From: Jeannette Wing [Jeannette.Wing@cs.cmu.edu]
Sent: Wednesday, August 04, 2004 5:54 PM
To: David Garlan
Subject: FW: Misprogram a PCA pump? It's easy! (from ISMP)

A horror story.

-----Original Message-----
From: Jones, Paul L. [mailto:PXJ@CDRH.FDA.GOV]
Sent: Fri 7/30/2004 2:14 PM
To: 'Edmund Clarke'
Cc: Jeannette Wing
Subject: FW: Misprogram a PCA pump? It's easy! (from ISMP)

Here is an all too common instance of an infusion pump killing someone.
There is no evidence at this point that the incident is related to a software error, however, system defaults and information display problems are often linked to software design decisions.

Paul

-----Original Message-----
From: Albersheim, Harriet B.
Sent: Thursday, July 29, 2004 12:07 PM
To: CDRH-Home Care Committee; Eakle, Melissa*
Cc: Albersheim, Harriet B.
Subject: Misprogram a PCA pump? It's easy! (from ISMP)

The following is for your information.
Harriet
From the Institute For Safe Medication Practices (ISMP)
Subject: ISMP Medication Safety Alert! July 29, 2004, Vol. 9, No. 15
ISMP Medication Safety Alert!
Misprogram a PCA pump? It's easy!
Problem: One patient died and another recovered after two nurses accidentally misprogrammed Deltec CADD-Prizm PCS Pain Control System pumps (model 6101) used for patient-controlled analgesia (PCA). But while it's clear that human error played a small role in the mistakes leading up to these events, the real culprit is more likely a variety of system problems, including the pump's unseen default to a prior setting.

Here's what happened: The errors were first recognized when a postoperative patient became unresponsive after a bolus of fentanyl. The physician had ordered fentanyl PCA "per protocol," which called for a 50 mcg/mL concentration, a 10 mcg demand dose, a 6 minute lockout, and clinician boluses of 20 mcg (every 5 minutes x 3, repeat every 4 hours as needed). To program the pump, the nurse first scrolled through a wide range of numbers to select the correct concentration, but she accidentally programmed 1 mcg/mL instead of the actual concentration of 50 mcg/mL. Next, she programmed the demand dose as 0.10 mcg instead of 10 mcg. Two nurses were initially present when the pump was

being programmed, but one left to take a phone call. When she returned, she asked the other nurse to read the settings to her for verification, but the programming errors were missed. Since the pump had been programmed to deliver fentanyl in a 1 mcg/mL concentration, each demand dose delivered only 0.1 mL. So, despite an actual concentration of 50 mcg/mL, the patient received only half of the intended dose (0.1 mL of 50 mcg/mL, or 5 mcg). When the patient continued to complain of severe pain, a nurse on the next shift decided to give the patient a 20 mcg bolus. She correctly programmed the bolus dose, but since the pump had been set incorrectly at a 1 mcg/mL concentration, the patient received 20 mL of the 50 mcg/mL concentration, or 1,000 mcg! About 15 minutes later, the patient was found unresponsive and quickly transferred to ICU, but the patient died 3 days later.

A similar incident had occurred in this hospital several weeks earlier, but went unrecognized until the above event. The physician had ordered fentanyl PCA "per protocol" with 10 mcg demand doses. But again, with a 50 mcg/mL concentration actually in the cassette, the pump was erroneously set at 1 mcg/mL. The patient received one demand dose postoperatively, which delivered about 500 mcg of fentanyl; 5 minutes later, the pulse oximetry alarm sounded, and the patient was found unresponsive and with poor respiratory effort. Suspecting postoperative hemorrhage, the patient was taken back to the OR for an exploratory laporatomy. When no blood was found in the abdomen, the cause of the respiratory failure was initially attributed to a seizure. The patient required care in the ICU, but recovered.

Now, here's why the errors happened: The nurses' infrequent use of fentanyl for PCA could have contributed to the error in the first event. But in the most recent fatal event, the nurses were familiar with fentanyl, and both were well aware of the correct concentration and demand dose that should have been entered into the pump. In fact, the nurse who verified the pump settings mentioned the need for "extra care with fentanyl" to the programming nurse, and both nurses felt certain that the fentanyl concentration had been set at 50 mcg/mL, and the demand dose at 10 mcg. And this may well have been the case initially, at least for the concentration. During investigation of these events, the hospital learned that the pumps could automatically default to a prior setting if the current setting was not confirmed by pressing "Enter" within a short period of time. As such, the nurse could have initially entered the correct concentration, but failed to press the enter key within the allotted time. Thus, the setting could have defaulted back to a prior setting on the scroll of numbers - 1 mcg/mL for the concentration.

Failures in the system of double checks also played a role in both events. While the hospital required two nurses to confirm PCA pump settings, the policy did not clarify that the double checks should be performed independently with one nurse setting the pump, and another nurse independently checking the patient, drug, and settings against the orders. A final causative factor was that the pump manufacturer had not alerted the hospital that they could set default values for PCA drugs by locking out the unused range of numbers available.

Safe Practice Recommendation: As noted above, and in other reports in our newsletters, PCA errors can be deadly. Thus, special precautions are needed when administering narcotics to patients using this method of delivery, including the following:

Limit choices. Limit the variety of medications used for PCA. Also consider restricting fentanyl PCA use to anesthesia or pain management team members only.

Improve access to information. Develop a quick reference sheet on PCA use for nurses, including programming tips and maximum dose warnings for each of the PCA medications in use.

Improve label readability. Match the sequence of information that appears on PCA medication labels and order sets with the sequence of information that must be entered into the PCA pump (or entered into PCA protocols or other related documentation, if applicable). Highlight the concentration of PCA medications on drug labels using bold font or other means.

Program default settings. Actively query the pump manufacturer to learn about any safety features available with your PCA pumps, and fully employ their use. Standardize the concentrations of PCA medications, and when possible, set default values for each concentration, or lock out inappropriate ranges for the concentrations that you do not use. If a single option exists for default settings, select "zero" to force an entry. As an added measure, check if your pumps can be set to a maximum bolus dose for each medication (at least a maximum volume for each drug). Perform periodic biomedical checks on the pumps to ensure proper default settings. Be sure to alert staff to situations in which the pump will default to a standard setting.

Introduce new pumps slowly. After performing a failure mode and effects analysis on any new PCA pump considered for use, introduce the pumps initially in a small controlled setting to ensure that the safety features are operational, and to uncover any unanticipated problems.

Suspect a problem. If the patient is not responding to the PCA doses as anticipated, suspect an error and re-verify the drug, concentration, pump settings, and line attachment (with comparison against the original order), especially before administering a clinician bolus dose.

Employ double checks. Clearly define a manual independent double check process that clinicians should follow when verifying PCA medications, pump settings, the patient, and line attachments. When possible, use bar-coding technology; when available, use "smart" PCA pumps that can alert clinicians to potential programming errors. However, until "smart" pumps are adapted for bar-coding, automated checks won't entirely replace manual independent double checks to verify other dimensions not covered by the automation (e.g., patient identification when using current "smart" pumps, pump settings when using current bar-code systems).

Additional recommendations for safe use of PCA can be found in our July 24, 2003 issue (click on link below).

http://www.ismp.org/MSAarticles/issue2.htm <http://www.ismp.org/MSAarticles/issue2.htm>