Reducing the risks associated with infusion pumps

Infusion pump hazards are among the most commonly reported problems relating to medical devices. This article outlines some of the related issues and options to mitigate associated risks.

In its first issue for 2014, Medical Devices Safety Update (MDSU) outlined the top 10 health technology hazards identified by the Emergency Care Research Institute (ECRI) for this year.

An article in the May 2014 issue of MDSU covered the no. 1 issue listed, ‘alarm hazards’.

No. 2 on ECRI’s list was ‘Infusion pump medication errors’, a high ranking that is supported by the large number of incident reports submitted to the TGA which include references to infusion devices.

The TGA received a total of 1016 incident reports which included references to infusion devices from 2002 to 2013. These included 36 incidents in which the patient died, 99 potential deaths (incidents that could have been fatal if there had been no medical intervention) and 153 cases of serious injury.

It is important to note that being included in these reports does not necessarily mean that the associated device caused the outcome.

Most recent reports involving infusion devices associated with actual deaths and serious injuries involve patient-operated devices; including insulin pumps, and patient-controlled analgesia (PCA) machines.

Relatively few of the recent reports are related to general infusion devices (bulk fluid pumps) as used in hospitals.

An article in an upcoming edition of MDSU will focus specifically on issues involving infusion pumps used outside health facility settings.

Some recent, indicative, infusion-related problems reported to TGA include:

- blood glucose readings high or low (associated with use of an insulin pump)
- incorrect drug dose delivery from a patient-controlled analgesia pump, despite correct setup and programming
- possible ketamine infusion overdose (patient appeared ‘delirious’ – patient condition improved after cessation of infusion)
- missing internal assembly clamp led to free-flow
- pump ‘blacked out’ and stopped infusing
- device should have delivered the medication over a 24-hour period but delivered the medication over a 20-hour period only
• five times the set dose delivered, one occurrence, morphine/midazolam overdose
• device alarm sounded and then it shut down mid-infusion of noradrenaline. Not able to download event history – battery power was gone, corrosion within the pump – evidence of fluids inside the pump.

These issues illustrate the varied nature of pump faults.

Users need to be sure they receive adequate training, pumps are maintained, configurations are well-managed, and patients receive adequate support for pumps they are using.

In a recent survey the US Food and Drug Administration (FDA) determined that there were more than 2 million infusion pumps in the USA and they had been associated with 500 deaths in a five-year period (2005 to 2010). That is about 100 related deaths per annum over that period.

When compared on a population basis (USA has about 20 times the population of Australia) the results appear similar – the current five-year average in Australia being about four related deaths per annum.

The below chart shows the annual rates of deaths, possible deaths and serious injuries associated with infusion devices that were reported to the TGA from 2002 to 2013. Solid lines show the moving five-year averages.

In relation to infusion devices, the data show a stabilisation of the five-year average over time, indicating a possible maturity in reporting, as the five-year averages appear to be levelling out. In addition, during the time period shown there was a 683% increase in the reporting of all incidents, illustrated by the dashed line.

See over page for some tips regarding the safe use of infusion pumps.

**Serious incidents involving infusion devices 2002-2013**

<table>
<thead>
<tr>
<th>Year</th>
<th>Death</th>
<th>Possible death</th>
<th>Serious injury</th>
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<tbody>
<tr>
<td>2002</td>
<td>2</td>
<td>6</td>
<td>11</td>
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<tr>
<td>2003</td>
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<td>2</td>
<td>16</td>
<td>21</td>
</tr>
<tr>
<td>2013</td>
<td>2</td>
<td>17</td>
<td>22</td>
</tr>
</tbody>
</table>

1. Reports in which the patient died and which included reference to an infusion device. Being included in a report does not mean the device caused the outcome.
2. A possible death report relates to an incident which could have been fatal if intervention had not occurred.
3. Reports in which the patient sustained a serious injury and which included reference to an infusion device.
4. Reporting for incidents involving all medical devices increased substantially over this period, with completed reports rising from 484 in 2002 to 3306 in 2013.
Some tips regarding the safe use of infusion pumps

Below is some general advice regarding safe use of infusion pumps:

- have a back-up plan in case of an infusion pump failure - know how or where to obtain a spare pump or set
- participate in education regarding the safe use of infusion pumps
- label infusion pump channels and the tubing according to your health facility’s guidelines
- check settings (rate, volume, or dose), and cross check for high-risk infusions (for example insulin, heparin, vasopressors, morphine)
- monitor for signs of over- or under-infusion of high-risk medications (for example using ECG, pulse oximetry, ETCO2, glucose meters)
- seek help when experiencing problems (for example colleagues, supervisors, manuals or troubleshooting guides)
- use the drug library when applicable
- promptly respond and pay close attention to displayed alerts and cautions
- use the ‘5 rights’ for safe medication administration: the right patient, the right drug, the right dose, the right route, and the right time.

Accu-Chek Multiclix lancets not for use on multiple people

Health professionals are reminded that the Accu-Chek Multiclix lancet device is not intended to be used on more than one person due to the risk of transmitting blood-borne infections.

The Accu-Chek Multiclix lancet is used to prick a patient’s finger to obtain a blood drop for testing, most commonly to check blood sugar levels as part of the treatment for diabetes.

The device contains a rotating cartridge with six lancets which should be replaced after its sixth use, as indicated by a counter.

Once the cartridge rotates to the sixth lancet it remains in that position and, if not replaced, there is a risk of it being used repeatedly.

The TGA’s Incident Report Investigation Scheme (IRIS) has received reports of situations in which Accu-Chek Multiclix devices were used on multiple patients at health facilities.

There have been no reports of disease transmission resulting from these incidents.

The Instructions for Use (IFU) state: ‘The Accu-Chek Multiclix lancing device is intended for patient self-monitoring by a single person. It must not be used for obtaining blood on more than one person owing to the risk of infection.’

The TGA is working with the sponsor, Roche Diagnostics Australia, to minimise the potential for misuse of the Accu-Chek Multiclix lancing device.

Health facilities are advised to use single-use lancets to eliminate any potential for cross-contamination during finger-prick blood testing.
Introducer/bougie instructions reminder

Health professionals are reminded of the importance of following the Instructions for Use when using an introducer/bougie to insert an endotracheal tube.

The TGA has investigated an adverse event report regarding an inability to remove a bougie from an endotracheal tube after placement. The Instructions for Use (IFU) recommend lubricating a bougie before intubation to aid in removal from the endotracheal tube. The IFU also recommend that bougies not be stored at temperatures higher than 49 degrees Celsius to reduce the risk of heat damage.

The manufacturer has advised that difficulty in removing a bougie from the endotracheal tube may be due to electrostatic forces generated by traction, making the bougie adhere to the endotracheal tube wall. Bougies inserted too deeply and past the tracheal ring may also be difficult to remove.

There have been no other similar events reported to the TGA.

Recent safety alerts

The TGA publishes alerts on its website when there is new safety information regarding therapeutic products.

Below are TGA safety alerts relating to medical devices published since the last edition of Medical Devices Safety Update.

Accu-Chek Mobile blood glucose meter: Roche Diagnostics Australia has undertaken a recall for product correction of its Accu-Chek Mobile blood glucose meter due to the potential for incorrect blood glucose readings.

Accu-Chek Spirit Combo insulin pump: Roche Diagnostics Australia has notified users of some Accu-Chek Spirit Combo insulin pumps of a potential fault that may prevent treatment. Affected units are being recalled.

Cereform breast implants and associated sizers – update: The TGA has suspended the Cereform silicone gel-filled breast implants and associated sizers from the Australian Register of Therapeutic Goods. The suspension took effect on 23 May 2014 and is for a period of six months unless earlier revoked by the TGA.

Aquatec Ocean VIP mobile shower and toilet commode: Invacare Australia has undertaken a recall for product correction of some units of its Aquatec Ocean VIP mobile shower and toilet commode due to an issue with the snap-on connectors that secure the backrest cushion.

MiniCap Extended Life Peritoneal Dialysis transfer set with twist clamp: Baxter Healthcare has undertaken a recall of one lot of its MiniCap Extended Life Peritoneal Dialysis transfer set with twist clamp.

Alere INRatio2 PT/INR heparin-insensitive test strips: Alere has issued a safety alert for Alere INRatio2 PT/INR heparin-insensitive test strips due to the potential for incorrect INR results. Alere is also undertaking a recall for product correction to update the Instructions for Use.

Laparoscopic power morcellators: Health professionals have been advised against the use of laparoscopic morcellators during certain uterine surgery procedures in patients with fibroids because of the risk of spreading malignant cells in patients with previously undetected uterine cancer.

Craniomaxillofacial Distraction System - BC Distractor Body: Synthes Australia has issued a hazard alert for its BC Distractor Body, a component of the Craniomaxillofacial (CMF) Distraction System. Synthes Australia has also recalled unused stocks of the affected devices.

Otto Bock A200, Skippi and Skippi Plus power wheelchairs: Otto Bock Australia has undertaken a recall for product correction for some Otto Bock A200, Skippi and Skippi Plus power wheelchairs due to the potential for the front wheels to break.

Accu-Chek Mobile glucose tests: Roche Diagnostics Australia has undertaken a recall for product correction of its Accu-Chek Mobile glucose tests due to the potential for a commonly used antibiotic to interfere with blood glucose test results.
How you can contribute to the regulation of medical devices

Health professionals with a broad range of skills and experience are being sought for the TGA’s various statutory advisory committees. They provide independent advice regarding medicines, vaccines, biologicals and medical devices.

The TGA is currently seeking expressions of interest from experts for various statutory advisory committees, including the Advisory Committee on Medical Devices (ACMD) and the Advisory Committee on the Safety of Medical Devices (ACSMD).

The ACMD advises and makes recommendations to the Minister for Health and the TGA on the inclusion, variation, removal or retention of a medical device or other therapeutic goods on the Australian Register of Therapeutic Goods.

The ACSMD advises and makes recommendations to the Minister for Health and the TGA on the safety, risk assessment, risk management and performance of medical devices supplied in Australia.

These committees may also be asked to provide advice on other matters.

The TGA regularly seeks expressions of interest from people interested in joining expert advisory committees. By serving as a member of one of these committees, you can help the TGA to effectively regulate increasingly complex therapeutic goods to protect the continuing health and safety of all Australians.

If you wish to apply for one of these positions visit the TGA website.

What to report? Please report adverse events, as well as near misses

The TGA encourages the reporting of any suspected adverse event or potential adverse event relating to a medical device. Adverse events can involve actual harm to a patient or caregiver, or a near miss that may have resulted in harm.

Some issues relating to medical devices that may lead to adverse events and prompt you to report include:

- mechanical or material failure
- design issues
- labelling, packaging or manufacturing deficiencies
- software deficiencies

- device interactions
- user/systemic errors

Suspected adverse events or near misses can be reported directly to the TGA:

- online at www.tga.gov.au (click ‘Report a problem’)
- by emailing iris@tga.gov.au
- by mail to IRIS, TGA, PO Box 100, Woden ACT 2606
- by fax to 02 6203 1713

For more information about reporting, visit www.tga.gov.au or contact the TGA’s Office of Product Review on 1800 809 361.

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For correspondence or further information about Medical Devices Safety Update, contact the TGA’s Office of Product Review at iris@tga.gov.au or 1800 809 361

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