

Latent Failures Identified with CADD[®] Pump Error Analysis

ISMP Canada provided assistance with a medication error analysis of an accidental overdose with hydromorphone administered subcutaneously by a CADD-Legacy[®] PCA Model 6300 pump. The analysis focused on identifying relevant underlying contributing factors (latent failures) for the purpose of developing recommended actions to prevent recurrence. Findings are shared in this bulletin with permission from the hospital.

The event involved an opioid tolerant patient who had been receiving hydromorphone at home by a CADD[®] pump for cancer-related pain prior to admission. After several days in hospital, the attending physician determined that the patient was exhibiting signs of opioid toxicity. The patient's dose was reduced several times over the following three week period. A subsequent order was written to further decrease the infusion rate from 10 mg/h to 8 mg/h and to decrease the bolus dose to 2 mg. The physician also ordered a change of concentration of hydromorphone from 40 mg/mL to 10 mg/mL, expecting that the CADD[®] pump would not be able to deliver a bolus dose of only 2 mg (0.05 mL of 40mg/mL).

The day shift pharmacist receiving the order late in the afternoon: (i) knew that the CADD[®] pump could deliver a 2 mg dose with a 40 mg/mL concentration; (ii) realized that a replacement cassette with a 40 mg/mL concentration had just been initiated that day; and (iii) that technician staff were preparing to end the parenteral preparation shift. The day shift pharmacist then verbally instructed the nurse to adjust the pump rate to the newly prescribed dose using the 40 mg/mL concentration. The nurse was uncomfortable with the pharmacist's suggestion and requested that the pharmacist contact the physician to obtain a new order. There were several unsuccessful attempts to contact the physician by pharmacy. In the interim, the problem was transferred to the evening shift pharmacist who decided to send a written order change notice to authorize the continuation of the current concentration until the following day.

The doctor's order to change the dose and concentration had been earlier transcribed onto the MAR by the day shift nurse. At shift change, the day shift nurse verbally requested that the night shift nurse change the pump settings. The night shift nurse reviewed the written pharmacy order change notice but found it difficult to understand. Based on the MAR and the physician's order information, the nurse changed the pump concentration setting to 10 mg/mL and

programmed the dose to 8 mg/h. Because the programmed concentration did not match the actual concentration, 32 mg/h of hydromorphone was delivered instead of the intended 8 mg/h. By the following morning, the patient's level of consciousness had markedly deteriorated. The error was discovered in the afternoon of the next day, when another nurse noticed the pharmacy order and double checked the drug concentration of the patient's cassette. Once the pump programming was corrected, the patient regained their previous level of consciousness. The error was disclosed to the patient and family and also reported to ISMP Canada.

Contributing factors to this incident included:

- Unclear or absent interdisciplinary and intradisciplinary communication
- Inadequate training with (and infrequent use of) the CADD[®] pump
- Lack of understanding of the functions of the pump
- Lack of a formal mechanism for a nurse to obtain assistance when using a pump that is unfamiliar
- Conflicting order information
- Omitting to check the concentration of the cassette contents when changing pump settings was a critical causal factor

Note: Although not directly contributing to the incident, it was found that the cassette label was not visible unless the cassette was removed entirely from the pump case and turned

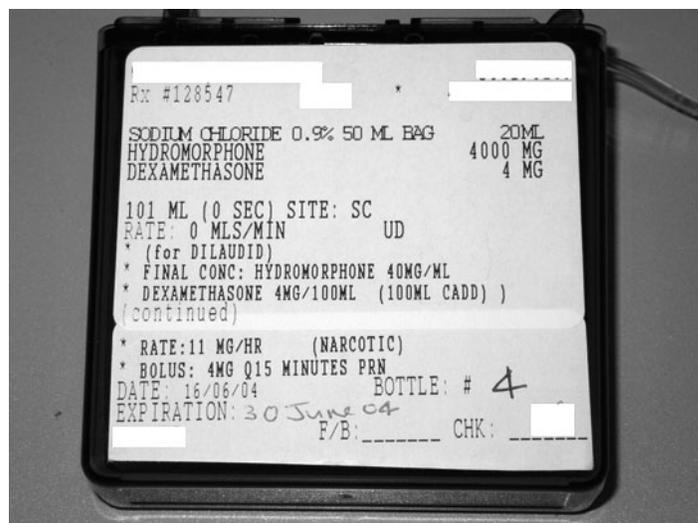


Figure 1: CADD[®] pump cassette label

over. It was also found that critical information was not prominent and was difficult to comprehend on the pharmacy-generated cassette label. See Figure 1.

The following **recommendations** are provided for consideration by hospitals:

- Use pre-printed orders for initiation and all changes of opioid CADD[®] infusions.
- Design the pre-printed orders (consider assistance from a human factors specialist) to:
 - Ensure prominence of critical information
 - Instruct the user to check the concentration of cassette contents and make sure they correspond with the pump setting
 - Describe the *independent* double check¹ process and documentation (recommended with initiation, dosage adjustments and cassette changes)
 - Instruct the prescriber to consult pharmacy when writing orders for in-house prepared specialty products
- When orders for high alert drugs are initiated, or changed, provide verbal communication in addition to a written order to the attending nurse on shift.
- Review “change of shift” procedures to ensure adequate overlap of nursing staff shifts to facilitate communication (opportunity for questions) and to provide opportunity to complete selected tasks together.
- Ensure that formal training and skill assessment on pump characteristics and use are in place before staff may manage patients receiving infusions by a CADD[®] pump.
- Provide a mechanism and a procedure for nursing staff to obtain assistance in the care of a patient with an unfamiliar device.

- Provide a mechanism and a procedure for nursing staff to resolve conflicting order information.
- Review pharmacy labels so that they are designed with the end-user in mind and to prominently display critical information. Work with pharmacy computer system vendors, and ensure input from nursing representatives, to optimize label information display.
- Implement pharmacy processes for standardization of label placement on cassettes to ensure optimal visibility.
- Standardize the concentrations of formulary opioid solutions. For added safety use the lowest concentration possible.

The following **recommendations** are provided for consideration by the CADD[®] pump manufacturer:

- The design of the CADD[®] pump should provide a REMINDER or WARNING to the user to verify the cassette product concentration whenever the concentration settings are changed in the pump.
- The pump should allow bar code verification when concentration settings are changed and provide an error message if there is no match.

ISMP Canada will be notifying the pump manufacturer and Health Canada of the incident and the above recommendations.

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References:

1. ISMP Medication Safety Alert! The virtues of independent double checks – they really are worth your time! Available at <http://www.ismp.org/msaarticles/timeprint.htm>. Accessed October 5, 2004.

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To report a medication error to ISMP Canada: (i) visit our website www.ismp-canada.org, or (ii) e-mail us at info@ismp-canada.org, or (iii) phone us at 416-480-4099. ISMP Canada guarantees confidentiality and security of information received. ISMP Canada respects the wishes of the reporter as to the level of detail to be included in our publications.

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