropriate, issue safety advice to the healthcare sector.

For the majority of reported adverse incidents, the manufacturer leads the initial investigations. In these cases, the manufacturer is provided with information about the incident, the location and the device involved. Although the manufacturer takes responsibility for resolving the incident, the MHRA monitors progress, reviews the manufacturer's response, and informs the reporter of the outcome.

If, at a later stage, new information is brought to light, previously concluded investigations are re-appraised. Outcomes of investigations are routinely reviewed in order to identify patterns or clusters of incidents, which may require further investigation.

Local procedures should ensure that:

- devices involved in an adverse incident, together with other material evidence (e.g. packaging of a single-use device) are clearly identified and, where practicable, kept in quarantine until MHRA device specialists have been consulted. Where quarantine is not practicable, the state of the device(s) at the time of the incident should be recorded for use in any subsequent investigation. Further advice is given in this document and on the website;

- local action is taken as necessary to ensure the safety of patients, users and others;

- regular reviews should be undertaken to ensure that local procedures are effective and are being followed.

**Reporting to other organisations**

**National Patient Safety Agency (NPSA)**

The NPSA has introduced the National Reporting and Learning System (NRLS) for logging all failures, mistakes, errors and near-misses across the health service, with the aim of ensuring that lessons are learned and spread throughout the health service.

MHRA continues to work alongside the NPSA to ensure mutually beneficial development of reporting systems, with the common goal of maximising their effectiveness in preventing harm arising from the use of medical devices. Incidents involving the use of a medical device that are reported to the NPSA using their electronic reporting form will be shared with the MHRA. However, because the anonymous nature of NPSA information will prevent the MHRA from investigating what happened, the NPSA actively encourages reporting of these incidents directly to the MHRA.

National Patient Safety Agency
4-8 Maple Street
London
W1T 5HD

Tel: 020 7927 9500
Fax: 020 7927 9501
Website: www.npsa.nhs.uk
Medicines
Incidents involving defective medicines should be reported to the Medicines sector of the MHRA.

Suspected adverse reactions to medicines not thought to be a consequence of a defective product should also be reported to MHRA Medicines sector through the Yellow Card Scheme. For further details on how and what to report see the website at www.mhra.gov.uk. Reports should be sent to:

MHRA Defective Medicines Report Centre  Tel: 020 7084 2574
Market Towers  Fax: 020 7084 2676
1 Nine Elms Lane  E-mail: dmrc@mhra.gsi.gov.uk
London SW8 5NQ

RIDDOR
Incidents involving certain types of injury, occupational disease or dangerous occurrence, whether involving medical devices or not, should 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 Health and Safety Executive (HSE), but may for some premises be the local authority. Reports should be made to the local office of the relevant body.

There is an UK Incident Contact Centre to which all notifications under RIDDOR may be made by post, telephone or fax to:

The Manager  Tel: 0845 300 9923
Incident Contact Centre  Fax: 0845 300 9924
Caerphilly Business Park
Caerphilly
CF83 3GG

Internet reporting is available via the website: www.riddor.gov.uk
Copies of report forms may also be downloaded from the site.

Non-medical equipment, engineering plant, installed services and building fabric
Incidents involving non-medical equipment, engineering plant, installed services and building fabric should be reported using the guidance in EPL (95) 16 to:

Head of Engineering  Tel: 0113 254 7000
NHS Estates  or
1 Trevelyan Square
Boar Lane  Out of hours: 020 7210 3000
Leeds  www.nhsestates.gov.uk
LS1 6AE