Medical Device Incident Investigations: Recommendations

Update on high flow fluid warmers

DIR14262, DIR14118

The TGA continues to receive reports of deaths or serious injury to patients due to intra-vascular air embolisms associated with the use of high-flow fluid infusers/fluid warmers. These devices are generally used in emergency situations. It is believed that, in most of the incidents, the injury has resulted from re-attachment of partially-exhausted fluid bags to the system. The latest incidents occurred in December 2003 and May 2004.

In January 2002, after consultation with and in cooperation with the TGA, all sponsors of these devices issued a Safety Alert to remind users of the risks of introducing air into these systems and the possible consequence of serious injury to patients connected to these systems. The recommendations read as follows:

- **REMOVE ALL AIR** from fluid bags and lines before connection to patients;
- **FOLLOW** appropriate instructions for PRIMING the infusion line and set; and
- **MONITOR** fluid lines to ensure that they are free of air.
- **DO NOT** open ports in the infusion system, unless appropriate measures are in place to prevent the entry of air.
- **DO NOT** reconnect partially-emptied fluid bags — significant volumes of air may be sucked into the bag when disconnected.
- **DO NOT** use auto-transfusion bags with these systems, unless the infuser is clearly indicated for this use.

In response to continuing concern from the TGA regarding air embolism, in November 2002 Level 1 Incorporated developed a new device — the Air Detector/Clamp. This device is designed to be used with all existing Level 1 high flow fluid warmers and provides additional safety features that reduce the likelihood of air entering the patient. All users of Level 1 high-flow fluid warmers were notified of the availability of the new device and the additional safety features that it offers. The fluid warmer being used during the incident that occurred in December 2003 had not been fitted with an Air Detector/Clamp.

While the Air Detector/Clamp provides additional safety, it is extremely important that the information in the instructions for use regarding priming and use of partly-empty bags are adhered to. These warnings and precautions appear in several places in the instructions for use for both the warmer, disposable equipment, the service manual and on laminated product instruction cards. It is important to understand that the Air Detector/Clamp is intended to supplement, not replace, procedural measures to prevent air emboli, like adequate priming, and not using half-full bags or auto-transfusion bags.

If an Air Detector/Clamp is being used, it is also important that users are trained in both the use of the device and the procedures to be followed in case an air bubble is detected and the clamp is deployed. In a separate incident that occurred in May 2004, the air detector functioned as intended and alarmed. The air was cleared from the line but infusion could not be restarted because the user had not reopened the clamp after clearing the line. The procedure for re-starting flow is clearly stated in the product instructions. The patient died, but it is not clear whether the delay in infusion contributed to this outcome. The TGA appreciates that in emergency situations such as this users must rely on their training and product prompts and that user instructions are of limited use. The incident is currently under investigation to determine what measures are possible to minimise the likelihood of a recurrence.

Recommendations

If you have questions regarding labelling precautions, or if you do not have the labelling and product cards referred to above, please contact Smiths Medical Australasia on free call 1800 654 949.

Ensure that all staff who use or are likely to use the Level 1 fluid warming system are trained in the use of the device and have read and understood the instructions for use. If an Air Detector/Clamp is fitted then users should be familiar with the behaviour of the device when deployed and the procedure for re-establishing flow.

Abbott "Pain Management Provider" Drug Infusion Pump — Faulty patient bolus cable

DIR 14152

A damaged patient cable on an Abbott pump had an intermittent open- and closed-circuit fault between its wire conductors. The fault simulated the repeated pressing of the patient button that resulted in delivery of a series of programmed boluses.

Setting a limit to the Volume To Be Infused (VTBI) in a certain time (4 Hr Limit function) may have prevented the over-delivery of analgesic. Abbott suggested this change in operating procedure when using a PCA pump and the hospital involved has examined their procedures when setting the pump. The hospital is also investigating a regular preventative maintenance program so that cords are replaced before they fail.

Even though the reported incident involved an Abbott Pain Management Provider (PCA) pump, the principles apply to all brands of PCA pump.

Recommendation

Where possible, consider establishing procedures to ensure that PCA pumps in your facility are programmed in such a way as to limit the amount of drug delivered per hour to a safe dose (regardless of patient demand).

PCA pump cables can be damaged by bed rails, castors and general use. They should be routinely inspected for kinks and obvious signs of damage or wear.

Severe adverse events associated with the use of absorbable haemostatic agents

The TGA is aware of an important notice issued by the US FDA about adverse events associated with absorbable haemostatic agents.

Rare, but devastating, adverse events can occur with the use of an absorbable haemostatic agent, a device used to promote coagulation and stop internal bleeding during surgical procedures. These events continue to occur despite specific advice and warnings in the device labelling.

Nature of problem

Since 1996, the FDA has received reports of over 110 adverse events related to absorbable haemostatic agents. Eleven of the events resulted in paralysis or other neural deficits. The last reported paralysis occurred in October 2003. The common thread in all eleven events was an absorbable haemostatic agent that was used on or near a bony or neural space and left inside the patient. When wetted, the material swelled and exerted pressure on the spinal cord or other neural structures, resulting in pain, numbness or paralysis. In some cases, blood pooled behind the implanted absorbable haemostatic agents, forming a haematoma that exerted pressure on neural tissues and caused a range of neural deficits. Although these events are rare, they can have serious consequences. These consequences are preventable**.**

Recommendations

It is recommended that users of absorbable haemostatic agents review the device labelling, especially the contraindications, warnings and precautions. If you use an absorbable haemostatic agent on or near bony or neural spaces:

- use the minimum amount necessary to achieve haemostasis; and,
- remove as much of the agent as possible after haemostasis is achieved.

This will reduce the likelihood of neural and other soft tissue damage from swelling of the absorbable haemostatic agent, and/or migration and swelling of fragments of the agent.

Central venous catheter-pump injectors

Problem

The Medicines and Healthcare Products Regulatory Agency in the UK has issued a notice about the risk of central venous catheter rupture during contrast CT investigation due to over-pressurisation when used with a powered injector.

There have apparently been a number of adverse events reported where multi-lumen central venous catheters have ruptured through the injection of contrast medium during CT imaging. This has resulted in severe complications such as blood loss, interruption of essential medication and the circulation of pieces of catheter, which could lead to occlusion of blood vessels. Tunnelled lines are also at risk and rupture of these lines is more difficult to detect.

Recommendation

- Wherever possible insert a peripheral line for pump injection of medium. This should be removed following the procedure.
- If no peripheral access is possible then the patient should be informed of the risk.
- Hand injection of medium should preferably be used and this should be injected by qualified personnel.
- Avoid using tunnelled central venous catheters if at all possible.
- If using a pump injector limit the flow rate of contrast to a maximum of 2ml/sec and connect the injector to the widest bore lumen of the line using aseptic technique.
- Flush line and inspect for damage before and after use of central venous catheter.

MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS) STATISTICS REPORT 01/01/2004 to 31/03/2004

Total Number Received: 121

Cause of Problem[1]	
Biocompatibility	1
Component Failure	18
Contamination	2
Design	5
Electrical	3
Inadequate Instructions	2
Labelling	3
Maintenance	4
Manufacture	4
Material/Formulation Deficiency	10
Mechanical	13
Not Device Related	19
Other	15
Packaging/Sterility	2
Quality Assurance	2
Unknown	26
Wear/Deterioration	7

Effect	
Death	6
Serious Injury	15
Temporary Injury	21
No Injury	79
Source Category	
Medical Administrator	4
Specialist	8
General Practitioner	0
Coroner	1
Nurse	9
Blood Bank	11
Hospital Supply Service	15
Other	16
Sponsor	46
Overseas Advice	8
Biomed Engineer	3

Result of Investigation	
TGA News article	2
Compliance Testing	1
No Further Action	54
Not Investigated [2]	38
Other	3
Problem Not Confirmed	3
Product Improvement	6
Recall/Hazard Alert	4
Refer to GMP	2
Safety Alert	9
User Education	10

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.