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ISMP Calls for Safety Improvements in Use of Elastomeric Pain Relief Pumps

Horsham, Pa.— The Institute for Safe Medication Practices (ISMP) has received numerous reports of potential safety problems in the hospital management of elastomeric pain relief pumps such as the ON-Q PainBuster Post-Op Pain Relief System. ISMP is calling on hospitals to review their processes and procedures for utilizing these devices to safely provide surgical wound analgesia and/or peripheral nerve block.

Reported Problems

Elastomeric pain relief pumps are used after cardiovascular, cardiothoracic, urologic, gynecological, obstetrical, orthopedic, and general surgical procedures to provide continuous infusion of a local anesthetic directly into the surgical site. The July 16, 2009 issue of the *ISMP Medication Safety Alert!* newsletter details safety concerns with use of the pumps reported by hospitals and outpatient surgical centers. The full article can be found at www.ismp.org/newsletters/acutecare/articles/20090716.asp.

Safety issues with the use of these devices include lack of staff education on the management of the pumps, lack of pharmacy involvement in preparing and dispensing the pumps that leads to lack of documentation and screening of medications used, filling the devices with medications other than local anesthetics, use of varying infusion rates and concentrations, failure to label the drug reservoir housing, lack of medication administration record (MAR) documentation, extended duration of use, and use of infusion admixtures that combine local anesthetics and potent opioids when the labeled accuracy of medication delivery from the device may be plus or minus 20%.

ISMP Safe Practice Recommendations

ISMP suggests that hospitals using or considering use of elastomeric pain relief devices conduct a failure mode and effects analysis (FMEA) to detect potential problems in ordering, preparing, dispensing, and documenting and managing therapy with these devices. A complete list of suggestions to improve safety with these devices can be found at www.ismp.org/Newsletters/acutecare/articles/20090716.asp.

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ISMP recommendations for safe use of elastomeric pain relief devices include:

- Establish protocols for use of ON-Q pumps that include: indications; specific models and tubing to be used for each indication; process steps for prescribing, preparing, and dispensing the device and associated medications; required testing of knowledge and skills; hand-off communication between providers; patient/family education; and patient monitoring.

- Have the Pharmacy and Therapeutics Committee approve the drugs that can be administered through the ON-Q pump, taking into consideration the accuracy of the infusion rate (± 15-20% of desired rate) and conditions that could influence the rate (e.g., heat and cold).

- Ensure clinical staff education before use—even "trial" use—of the pumps. The manufacturer may provide orientation materials and some staff education if requested.

- Establish standard order sets for prescribing the pumps that includes specific medications. Specify any concomitant analgesics that are acceptable or should be avoided. Require activation of the appropriate order set before the patient is transferred from the OR.

- Label pump with drug name, concentration, infusion rate (in mL/hour and dose/hour), and start date.

- Establish standard concentrations for local anesthetics (and other drugs, if appropriate) used in the pumps. Also establish pharmacy compounding procedures for preparing any mixtures of drugs.

- Require pharmacy filling of the medication reservoir following a protocol that specifies the exact amount of solution to instill based on the duration of therapy and expected rate of infusion. Outsourced compounding can also be utilized.

- Require an independent double-check in the pharmacy of the drug, strength, and total volume added to the reservoir by comparison to the prescriber's order and the protocol.

- Ensure that any medications administered via the pump are listed as an entry on the patient record and nursing medication administration record.

- Monitor the patient's level of pain and response to medication while using this device.

- Provide patients with the patient guidelines provided by the manufacturer of ON-Q pumps (www.iflo.com/prod_onq_classic.php).

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