



MHRA
Regulating Medicines and Medical Devices

Medical Devices - Reporting to MHRA

Emma Rooke, December 2015



Topics to be covered today:



- The MHRA and what we do
- What is a Medical Device?
- Adverse Incidents
- Reporting adverse incidents to the MHRA



Medicines and Healthcare Products Regulatory Agency

IRA



MHRA

The Medicines and Healthcare Products Regulatory Agency



CPRD

Clinical Practice Research Datalink



NIBSC

National Institute for Biological Standards and Control



What we do...(not exhaustive!) MHRA

- Medicines (inc herbal and homeopathic)
 - Licence
 - Monitor adverse incidents
 - Enforce regulations

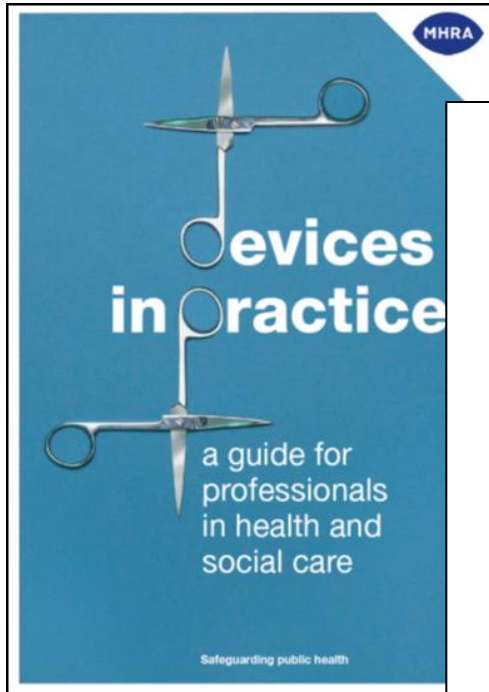



- Medical Devices
 - Monitor Notified Bodies
 - Monitor adverse incidents
 - Enforce regulations



- Blood Establishments & Blood Banks
 - Authorise
 - Monitor adverse incidents
 - Enforce regulations




Managing Medical Devices
Guidance for healthcare and social services organisations

April 2014

Medicines and Healthcare Products Regulatory Agency



ONE LINERS

Medicines and Healthcare Products Regulatory Agency

Issued June 2015

ALL medical devices can fail but an increasing number of incidents that result in significant morbidity or mortality arise out of user/device interface problems or because of poor practices. The aim of this series should be to detail briefly some of these problems in an attempt to make users more aware of what can go wrong – it is all too easy to take equipment for granted.

DON'T LET THIS PASS YOU BY!
MHRA has received reports of water to blood leaks occurring at the heat exchanger in oxygenators used in heart/lung bypass.

IN CONFIDENCE!
Patient information can be left on the memory of devices returned to the manufacturer/service agents to repair or maintenance.

Check for water-side leaks before the oxygenator is primed for cardiopulmonary bypass and that the manufacturer's instructions for use are followed when setting up and priming an oxygenator. These pre-use checks must be incorporated into Departmental protocols.

Users should ensure they fit adequate local policies and procedures to ensure that such information is removed from the memory prior to removal from the user of the device.

Pee "T" ERR OUT
Urinary catheter valves may encourage microbial colonisation of the bladder due to the presence of the catheter and urine stagnation.

HOIST WITH ONE'S OWN PETARD
Lack of maintenance and inspection of hoists and lifting lifts can lead to serious injury for the patient.

The use of these devices should be considered carefully, especially in patients with pressure ulcers or raised intracranial pressure.

Ensure that systems are in place to regularly inspect and maintain the use of all hoists, in accordance with the manufacturer's instructions. (see MDA20150016)

THERMOSTATIC!
MHRA has received a report that a number of infra-red ear thermometers designed to be accurate to +/- 0.2° Celsius are only being tested to +/- 1° Celsius by third party service providers.

SCOPE FOR IMPROVEMENT?
MHRA are aware of an issue where a laryngoscope failed to light during an emergency procedure and no replacements were available.

When drawing up service components, ensure that the vials are maintained to their original specification.

Where laryngoscope blades and handles are to be used (especially where this is not covered in a specific licence, manufacturer's instructions should be readily available).

The One Liners Series are published by the MHRA, an executive agency of the Department of Health. Adverse incidents should be reported at the earliest opportunity. For more information on the online reporting system or our website visit www.mhra.gov.uk. You may also use this online system to send an email copy of your report to your medical device liaison officer. You may also have an adverse incident hotline (02) 7584 5686. You can find detailed reporting guidance on our website.

Issue Date



Medical Device Alert

MDA20150018 Issued 21 April 2015 at 14:30

All posture or safety belts fitted to supportive seating, wheelchairs, hoists and bathroom equipment.

Summary
Using the wrong type of belt or a belt that isn't fitted or adjusted properly can lead to serious injury or death of the person using the equipment.

Action

- Ensure that all posture/safety belts for supportive seating, wheelchairs, hoists and bathroom equipment are fitted, adjusted, used, cleaned, checked and maintained in accordance with the manufacturer's instructions.
- Ensure all users and carers are aware of the manufacturer's instructions for use and have received training on how to check, adjust, clean, and maintain such devices.
- Before each use, ensure that the posture/safety belt is in a satisfactory condition, is the right type for the user, and is adjusted correctly.
- Ensure that each review of an individual's needs includes a check that the posture/safety belt is the right one for the user and carers.
- Report all adverse events associated with the use of these devices to the manufacturer and the MHRA.

Action by
Anyone involved in the provision, prescription, use and maintenance of the above equipment.

Deadlines for actions
Actions underway: 08 May 2015
Actions complete: 22 June 2015

These are deadlines to check if the equipment is still suitable, that it is still set up correctly for the user and that it has been properly maintained.

Device details
This alert also applies to belts referred to as petal, jet, seat or waist belts and also straps or harnesses.

Problem
The MHRA continues to receive reports of injuries and fatalities because posture/safety belts on sensitive technology devices aren't used, fitted or adjusted properly or they haven't been maintained correctly.

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What is a Medical Device?



Any instrument, apparatus, appliance, material or other article...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;



Adverse Incidents



What is an Adverse Incident?



- *An event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, users or other persons.*



What to report



Report to MHRA when

a) the problem involves a medical device

and

b) the problem with/failure of the product has caused or could have caused injury

If in doubt, please report it!



Medical devices you may come across can include:



- Powered wheelchairs
- Mobility Scooters
- Oxygen Concentrators
- Electrically powered medical devices



Who should report and when?



Anyone! Clinicians, Suppliers, Patients, Medical Device Liaison Officers, Manufacturers...

If you would like to discuss it first, get in touch:

MHRA Adverse Incident Centre

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

Please report any issues as soon as possible, providing as much detail as you can




How to report



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www.mhra.gsi.gov.uk

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Medicines &
Healthcare products
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Drug and device alerts

Drug Safety Update

[Report a problem with a medicine or medical device](#)



Report a serious blood adverse event or reaction

Marketing authorisations and licensing guidance



Yellow card scheme - now covers Medical Devices too



The screenshot shows the Yellow Card reporting website interface. At the top left is the 'Yellow Card' logo. To the right is a search bar with the text 'Enter Keyword(s) to Search' and a magnifying glass icon. Below the search bar is a navigation menu with links for 'Home', 'About Yellow Card', 'Downloads', and 'Contact Us'. The main content area is divided into two columns. The left column is titled 'Welcome to the reporting site for the Yellow Card Scheme' and contains a section 'Report a suspected problem or incident:' with four options: 'Side effect to a medicine, vaccine, herbal or homeopathic remedy' (with a yellow 'Side effects' button), 'Medical device adverse incident' (with a blue 'Devices' button circled in red and a red arrow pointing to it), 'Defective medicine (not of an acceptable quality)' (with a purple 'Defective' button), and 'Counterfeit or fake medicine or medical device' (with a green 'Fake' button). The right column is titled 'Welcome to the MHRA's new reporting site' and contains text explaining that the scheme now supports reporting for all healthcare products, not just medicines. It also includes a link to 'contact us' and a section 'Already Registered?' with a login form for email address and password.



Please include:

- Manufacturer, device type and model name
 - Without these
 - the manufacturer cannot investigate
 - MHRA will not be able to determine whether your report is part of a wider problem
- Details of what happened
- Who MHRA and the manufacturer can contact for further information about the incident report



What happens next?

We will tell you within 10 working days of receipt of your report what we plan to do

We will always:

- send your report to the manufacturer for their internal investigation
- add your report to our database

Our database is reviewed regularly to identify patterns where further action is needed



We do not investigate every report



Therefore, please do not automatically expect updates from us

The manufacturer will carry out an internal investigation

Please provide them with any details they request, and contact them for their findings



When do MHRA investigate?



- When we receive a report of death or serious injury
or
- When the manufacturer's investigation indicates a wider problem
or
- When we detect a pattern in reported problems

If we decide to do this, we will let you know and keep you informed of our progress



What does an MHRA investigation involve?



We may

- ask the manufacturer for details of their findings
- ask them to investigate further
- ask them to consider corrective action



Why should I report?



If problems are not reported, they won't be resolved

MHRA investigations can result in:

- Changes to design/instructions
- Safety related warnings/advice being issued
- Education to reduce “use-errors”
- Field Safety Corrective Actions
- Removal from the market



Why your report counts



Receipt of **13,282*** reports in 2014 resulted in the following actions:-

- **104** design modifications
- **130** labelling/instructions-for-use changes
- **26** cases of production being ceased
- **341** manufacturer undertakings to manufacturing process and quality assurance
- **42** medical device alerts issued

*Total incidents reported – includes periodic summary reports



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If you have any questions, please get in touch

MHRA Adverse Incident Centre

aic@mhra.gsi.gov.uk

Tel: 020 3080 7080

Thank you

