Medication Errors

Smart Pump Custom Concentrations Without Hard “Low Concentration” Alerts

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Problem: “Smart” infusion pump technology has evolved considerably since its introduction more than 10 years ago, and its application has spread substantially throughout U.S. hospitals. Based on results from our 2011 ISMP Medication Safety Self Assessment for Hospitals, about half of the respondents now use smart pump technology throughout the organization to intercept and prevent errors due to misprogramming or mis-calculation of doses or infusion rates. Another quarter of hospitals use smart infusion pumps in some patient care units. Yet preventable errors associated with the misprogramming of smart infusion pumps still occur, sometimes causing serious harm to patients.

Failing to employ available dose error reduction software (DERS) as intended and to heed important clinical alerts are common contributors to these errors. In particular, the misuse of custom concentration options (i.e., the user must fill in the concentration) that do not employ a hard (requires reprogramming) minimum concentration limit is a prime example. This issue contributes substantially to preventable errors with smart pumps given the counterintuitive, inverse relationship between concentration and volume. More-concentrated drugs require less volume to deliver a specified dose; less-concentrated drugs require more volume to deliver a specified dose. When using “fill-in-the-blank” custom concentrations, the concentration must be programmed into the pump so it can calculate the volume needed to deliver the prescribed dose. If the programmed concentration is lower than the actual concentration in the infusion bag or syringe, the pump will deliver an overdose. If the programmed concentration is higher than the actual concentration in the bag or syringe, the pump will deliver an underdose. Without a hard minimum concentration limit, the former scenario has led to life-threatening events, such as those described below.

A physician prescribed intravenous (IV) hydromorphone 20 mg/100 mL (0.2 mg/mL) to infuse at 2.5 mg/hour. In this hospital, the standard concentration for this infusion was 0.1 mg/mL, so the custom concentration of 0.2 mg/mL had to be entered into the smart pump. The nurse selected the custom concentration option, then mistakenly entered 2.5 mg/100 mL as the concentration instead of 20 mg/100 mL. Given the erroneously programmed concentration of 0.025 mg/mL, the pump issued a soft (can be overridden) low-concentration alert. The nurse overrode the warning, mistakenly believing the warning was inconsequential. Based on the erroneous concentration, the smart pump infused the drug at a rate of 100 mL/hour, while the intended rate was 12.5 mL/hour. The pump delivered the entire bag of hydromorphone 20 mg to the patient in one hour. The outcome to the patient was not reported.

An infusion of IV furosemide 10 mg/hour was prescribed. When programming the smart pump, a nurse selected the custom concentration option and accidentally entered the concentration as 10 mg/100 mL (0.1 mg/mL) instead of 100 mg/100 mL (1 mg/mL). The pump had a soft low-concentration limit set at 0.2 mg/mL, so a soft alert was issued. The nurse bypassed the alert, and the entire bag containing 100 mg of furosemide infused in one hour instead of 10 hours. Fortunately, the patient was not harmed.

Milrinone IV was prescribed to infuse at 2.5 mg/hour. The pharmacy dispensed a 20-mg/100 mL (0.2-mg/mL) milrinone infusion bag. Using the custom concentration option, a nurse set the concentration as 0.2 mg/100 mL. The entire bag containing 20 mg infused in a matter of minutes instead of infusing over eight hours. The patient required a bolus of IV fluids to treat hypotension, but no changes in the patient’s heart rhythm were reported.

Other serious smart-pump-related errors have occurred when practitioners have unnecessarily selected a custom concentration option—and then entered the wrong concentration—even though a standard concentration option for the drug was available in the pump library. In these cases, programming errors would have resulted in a hard clinical alert (requiring reprogramming) had the standard concentration pathways been employed rather than the custom concentration pathways. Examples of this type of error follow.

A physician prescribed IV heparin to infuse at 800 units/hour. The pharmacy dispensed the heparin in a 250-mL bag (25,000 units/250 mL). This option was available in the smart pump library, but the nurse selected the custom concentration option and erroneously entered the heparin concentration as 800 units/250 mL. Given the erroneously programmed concentration of 3.2 units/mL, the smart pump infused the drug at a rate of 250 mL/hour, not the intended rate of 8 mL/hour. The pump delivered the entire 25,000 units of heparin to the patient in one hour. The patient required treatment with IV protamine but did not experience significant bleeding.

A physician prescribed IV insulin (regular) 12.5 units/hour for a patient with hyperglycemia. A standard insulin infusion (100 units/100 mL, 1 unit/mL) was dispensed from the pharmacy. When programming the pump, the nurse failed to select the standard insulin concentration and instead used the custom concentration option to enter an erroneous concentration of 5 units/100 mL (0.05 units/mL). The smart pump infused the drug at a rate of 250 mL/hour. The whole bag containing 100 units of insulin infused in approximately 20 minutes. The patient’s outcome was not reported.

A physician prescribed morphine as patient-controlled analgesia with a demand
dose of 1.5 mg, a lockout of 10 minutes, and a basal rate of 1.5 mg/hour. The pharmacy dispensed a 60-mL syringe containing morphine 55 mg/55 mL. Instead of using the standard concentration option (1 mg/mL) in the library, the nurse entered a custom concentration of 1.5 mg/55 mL, which resulted in a concentration of 0.027 mg/mL. Given the basal rate of 1.5 mg/hour, the patient received the entire 55 mg of morphine within an hour and was transferred to an intensive care unit for treatment. No outcome was reported.

Some of the above-cited errors appear to be mental mix-ups in which the “per mL” concentration was paired with the total infusion volume—for example, a 1-mg/mL concentration of morphine in a 25-mg/25-mL syringe ends up as a 1-mg/25-mL concentration. Sometimes, the way the concentration is expressed on labels—particularly if the label includes technician instructions for admixture—has also contributed to mistaken concentrations.

If a soft low-concentration alert is provided, the significance of the alert may not be fully appreciated. Since the primary emphasis on averting IV errors is often on doses that exceed maximum limits, it appears that “low-concentration” soft alerts may be misinterpreted as being similar to “low-dose” alerts. Pharmacists responsible for building and maintaining smart pump libraries also may not fully appreciate the significance of “low-concentration” alerts and the importance of making them hard alerts, particularly for high-alert drugs.

Residual custom concentrations that inadvertently remain in the drug library after a limited number of standard concentrations have been added to the library are additional factors associated with these errors. This problem has been reported with pediatric drug infusions for which standard concentrations have more recently been established. Custom concentrations may be required for some medications that are dosed according to body weight or surface area. But retaining the option of entering the concentration of infusions that have since been standardized needlessly increases the risk of patient harm.

Safe Practice Recommendations: Several lessons can be learned from the events described above when it comes to maximizing the safety of smart infusion pumps.

Assess vulnerability to serious errors. Look for potential problems with programming mistakes related to the use of multiple standard concentrations and custom concentration options available in the pump library. The risk of serious adverse drug events due to these vulnerabilities should be explored and addressed as suggested below.

Standardize concentrations. When possible, use a single, standard concentration for each drug infusion. If more than one concentration is necessary, limit the number of standard concentrations to two, and avoid concentrations that differ by a factor of 10 (e.g., 0.1 mg/mL and 1 mg/mL, 1 mg/mL and 10 mg/mL), which could be confused. Use of custom concentrations should be curtailed and, when possible, restricted to selected patient care areas. Remove custom concentration options from the pump library when a standard concentration for that drug has been established and entered into the library.

Set hard minimum concentration limits. For each drug that allows a custom concentration option in the library, set a hard minimum concentration limit that requires reprogramming to avoid a catastrophic overdose. This is especially important for infusions with high-alert medications.

Distinguish custom concentrations. Should a custom concentration be unavoidable, make the container label distinctive and affix auxiliary labels as appropriate.

Require doses to be expressed in the drug's metric weight. Ensure that protocols and prescribers’ orders for infusions include a metric weight per time period (mg/hour, mcg/kg/hour, etc.). An order for an infusion with just the infusion rate (e.g., mL/hour) should not be accepted, even if only one standard concentration of the medication is being used hospital-wide. As appropriate, handwritten orders for infusions should not be prescriptive regarding the concentration—only the patient’s dose (mg/hour, mcg/kg/minute, etc.) should be specified to avoid the risk of variable concentrations. Standardized order sets and electronic prescribing systems should allow the prescriber to select only the standard concentration(s) when applicable.

Match the medication administration record (MAR) and labels to pump settings. The MAR and the infusion label should present the drug and concentration (and infusion rate, if provided) in the same manner required when programming the pump, with specific instructions for custom concentrations as necessary. Extraneous technician preparation instructions should not be included on the final product label.

Verify pump programming. For infusions with key high-alert medications (e.g., patient-controlled analgesia, insulin), require an independent double-check of the product label, MAR, and pump settings. Employ barcode scanning technology to verify patients and infusions, as well as interoperable electronic medical records or other technology that can automatically populate required pump fields (as this functionality becomes available). For all infusions, assess the final infusion rate to be sure it falls within an expected range. Entering an erroneous, low concentration will often result in a very high, atypical infusion rate, which should serve as a signal to reverify the pump settings.

Educate staff. Educate staff regarding the inverse relationship between concentration and volume and the significance of low-concentration alerts.

Analyze data. Routinely evaluate quality reports that are available with smart pumps to identify soft alert overrides and other vulnerabilities to errors, and take action to reduce identified risks. Be sure to identify any issues associated with the reasons why nurses would use a custom concentration option to program an infusion dispensed in a standard concentration that is available in the drug library.