The Joint Commission

Sentinel Event Alert

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The Joint Commission offers this information for health care organizations to consider in their continuing efforts to reduce the risk of adverse events in the care of their patients, residents or individuals served.

In the past two years, health care organizations have reported to Joint Commission two sentinel events involving the use of infusion pumps. While it is difficult to reach meaningful conclusions from only two cases, these cases have raised a concern about patient safety involving the use of infusion pumps. In recent months there has been a great deal of discussion about potential problems with infusion pumps. Therefore, Joint Commission provides the following expert comments and recommendations to alert health care organizations on how to prevent such adverse events from occurring.

Infusion Pumps: Preventing Future Adverse Events

Mishaps involving the use of infusion pumps have led to deaths and near-fatal drug overdoses in health care organizations nationwide. Experts have identified several human and mechanical errors, however, the main problem they emphasize is organizations' use of pumps that do not provide protection from the free-flow of intravenous fluid/medication into the patient. In addition, problems can occur when the wrong drug concentration is given or the wrong rate is set.

The U.S. Pharmacopeia (USP), Rockville, MD, reports that six cases have been submitted to its Practitioners' Reporting Network (PRN) from October 1991 to November 1999 in which a person died due to the use of an intravenous pump that did not provide protection from free-flow of intravenous solutions. Four additional cases resulted in a near-death. Root cause analyses were not conducted. The majority of the cases took place in hospitals, according to USP. Sources for the data include the USP-ISMP (Institute for Safe Medication Practices, Huntingdon Valley, PA) Medication Errors Reporting Program and the Food and Drug Administration's (FDA) MedWatch Program. USP officials were not aware of any deaths resulting from infusion pumps since November 1999, but emphasize that the PRN is a voluntary reporting system so the data probably do not include all infusion pump-related incidents.

"During on-site surveys in 2001, Joint Commission surveyors will inquire about health care organizations' use of infusion pumps without free-flow protection."

Russell P. Massaro, M.D.
Executive Vice President
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Causes that Experts Identified

Causes of adverse events involving infusion pumps that experts primarily point to are human errors such as providing the wrong dose, incorrectly programming the pumps, administering the wrong medication and improperly using the equipment. Underlying causes of these human errors include staffing patterns, work pressures, having many different concentrations of critical care drugs, and lack of standards, according to Michael Cohen, R.Ph., M.S., F.A.S.H.P., president of ISMP, a non-profit organization dedicated to reducing medication errors.

"Standardize the way medications are used," Cohen says. "Standardize the concentration of critical care drugs to take advantage of commercially available premixed solutions."

Cohen recommends that when dealing with high alert drugs such as heparin or morphine where a critical failure could cause a serious adverse event, organizations should have one person set the controls and a second individual check the person's work.

Providing Free-Flow Protection

Experts say many errors could be prevented if organizations only use infusion pumps that require set-based free-flow protection. Free-flow occurs when the infusate flows freely, under the force of gravity, without being controlled by the infusion pump. Free-flow typically occurs after a caregiver temporarily removes an administration set from the pump to transfer a patient to another area, change the person's gown or place a patient on an X-ray table. Caregivers can greatly reduce the risk by using administration sets with set-based anti-free-flow mechanisms that

"Organizations should not use pumps that don't have set-based

prevent gravity free-flow by closing off the tubing to prohibit flow when the administration set is removed from the pump.

ECRI in Plymouth Meeting, PA, monitors problem reports and performs accident investigations related to infusion pumps. The non-profit health services research agency rates pumps that do not have set-based free-flow as unacceptable and recommends that health care organizations no longer purchase or rent units with unprotected sets. If such pumps and sets are currently used, a facility should take immediate measures to eliminate them, according to ECRI. The agency also recommends that pumps used in critical care areas should be targeted first for replacement.

free flow protection on critical care patients."

Tim Ritter
Senior Project Engineer
ECRI
Plymouth Meeting, PA

Some organizations may be considering a device that attaches to an administration set to prevent unintended gravity flow for existing pumps that lack set-based free flow protection. However, because these mechanisms are packaged separately and must be manually attached to a set, clinicians may forget to use these mechanisms or may inadvertently remove them. ECRI only rates pumps with free-flow protection integral to their set as acceptable.

Another factor contributing to errors is that some health care organizations may have a variety of pumps. Tim Ritter, a senior project engineer at ECRI, explains that while pumps look the same and may operate similarly, some have the set-based mechanisms while others do not. Patricia Kienle, R.Ph., M.P.A., F.A.S.H.P., medication safety manager at Houston-based Owen Healthcare, a pharmacy management company, also finds having a variety of pumps in one organization to be problematic. She emphasizes that when purchasing pumps, the materials management staff should involve the nursing and education staffs in the process.

Risk Reduction Strategies Recommended by USP

USP recommends that health care professionals and organizations consider the following to prevent errors involving infusion pumps:

- "Identify all pumps with potential for free-flow errors, including those with confusing labeling.
- Sequester/quarantine/phase out the use of unprotected devices.
- Petition the FDA to withhold or withdraw approval of intravenous pumps that permit free-flow.
- Petition manufacturers to stop production and sale of free-flow pumps."

"There are multiple types of pumps and no coordinated education. There should be a multidisciplinary team that deals with the purchase of any pump, whether it is an infusion pump or a patient-controlled analgesic pump."

Patricia Kienle, R.Ph., M.P.A., F.A.S.H.P.
Owen Healthcare, Houston

Experts also emphasize that training and education are important. However, Ritter cautions that even if training is done faithfully, a patient, family member or visitor may still handle a pump incorrectly. Kienle says there usually is in-service education on the pumps for nurses but not for others that may handle the pumps such as orderlies, radiology technicians and nurse assistants who transport patients. She says these caregivers should be aware of steps to take if alarms go off or a patient shows signs of distress.