The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national nonprofit 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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System Vulnerabilities across the Spectrum of Care: Another Mix-up between Choral Hydrate and Potassium Chloride

In November 2003, ISMP Canada reported an error that occurred when an infant was inadvertently given potassium chloride (KCl) oral liquid instead of chloral hydrate oral liquid.[1] A contributing factor to the error was the similar appearance of the two products. Fortunately, there was no adverse outcome in that case, but recently, the same substitution error occurred in reverse, with disastrous consequences. An 80-year-old resident of a nursing home died after receiving seven doses of chloral hydrate oral liquid (a total of 27 grams) instead of the KCl oral liquid that had been prescribed. ISMP Canada was asked to assist with a root cause analysis of the incident.

The chronology of the events in this case is of interest because it illustrates deficiencies in the medication system across the continuum of care, beginning with a "picking error" at the drug distribution warehouse, which was not detected when the medication was received at the community pharmacy. The nursing home resident had been receiving KCl 200 mEq daily, divided into four doses, on a long-term basis. To provide a prescription refill, the community pharmacy ordered three 500-mL bottles of KCl liquid (20 mEg/15 mL) from the warehouse. The warehouse mistakenly shipped one bottle of chloral hydrate (500 mg/5 mL) along with two bottles of KCl. The error was not detected when the product was received at the pharmacy or during the dispensing process. The three bottles were labelled by the pharmacy as containing potassium chloride oral liquid and then delivered to the nursing home. The nurses did not detect that the chloral hydrate product was labelled as containing potassium chloride oral liquid, and seven doses of the medication were administered to the resident. Over a period of 2 days, the resident became lethargic, very sleepy, and apneic and died. The day after the resident's death, during the community pharmacist's regular visit to the nursing home, it was discovered that chloral hydrate had been dispensed instead of KCl.

Analysis of the incident revealed a number of contributing factors:

- The original packaging and labelling of the chloral hydrate and KCl oral liquids were very similar. At the time of the incident, both products were available in opaque white 500-mL plastic bottles with identical label formatting (see Figure 1).
- The drug distribution warehouse relied on visual verification of the "picked" order.
- The words "chloral" and "chloride" are similar in appearance.
- Chloral hydrate liquid is packaged in 500-mL bottles despite high potential for toxic effects and low frequency of use.



Figure 1. Original packages for chloral hydrate and potassium chloride

- Nondispensary staff was responsible for receiving and checking orders from pharmaceutical suppliers.
- The dispensary area of the community pharmacy providing medications for the nursing home had limited workspace for filling and checking functions.
- The dispensing process at the community pharmacy did not include a systematic method to ensure that drug identification numbers (DINs) were consistently checked and documented.
- The resident had been receiving a high dose of KCl oral liquid (200 mEq daily) for over a year to manage hypokalemia related to long-term treatment with furosemide for congestive heart failure. A medication review process was in place in the nursing home, but it was being conducted in a fragmented way because of lack of a coordinated review process among the nursing home, the physician and the community pharmacist.
- Nursing staff had no specific training in medication system safety.

Chloral hydrate oral liquid is considered to be a "high-alert" medication¹. ISMP Canada has asked the manufacturer to make changes to the bottle size, shape and label of the chloral hydrate and potassium chloride oral liquids. Label changes have been implemented since this event occurred, but bottle size, shape, and colour remain the same. All manufacturers are encouraged to employ human factors engineering expertise in designing

¹High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error.

Although mistakes may or may not be more common with these drugs, the consequences of an error with these medications are clearly more devastating to patients

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medication labels and packaging to reduce the potential for lookalike product confusion. In addition, ISMP Canada recommends that manufacturers limit the package sizes of high-alert drugs, similar to the poison prevention strategies used for over-the-counter medications such as paediatric acetaminophen.

To reduce the likelihood of recurrence of this event, the following recommendations are suggested for community pharmacies:

- Ensure that all drug orders are completely unpacked and separated on receipt from suppliers.
- Ensure that the physical space in the dispensary is adequate to perform required functions. Consider physically separate work areas for dispensing and checking of medications for nursing homes.
- Implement a standard process whereby both the pharmacy technician and the pharmacist check the DIN of each container of medication during the dispensing process and document that the check has occurred.
- Ensure that high-alert drugs like chloral hydrate (particularly those in packages that resemble the packages for other, less toxic medications) are stored in physically separate locations in the drug store inventory.
- Consider bar code verification of each item during the dispensing process.

The following recommendation is suggested for drug distribution warehouses:

• Implement bar code verification for every aspect of the warehouse inventory process from stocking items, to picking and checking of orders.

The following recommendations are suggested for nursing homes:

- Require a combined prescription renewal and interdisciplinary medication review for each resident at least every 6 months, with documentation in the resident's medical record. (Note that the minimum frequency of a medication review must comply with provincial legislation and regulations.)
- Ensure that nursing staff participate in education sessions on pharmacology, the signs of adverse drug events, and the principles of medication system safety, to raise awareness about prevention and recognition of adverse drug events.

To date, much of the activity related to patient safety has focused on acute care facilities. This incident illustrates the need to increase awareness of medication system safety across the spectrum of health care settings and among all levels of health care providers. Full investigation with root cause analysis of critical incidents often reveals system deficiencies that are not apparent to individuals working at various levels of the health care system.

Acknowledgements

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References:

1. More on potassium chloride. ISMP Can Saf Bull 2003;3(11):1-2. Available at: http://www.ismp-canada.org/download/ISMPCSB2003-11KCl.pdf. Accessed October 5, 2005.

Michael Cohen Awarded Prestigious Fellowship

Michael R. Cohen, RPh, MS, ScD, President of the Institute for Safe Medication Practices (ISMP), has been named a John D. and Catherine T. MacArthur Foundation Fellow for 2005. The highly selective Fellowships are awarded to individuals who have shown extraordinary originality and dedication in their professional pursuits, and outstanding promise for important future advances. Dr. Cohen, a founding member and current Board member of ISMP Canada, is being honored for his ability to lead national efforts to ensure safe medication use and protect patients.

The MacArthur Foundation is one of the

ten largest private philanthropic foundations in the U.S., and Fellows are chosen through a rigorous process. The program does not accept applications or unsolicited nominations. Between 20 and 30 Fellows are chosen each year, each receiving an unrestricted, five-year grant totaling \$500,000, which is considered an investment in their potential to use their abilities to benefit society at large. Recent Fellows include academics in the field of science and medicine at top-ranked U.S. universities such as Harvard, Yale, and Stanford.

Dr. Cohen has dedicated his 40-year career in healthcare to bringing about greater

understanding of the causes of medication errors and providing the healthcare community with practical prevention strategies. Other accomplishments include helping launch a continuous, voluntary practitioner medication error reporting system; publishing extensively on medication use issues; serving on key national medication safety committees; and providing consultation, education, and assistance on safe medication use to healthcare professionals and organizations around the world.

Please join ISMP Canada in congratulating Dr. Cohen on receiving this prestigious honor for his dedication and innovative approach to medication safety.

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ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

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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