Medical Device Incident Investigations: Recommendations

Interference between Extraneal Peritoneal Dialysis Solution and Advantage II Blood Glucose test strips for Accu-Chek and Accu-Trend blood glucose monitors

DIR 14816

Problem

The TGA has received a small number of adverse event reports, including one death, associated with the use of certain types of blood glucose test strips by patients who are also on peritoneal dialysis.

In the case of the reported death, the peritoneal dialysis fluid being used was Extraneal or Icodextrin, manufactured by Baxter Healthcare. The patient and the hospital appear to have been using an Accu-Chek blood glucose monitor with Advantage II test strips, manufactured by Roche to monitor blood glucose levels. The patient died of undetected severe hypoglycaemia.

Extraneal contains maltose which interferes with the blood glucose readings obtained when using Accu-Chek and Accu-Trend blood glucose monitors with Advantage II Blood Glucose test strips. The blood glucose readings in these cases are falsely high, causing the patient to overdose on insulin, leading to serious consequences.

The use of Advantage II test strips for patients on Extraneal is contraindicated by both Baxter and Roche. Maltose in the Extraneal reacts with the glucose dehydrogenase on the test strips and gives a false high level of blood glucose. The patient then gives themselves another injection of insulin or a higher dose of insulin. The patient is then hypoglycaemic and they can swiftly fall into a coma. The physician who reported the problem indicated that he knew that this false positive reaction does exist in the literature but is not commonly known by physicians.

The TGA investigated a similar (non-fatal) event in 2003 which led to both Baxter and Roche issuing Safety Alerts to all diabetes educators. Contraindications about the use of the two products in combination appear in the instructions for use of both Extraneal and the Advantage II test strips.

Recommendation

If a patient is prescribed Extraneal check if they are a diabetic and if so, what blood glucose monitor and test strips they are using. If there are doubts about the information received, contact a diabetic educator and the manufacturer(s) of the monitor and test strips to make sure that they are not using a glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) method for testing.

To ensure that this does not occur, the test method chosen (for both monitor and test strips) must use a glucose-specific enzyme such as glucose oxidase or hexokinase. GDH-PQQ BASED METHODS MUST NOT BE USED.

It is important that the patient carry their EXTRANEAL™ Safety Card at all times in case of medical emergency for correct treatment. The patient's relatives or anyone who might be involved in their care should also be aware of this information.

Recall for product correction of Laerdal Patient Cable Adapters (Laerdal Cat # 920650)

DIR 14748

Two people died in separate incidents in Queensland after the defibrillator needed to resuscitate them failed to operate. The defibrillators and pads used in the incidents were tested by the manufacturer and found to be working properly. Further investigation determined the problem to have been caused by broken Patient Cable Adapters (Laerdal Cat # 920650) that were being used so that Heartstart 3000 series electrode pads could be used with the Heartstart 4000 series defibrillator being used. The investigations indicate that these breaks were due to "wear and tear" and that there was no inherent problem in the design or manufacture of the cable.

The pre-shift checking procedures described in the defibrillator's instructions for use are not suitable for checking the system when a Patient Cable Adapter is being used. If the adapter is being used, the operator must use either a Heart Start Tester (Laerdal Cat # 903800) or a Laerdal Test Manikin, not the 50 ohm test load supplied with the defibrillator. The whole system, including the Patient Cable Adapter, must be connected to either the Heartstart Tester or the Manikin during the checking procedure for the procedure to be effective. The checking procedure is otherwise the same as that provided in page 11-3 of the Heartstart 4000 Operating Instructions. Advice to this effect was provided in a Safety Alert sent out by Laerdal to all users of the Cables on 18 February 2005.

While the users of the defibrillators involved in the incidents appear to have been using the pre-shift checking procedure given in the Operating Instructions for the defibrillator, they were not aware that this procedure provides no assurance that the Patient Cable Adapter (Laerdal Cat # 920650) is working properly. This is likely to have resulted in the faults in the cables going undetected.

The Heartstart 4000 Defibrillator does not need the Patient Cable Adapter to work properly. Users may simply use Heartstart 4000 Defibrillation Electrodes (Cat # M35601A-1), which connect directly to the Heartstart 4000 Patient Cable. While the tests that were recommended in the Safety Alert of 18 February would detect the vast majority of Patient Cable Adapters that may be faulty, Laerdal now considers that the procedure cannot guarantee that the cables would still work in 100% of cases. Laerdal has therefore decided to remove the Patient Cable Adapters from clinical service. The adapter cables are also used to connect the defibrillator to the Laerdal Manikin during training, therefore the cables may still be needed as a training tool. The action described is defined as a "Recall for Product Correction" in the *Uniform Recall Procedure for Therapeutic Goods*.

It is important to emphasise that both the Heartstart 4000 Defibrillator and the Heartstart electrodes being used were exonerated during the investigation, and that users can continue to use them as outlined in the Instructions for Use for those products.

Recommended action

Any Patient Cable Adapters (Laerdal Cat # 920650) in your facility must either be destroyed or labelled as being "Not For Clinical Use" with the label provided by Laerdal.

If you have Laerdal Patient Cable Adapters in your healthcare facility, please ensure that you have received the Recall for Product Correction letter from Laerdal, and that you follow the instructions in the letter carefully.

If you have Laerdal Patient Cable Adapters in your facility and you have not received the recall letter by 16 April 2005, please contact Laerdal on 1800 331 565.

Entrapment of patient's head in the side rail of a hospital bed

DIR 14334

The TGA has investigated a report of entrapment of the head of an elderly patient in the side rail of a Joyce 900 hospital bed manufactured by Huntleigh Healthcare. This is the first such incident reported. The investigation has led the Australian Sponsor to provide a design "fix" that will reduce the rail spacing at the head and foot end of the beds. This action is classified as a recall for product correction in Australia, but no beds will need to be taken out of service to apply the fix.

The Joyce 900 bed was first manufactured in 1994 and designed to meet the standard of the day, which was AS3200.2.38: *Approval and Specification-Medical Electrical Equipment - Particular Requirements for Safety-Electrically Operated Hospital Beds)*. AS3200-2-38 was largely cloned from IEC 60601-2-38 bearing the same title. However, IEC 60601-2-38 was amended in 2000 to incorporate dimensional requirements to the bed side rail to minimise the possibility of patient entrapment.

Huntleigh Healthcare advised the TGA that as of July 2004 the design of the bed rails was changed to eliminate the possibility of entrapment. The new design complies with the current IEC standard. Huntleigh Healthcare also agreed to supply a retrofit to beds supplied before July 2004. The retrofit introduces an extra bar in the two "D" shaped spaces at the foot and head end of the side rail. This will reduce the spacing between cross-members and minimize the risk and severity of patient entrapment in beds.

The retrofit is classified as a "Recall for Product Correction" under the *Uniform Recall Procedure for Therapeutic Goods*. The recall was initiated on 23 February 2005 and is being coordinated through the Australian Recalls Coordinator at the TGA.

Until recently most hospital beds were exempt from the requirement to be listed in the Australian Register for Therapeutic Goods. The application of technical standards such as those from the International Electro-technical Committee (IEC) is a not a mandatory requirement under therapeutic goods legislation. However, suppliers of medical equipment regulated by the TGA must be able to demonstrate products are safe and the preferred way to do this is compliance with the current international technical standards.

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Recommendation

If you own a Joyce 900 bed that is affected by the recall, the supplier of the bed in Australia will have contacted you directly with details of the problem and required actions. If that is not the case, you should contact Huntleigh Healthcare directly for more details.

This might not be the only bed side rail design that poses a risk of entrapment to patients' heads. The best way currently available to ensure that the risk of entrapment is at a minimum is to check that the bed side rails comply with the recommendations in IEC 60601-2-38 as amended in 2000. In general, any gaps between cross-members inside the perimeter of the side rails should not allow the possibility of a head to fit through (the gaps should be no more than 120mm in width). If you think that the side rails of the beds in your facility do not comply, we recommend that you contact the manufacturer and inquire about the availability of alternative bed side rail designs or consider what measures may be put in place to minimise the possibility of entrapment.

Spacelabs 1700 Central Monitor alarm settings

DIR 14791, 14793 and 14794

Problem

The TGA has received three reports about alarm settings with the Spacelabs 1700 Central Monitors. All three reports relate to inadequate alarm levels being set by the user resulting in episodes of asystole and ventricular tachycardia not being detected by the monitor. In the reports, the volume of the alarm had also been altered and the printer was turned off, which meant that no records were available to review the patient conditions at the time of the events.

There are default alarm limit settings programmed into the Spacelabs 1700 Central Monitors which users can choose to modify. This is a feature of many central monitors which are built into the devices as a result of user consultation. Ultimately, the alarm settings are defined by the user cognisant of the clinical conditions of the patients being monitored. In the case of the Spacelabs Central Monitors, episodes of asystole and ventricular fibrillation will always trigger a high alarm tone provided that the ECG alarms are enabled.

Recommendation

The manufacturer, Spacelabs, recommends that alarm settings are checked once per shift and on each admission. The user should check that these alarms are set at appropriate levels to the patient's needs. ECG alarm recording should be enabled to capture episodes of asystole and fibrillation and any other waveform considered important for recording.

Potential embolisation and/or unravelling of guide-wires following insertion of central venous catheters

The following is a transcript of a Safety Alert that was sent by the TGA in August 2002 to all public and private hospitals in Australia. It appears that the problem is still occurring and it was therefore decided that the TGA would reissue the alert in the *TGA News*. The Alert is addressed to the attention of all hospital staff, but especially: Medical Practitioners, Nursing Staff, ICU, Oncology, Operating Theatres, Hospital Wards, Hospital Executives.

Description of the problem

The TGA has received reports from both Australia and New Zealand of serious adverse events associated with guide-wires used with Peripherally Inserted Central (venous) Catheters (PICCs).

The reports relate to the inadvertent cutting of the guide-wire while trimming the length of the catheter at the time of insertion, resulting in a piece of guide-wire remaining within the patient's circulatory system and requiring further intervention to retrieve it.

In one instance, it was noticed that the guide-wire was difficult to withdraw. Once withdrawn, x-rays revealed that a section of the guide-wire had separated and had been left in the pulmonary artery. In most other cases, inadvertent cutting of the guide-wire during shortening of the catheter caused it to unravel inside the patient when an attempt was made to remove the guide-wire. A few guide-wires and catheters have been trimmed before attachment of the injecting hub because the user thought that the guide-wire was part of the catheter.

Guide-wires have also caused embolisation, vessel damage or have travelled via the patient's circulatory system into the heart, lungs or lower limbs causing further problems such as infection.

Guide-wires are of slightly different design depending on the catheter, but most often consist of an outer coil of guide-wire wrapped around and welded to a central core of wire at the proximal and distal ends.

Recommendations

It is important that the manufacturer's instructions for use are followed when inserting these catheters. Shortening of the catheter should be avoided whenever possible. This reduces the likelihood of guide-wires being inadvertently cut. The instructions for use of most PICCs caution against the inadvertent cutting of the guide-wire prior to insertion of the catheter. If it is necessary to shorten the catheter, the catheter manufacturer's instructions for doing so should be carefully followed, taking precautions to ensure that the guide-wire has not been inadvertently cut.

Some catheters are cut prior to the catheter being placed in the patient. For these types of catheters, the instructions for use direct the user to measure the length required and then trim the catheter at the insertion end. The guide-wire must be pulled back at least 4cm more than the length of the catheter to be cut. This guide-wire must not be pushed back down the catheter as it may damage the inner lumen and the guide-wire. There should be very little resistance when the catheter is cut. If there is resistance or difficulty in cutting the catheter the guide-wire may have been inadvertently cut. After cutting the catheter check that there is no wire in the cut portion.

Other catheters should only be shortened after the catheter has been inserted and the guide-wire has been removed. When inserting a catheter that is thread over a guide-wire, ensure that this guide-wire is visible at the distal or external end of the catheter following insertion of the catheter. This guide-wire should be removed before the catheter is trimmed and the injection hub connected to the catheter.

Extra copies of this alert may be obtained by contacting IRIS, the TGA's Incident Report Investigation Scheme: IRIS, PO Box 100, Woden ACT 2606, Facsimile: 02 6232 8555, Email: iris@health.gov.au

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MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS) STATISTICS REPORT 01/10/2004 to 31/12/2004
Total Number Received: 155

Cause of Problem[1]	
Biocompatibility	14
Component Failure	26
Contamination	1
Design	5
Diagnostic Inaccuracy	9
Electrical	5
Inadequate Instructions	2
Labelling	2
Maintenance	6
Manufacture	10
Material/Formulation Deficiency	15
Mechanical	12
Not Device Related	17
Other	16
Packaging/Sterility	1
Quality Assurance	6
Unknown	25
Wear/Deterioration	3

Effect	
Death	5
Serious Injury	14
Temporary Injury	26
No Injury	110

Source Category	
Medical Administrator	1
Specialist	8
General Practitioner	2
Coroner	0
Nurse	10
Blood Bank	13
Hospital Supply Service	16
Other	6
Sponsor	81
Overseas Advice	12
Biomed Engineer	5
Para Medical	1

Result of Investigation	
Company Warned	1
Compliance Testing	1
No Further Action	62
Not Investigated[2]	63
Other	4
Problem Not Confirmed	8
Product Improvement	5
Recall/Hazard Alert	5
Refer to GMP	3
Safety Alert	3
User Education	6

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.