The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

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Recall of Morphine 2 mg/mL (1 mL Ampoules) and Medication Safety Strategies in a Drug Shortage Situation

Background

On March 21, 2012, Sandoz Canada Inc. advised Health Canada that one package of morphine sulfate 2 mg/mL (10 × 1 mL ampoules) had been found by a hospital to also contain isoproterenol 0.2 mg/mL (1 mL ampoules). On the same day, the lots of morphine (lot CC2824, expiry 2014-12) and isoproterenol (lot CB8787, expiry 2012-11) were identified, and Health Canada advised hospitals and healthcare practitioners to quarantine both.[1,2]

Morphine is an opioid used to treat pain. Isoproterenol is an adrenergic agent used to increase heart rate. A mix-up in the use of these 2 medications could lead to severe harm or even death. Both drugs are high-alert medications that carry a heightened risk of causing significant harm as a consequence of error. Notably, no error reaching a patient has been reported in relation to the mix-up described above.

Late the next day (March 22, 2012), Health Canada issued an advisory stating that **Sandoz Canada Inc. was voluntarily recalling a portion of the 2 mg/mL (1 mL) morphine sulfate for injection (lot CC2824 expiry 2014-12).**[3] (The other portion of the lot had not yet been distributed and remains under the control of the manufacturer.) Health Canada continues to work with Sandoz Canada Inc., is monitoring the recall, and will provide updates as appropriate.[3]

This recall may exacerbate the current drug shortage situation. This bulletin is intended to reiterate and expand upon some of the medication safety strategies suggested in the recent safety bulletin on the topic of drug shortages,[4] with a focus on those that apply to this latest situation. The full discussion of concerns and recommendations related to drug shortages, along with supporting references, can be accessed from http://ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-03_Drug_Shortages.pdf.

Medication Safety Strategies

- Identify patient populations with the greatest clinical need *and* the greatest risk, and strive to avoid changes to the supply and selection of opioid products within care areas for these patients.
- Maximize the use of conservation strategies that may lower the potential for harmful errors, such as using oral rather than parenteral medications if appropriate.
- Note that substituting an opioid of a different strength or potency for an opioid that is in short supply may create opportunities for dangerous dosing errors. If alternative medications or alternative concentrations or dosage forms of existing medications must be used, consider measures such as additional warnings or alerts, independent double checks, product segregation, staff training, or special patient monitoring to reduce the risk of harmful medication incidents.[5]
- Avoid relying on front-line practitioners to do calculations and make adjustments during drug preparation.
- Ensure that temporary changes to drug inventories are supported by appropriate modifications to drug information resources, information systems, and other technologies.[5,6]
- To the extent possible, have pharmacy provide medications to care areas in patient-specific unit-dose or unit-of-use formats.
- Avoid preparing doses in advance in patient care areas. If a product is to be divided into multiple doses to avoid waste, this repackaging should ideally be performed in the pharmacy. If circumstances require that a product be divided in a patient care area, at a minimum ensure that independent double checks are used, that individual doses are appropriately labelled and used only within the care area where they are prepared, and that handling of doses remains consistent with safe practices. It is important to keep in mind that products intended for single use may not contain preservatives or stabilizers and therefore should not be stored for extended periods after being opened or prepared for administration.
- When substitutions or other changes are made, be alert for the introduction of new hazards, including look-alike/sound-alike issues. Be particularly aware of factors that may increase the likelihood of substitution errors when commercially manufactured products are replaced by products that have been packaged or

repackaged in house. Consider implementing suitable differentiation strategies, as described previously.[4]

- Inform practitioners of changes as far in advance as possible.
- Ensure that adequate resources are in place to address workload increases. It may be necessary to increase casual staff hours, reallocate staff, or reprioritize the activities of existing staff.
- Extra vigilance may be required when changes are made to address drug shortages. Any incidents (including reports of hazardous situations, near misses, safe practice compromises resulting from drug shortages, and unintended consequences of efforts to mitigate shortages) should be noted and reported as quickly as possible.

Conclusion

Packaging mix-ups like this one are rare. This occurrence highlights the key role that individual healthcare practitioners play in identifying potentially problematic situations, as well as in reporting hazardous conditions in a timely manner.

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