Medical Device Incident Investigations: Recommendations

Investigation of incidents with medical devices that have a 'memory' or an 'event log'

The TGA receives numerous reports about adverse events associated with devices such as infusion pumps and vital signs monitors which cannot be investigated adequately because the devices are not handled appropriately immediately after the incidents.

Some of the reasons that investigation is impossible are:

- The exact device is not known because it has not been removed from use and isolated.
- The information on the memory of the event has not been downloaded.
- Well-intentioned biomedical engineering personnel, prior to downloading the memory, have tried to repeat the problem and in so doing overwritten the log at the time of the event due to limited memory within the medical device.

The Therapeutic Goods (Medical Devices) Regulations 2002 requires Australian sponsors of medical devices to notify the TGA if the device has been involved in an event that caused or could have caused a serious injury, illness or death. Sponsors are also required to investigate those events and to periodically review event data in case a pattern emerges that can be addressed through product improvement or other actions. The loss of event log information seriously curtails the ability of the manufacturer to investigate an incident.

More importantly, the information that can be learnt by the healthcare facility, the manufacturer, other healthcare facilities or the TGA from an incident is greatly diminished if the device is not isolated and the event log is lost. This may lead to a recurrence or even a more serious event.

Recommendations

- **The importance of healthcare personnel immediately isolating medical devices and any other items that may have been associated with an incident can not be stressed strongly enough.**
- For programmable devices such as infusion pumps, knowing the sequence of key strikes is important in analysing whether there is a problem with the device or if there is another issue to be addressed. If the particular device features an event log, that log should be downloaded as soon as possible following the incident, before any further testing or inspection of the device takes place.
- The Australian supplier/sponsor should be contacted as soon as possible following the incident or event. They will be able to provide the equipment or information on how to download the information. The sponsor will also be able to interpret the data. They will also be able to fulfil their reporting obligation to the TGA and other regulatory agencies in a timely manner.
- Healthcare professionals should consider reporting serious incidents to both the sponsor and the TGA.

MRI injuries to patients with implanted neurological stimulators

On 10 May 2005, the US Food and Drug Administration (FDA) issued a notification to remind radiology personnel and physicians that serious injury or death can occur when patients with implanted neurological stimulators undergo MRI procedures, and to recommend preventive actions. The notice can be downloaded from the FDA website <http://www.fda.gov/cdrh/safety.html>.

The FDA has received several reports of serious injury, including coma and permanent neurological impairment, in patients with implanted neurological stimulators who underwent magnetic resonance imaging (MRI) procedures. The mechanism for these adverse events is likely to involve heating of the electrodes at the end of the lead wires, resulting in injury to the surrounding tissue. Although these reports involved deep brain stimulators and vagus nerve stimulators, similar injuries could be caused by any type of implanted neurological stimulator, such as spinal cord stimulators, peripheral nerve stimulators, and neuromuscular stimulators.

The TGA has also received a number of reports of injuries to patients undergoing MRI scanning, although none relate to neurological stimulators. However, there is a potential for serious injuries to occur if a patient with a neurological stimulator has an MRI scan without first notifying the hospital staff. This notification is being relayed to clinical staff in the hope that an adverse event will be prevented.

Recommendations

If you are a physician who implants or monitors patients with implanted neurological stimulators:

- Explain to the patient what MRI procedures are and stress that they must consult with the monitoring physician before having any MRI exam to find out whether it can be performed safely.

If you are a radiologist or healthcare professional who uses MRI equipment:

- Carefully screen all patients for any implanted devices prior to performing an MRI procedure, ***even if the implanted device has been turned off***. Also question patients about previously implanted devices that have been removed. Leads, or portions of leads, often remain in the body after pulse generators are removed, and these may act as an antenna and become heated.
- If the patient does have an implanted neurological stimulator, consider consulting with the referring physician to discuss other imaging options. For some implanted neurological stimulators, certain MRI procedures are contraindicated and cannot be performed.
- If an MRI procedure is to be performed on a patient with an implanted neurological stimulator, be sure to review the labelling for the specific model that is implanted in the patient, with particular attention to warnings and precautions. The radiologist may need to consult with the implanting or monitoring physician for this information. Also note and follow any instructions exactly for MRI imaging that may be in the labelling for the implant, including information on types and/or strengths of MRI equipment that may have been tested for interaction with the particular implanted device. The radiologist may need to consult with the device implant manufacturer for this information.

If any adverse events occur with these or any other medical device please contact the TGA's medical device Incident Report Investigation Scheme on 1800 809 361 or by email <iris@health.gov.au>.

Mobile electric patient hoists

The TGA is aware of incidents involving electrically activated patient hoists which may fail without warning, causing the sudden dropping of the hoist boom, which could lead to patient and/or carer injury. This problem is also the subject of a safety warning from the Medicines and Healthcare products Regulatory Agency

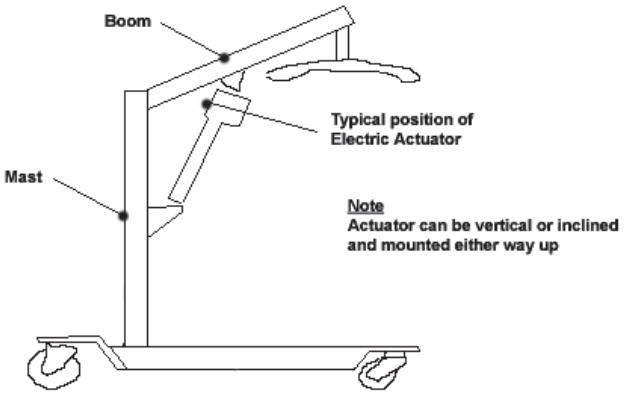
(MHRA) in the United Kingdom. The report from the MHRA has been used as the basis for this article.

Most incidents are related to damage and material fatigue caused by inappropriate handling, abnormal use and lack of proper servicing of the actuator mounting points. Excessive wear of the actuator mounting points can also lead to sudden failure of the actuator. The actuator failures are most influenced by usage, ie number of lifting cycles performed, rather than the age of the actuator. (Note: One lifting cycle = raising then lowering the patient.)

Establishing the 'life' of an actuator is difficult because hoists do not have counters fitted to record the number of lifting cycles.

Recommended actions

- Place patient hoists into the regular maintenance schedule for equipment in your healthcare facility. Welds, bolts, nuts, and strapping should be inspected regularly for signs of wear or damage.
- Identify mobile hoists with electric actuators, using the sketch below for guidance if necessary.



- Contact the hoist manufacturer, quoting the model and serial number, together with its rate of usage and age, to determine if the actuator is due for replacement.
- If the manufacturer cannot be contacted, for example because the hoist is unidentifiable or the manufacturer is no longer trading, a risk assessment should be carried out to determine if the electric actuator needs replacement.

  AS ISO 10535: 2002 recommends that actuators in patient hoists should be able to withstand 10,000 cycles. Guidance on how the rate of usage of a hoist relates to the life of the actuator in terms of years can be found in that standard*. In cases where the rate of usage and age indicate that the actuator is due for replacement, the actuator should be replaced unless the manufacturer states that the actuator has a longer design/service life than 10,000 cycles.
- Review the need for the electric actuator to be replaced as part of all future inspections and servicing of the hoist.

It should be noted that while compliance with technical standards such as AS ISO 10535: 2002 is strongly encouraged, it is not a legal requirement for supply. It is raised here as a guide for the management of patient hoist servicing in healthcare facilities.

** According to AS ISO 10535: 2002, the service life of the actuator should adhere to the following equation:*

[Service Life of Actuator in Years] < 10,000 ÷ (365 x [estimated number of lifts per day])

Clarification: Hand held Peak Expiratory Flow Meters (PFMs) for the assessment of pulmonary function and the self management of asthma; Medical Device Incident Investigations and Hazard Alerts; *TGA News* No 45, November 2004

Following the publication of the above article, the TGA has received communication from an Australian supplier of PFMs suggesting that some readers have interpreted our article to mean that EN13826 is the new standard to which PFMs *must* be calibrated in Australia. That interpretation is not correct.

Manufacturers of medical devices must be able to demonstrate compliance with the Essential Principles relating to medical device quality, safety and performance that are cited in the *Therapeutic Goods Act 1989*. Compliance with recognised standards is perhaps the simplest, *but not the only way*, to demonstrate compliance with the Essential Principles.

Readers should note that either EN13826: 2003 or AS/NZS 4237: 1994 or any other Standard that applies to PFMs may be used to demonstrate compliance with the Essential Principles provided that the use of one over any other is appropriately justified. In general, a manufacturer may need to demonstrate compliance with several technical and manufacturing standards in order to demonstrate compliance with regulatory requirements.

While compliance with a recognised standard is desirable and encouraged, the only way to ensure that a medical device meets Australian regulatory requirements and has TGA approval is to check that it is included in the Australian Register for Therapeutic Goods.

MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS) STATISTICS REPORT 01/01/2005 to 31/03/2005
Total Number Received: 152

Cause of Problem[1]	
Biocompatibility	2
Component Failure	26
Contamination	6
Design	13
Diagnostic Inaccuracy	2
Electrical	11
Inadequate Instructions	1
Labelling	7
Maintenance	5
Manufacture	13
Material/Formulation Deficiency	15
Mechanical	10
Not Device Related	13
Other	9
Packaging/Sterility	1
Quality Assurance	1
Unknown	38
Wear/Deterioration	4

Effect	
Death	6
Serious Injury	19
Temporary Injury	46
No Injury	81

Source Category	
Medical Administrator	7
Specialist	9
General Practitioner	0
Coroner	1
Nurse	11
Blood Bank	7
Hospital Supply Service	16
Other	8
Sponsor	60
Overseas Advice	18
Biomed Engineer	7
Para Medical	2

Result of Investigation	
Bulletin Article	4
Company Warned	2
Compliance Testing	1
No Further Action	57
Not Investigated[2]	49
Other	5
Problem Not Confirmed	9
Product Improvement	10
Recall/Hazard Alert	10
Refer to Surveillance	1
Safety Alert	3
User Education	9

Notes:

1. The problem causes are not mutually exclusive. For example, a material deficiency may have led to a mechanical malfunction or a biocompatibility problem.
2. Every report received by IRIS receives a risk analysis by the Scheme Coordinator and is discussed by a panel of technical and clinical professionals. In the case of reports that are 'Not Investigated' the panel has made a decision that further investigation of the particular event is not necessary at that time. However, these reports are logged into the database for future reference and the trend of reports is monitored. In making their decision, the panel considers whether any similar reports have been received previously.