NSW HEALTH Working as a Team

Safety Advocate

A NSW Department of Health Newsletter

Issue 5, September 2003

Current international activities

The issue of infusion device safety is currently high on the agenda of a number of organisations internationally.

The Joint Commission on Accreditation of Healthcare Organisations (JCAHO) in its National Patient Safety Goals that took effect on 1 January 2003, have included among the 11 required actions for all accredited organizations that the organisation assures that all intravenous infusion pumps have 'free-flow' protection. This reduces the risk that patients will inadvertently receive medication overdoses.

Researchers at the University of Toronto and the Institute for Safe Medication Practices-Canada (ISMP-Canada) have undertaken a comprehensive survey infusion pump use in Canadian hospitals. (The report was not available at the time of release of this Safety Advocate.)

The NPSA, in its *2003-2004 Business Plan* released in June 2003, has targeted infusion device safety, and is currently piloting four proposed solutions:

1. Introducing a new purchasing checklist to promote good purchasing practice, and with the aim of eventually standardising the equipment used.
2. Evaluating users' experiences of using infusion devices, through a questionnaire.
3. Exploring the feasibility of developing equipment libraries or central storage facilities.
4. Introducing interactive web-based training on use of the devices.

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Infusion pump safety

Infusion pumps of various types are used extensively for delivery of therapeutic liquids in hospitals, day procedure centres, outpatient facilities, nursing homes, at home and in other non-hospital settings. Examples of their use include hydration, feeding, pain management, anticoagulant therapy, insulin infusion and antibiotic administration. Most infusion treatment is delivered safely. However, health care organizations worldwide have recorded incidents involving infusion pumps that have lead to death, near-fatal drug overdoses or increased patient morbidity.

During a nine-month trial audit in 2002, the National Patient Safety Agency (NPSA) in the UK received 161 reports of incidents associated with infusion pumps. Data from the former UK Medical Devices Agency show that over half the 700 infusion incidents that were reported to that agency involved drips that were not faulty. The US Food and Drug Administration's (FDA) MAUDE database represents reports of adverse events involving medical devices. The number of adverse events in 2001-2003 involving infusion pumps exceeded 500, the search capacity of the database.

The Australian Therapeutic Goods Administration (TGA) has issued a number of Safety Alerts relating to incidents with infusion pumps over the last five years. In NSW Health several serious or potentially serious incidents associated with infusion pumps have also been reported over this period.

Factors that may lead to infusion pump incidents

Incidents with infusion pumps can arise from mechanical errors, including mechanical and electrical breakdowns and design faults, and from human errors, such as providing the wrong dose, incorrectly programming pumps, administering the wrong medication and improperly using the equipment. Investigations have also identified a number of underlying issues including staffing, work pressure, several different concentrations of critical care drugs being available, multiple different infusion devices used in one hospital or care setting (some that will look the same but operate differently), and lack of standards. Rapid advances in technology and an explosion in the variety and complexity of infusion devices have also made it increasingly difficult for staff to keep up to date and for the devices to be stored and maintained correctly. It should be noted that a number of Area Health Services in NSW have already instituted procedures to standardise the purchase of new infusion devices.

One of the main problems appears to be pumps with no protection from free-flow. Free-flow occurs when the liquid being infused flows freely under the force of gravity without being controlled by the infusion pump. This may occur when an administration set is temporarily removed or disconnected, eg when transferring a patient or changing his/her gown. Other errors include:

- delivery of the wrong volume of the liquid to be infused, or at the wrong rate
- false readings/displays
- electrical or mechanical malfunction
- false alarm or failure of alarm
- burst, broken or cracked parts; leaking or separation
- misassembly.

The TGA has also received several reports of deaths or serious injury to patients due to intravascular 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 bags contained significant volumes of air as a result of the handling and storage associated with detachment and re-attachment. This large volume of air is generally not present in a correctly handled fresh bag of solution when it is first attached to the infusion device. It is also believed that the likelihood of occurrence is higher when high flow consumables are being used.

There is usually in-service training for nurses, but there may not be such training for others who may handle the pumps such as orderlies and radiology technicians. Such staff should have training on what to do if the pump alarm goes off, or the patient shows signs of distress.

Strategies to reduce infusion device incidents

Health Services within NSW Health are expected to implement the following recommendations:

The UK Medical Devices Agency recommends:

- always position pumps away from potential sources of spillage and protect the pump if necessary
- don't leave a pump unattended until you are sure the desired flow rate has been established. Always have a policy for checking the delivered volume at frequent intervals to ensure the desired flow rate is being maintained
- limit the number of different infusion devices available within one unit or practice so that confusion of one for another is less likely to occur
- those who have not undergone correct training on the model in question should not operate it unless supervised, or until trained and competent in its use
- do not stretch giving sets when loading around peristaltic mechanisms as this can lead to overinfusion or free-flow
- in an emergency, ensure the flow has stopped by operating the set roller clamps. Do not rely on just switching off or stopping the pump.

The Therapeutic Goods Administration recommends:

- removing all air from fluid bags and lines before connection to patients
- following appropriate instructions for priming the infusion line and set
- monitoring fluid lines to ensure that they are free of air
- not opening ports in the infusion system, unless appropriate measures are in place to prevent the entry of air
- not reconnecting partially emptied fluid bags – significant volumes of air may be sucked into the bag when disconnected
- not using auto-transfusion bags with these systems, unless the infuser is clearly indicated for this use.

The President of the Institute for Safe Medication Practices (ISMP), Dr Michael Cohen, says that organisations should standardise the way medications are used, and standardise the concentration of critical care drugs. He also advocates that when dealing with high alert drugs such as heparin or morphine, where an error could cause a serious adverse event, organisations should have one person set the controls and a second person check the first person's work.

Australian/New Zealand Standard 3770:1993 recommends that institutions formally adopt an infusion protocol as part of the standard procedure manual, and that staff be accredited for the equipment available in their area.

Further information

Australian/New Zealand Standard 3770:1993 Guide to the safe use of infusion pumps and controllers.

Australian/New Zealand Standard 3200.2.24:1999 Medical electrical equipment – Particular requirements for safety – Infusion pumps and controllers.

Therapeutic Goods Administration (TGA) www.health.gov.au/tga

National Patient Safety Agency (NPSA) www.npsa.nhs.uk

Medical Devices Agency www.medical-devices.gov.uk

Joint Commission on Accreditation of Healthcare Organisations www.jcaho.org

Institute for Safe Medication Practices (ISMP) www.ismp.org

ISMP-Canada www.ismp-canada.org

US Food and Drug Administration – Manufacturer and User Facility Device Experience Database – (MAUDE) www.fda.gov/cdrh/maude.html

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