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.

The Healthcare Insurance Reciprocal of Canada (HIROC) is a member owned expert provider of professional and general liability coverage and risk management support.

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National Collaborative: Top 5 Drugs Reported as Causing Harm through Medication Error in Paediatrics

The Canadian Association of Paediatric Health Centres (CAPHC) and the Institute for Safe Medication Practices Canada (ISMP Canada) are working collaboratively, with support from the Canadian Patient Safety Institute, to enhance the safety of paediatric medication use. The treatment of acutely ill infants, children and youth presents unique challenges in the realm of medication safety. A variety of factors, including the age, size, and physiological status of these patients, can increase the likelihood that medication incidents*, particularly those involving high-alert medications†, will result in harm.[1] The collaborative project, guided by a national advisory committee of content experts, practitioners, and researchers, is being undertaken in 2 phases. This safety bulletin shares an overview of phase 1, which has identified the top 5 medications most frequently involved in errors reported as causing harm in paediatric patients, and some of the contributing factors identified.

Background

Seventeen CAPHC member organizations were invited to submit reports of medication incidents involving paediatric patients to ISMP Canada. Eleven facilities submitted more than 4000 paediatric incidents for the period October 2005 to June 2008. Six of the 11 facilities submitted detailed data that included free-text descriptions. The remaining 5 facilities submitted quantitative data that identified the medication involved and the level of patient harm.

Project Findings

Of the reported incidents, 305 had an outcome of harm‡. An incident was excluded from analysis if it was deemed to be an adverse drug reaction or if the clarity of the data was poor (e.g., medication class rather than medication name provided, medication name misspelt beyond recognition). Of the 305 reports of incidents causing harm, 294 reports, involving a total of 320 medications, met the criteria for analysis. From this group, the top 5 medications causing harm were identified (Table 1).

The medication most frequently cited as causing harm was morphine, representing 8.8% of the reports of incidents causing harm. Incidents involving fentanyl represented 3.4% of the harmful incidents. Together, these 2 opioids represented 36 (12.2%) of the 294 reports of medication incidents causing harm and accounted for just over 50% of the incidents for the top 5 drugs (36 of 71 reports) (Table 1).

Table 1: Top 5 Medications Reported as Causing Harm in Paediatric Patients as a Consequence of Medication Error (Based on Reports from 11 CAPHC Member Organizations)

Medication	Number (%) of Incidents (n = 294)
morphine	26 (8.8)
potassium chloride	14 (4.8)
insulin	11 (3.7)
fentanyl	10 (3.4)
salbutamol	10 (3.4)

It is impossible to infer or project the probability of specific types of incidents on the basis of these data, which come from voluntarily shared reports; however, a previous review of the ISMP Canada medication incident database also identified morphine, insulin, and fentanyl among the top 5 medications reported as causing harm, in both adult and paediatric patients, as a consequence of medication error.[5]

Contributing Factors Identified

A qualitative analysis of these top 5 medications was then conducted. The objective was to gain insight into factors contributing to the incidents and to identify potential interventions for improving system safety. Data for the qualitative analysis were limited to the detailed incident reports received from 6 of the facilities, as described above. Specifically, all of the 482 detailed medication incident reports involving the top 5 medications, both those causing harm and those not causing harm, were reviewed, to capture valuable insights that might also be gained from near-miss and other no-harm reports.

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* Medication incident — a term widely used to refer to the preventable subset of potential and actual adverse drug events; also recognized as an alternative term for medication error.[2]

† High-alert medications — drugs that bear a heightened risk of causing significant patient harm when they are used in error.[3]

‡ Harm — any error meeting or exceeding the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) criteria for a category E error (i.e., categories E to I inclusive); category E is defined as "an error that may have contributed to or resulted in temporary harm to the patient and required intervention".[4]

Morphine Incidents

A total of 176 detailed reports of morphine incidents were received, of which 20 were categorized as resulting in patient harm. Incidents involving a wrong dose accounted for more than half of all the morphine incidents analyzed (97/176) and also more than half of those that resulted in patient harm (12/20). Most of these incidents involved IV administration (intermittent doses and continuous infusions) and patient-controlled analgesia. Misinterpretation of orders was associated with a high number of multi-fold overdose incidents. In 2 cases, morphine 1.5 mg IV was ordered, and misinterpreted as morphine 7.5 mg resulting in 5-fold overdoses. There were 6 cases reporting 10-fold overdoses, and misinterpretation of the decimal place was a contributing factor in some cases. Other contributing factors to incidents included dosing unit mix-ups and incorrect pump programming. In 3 cases IV infusions ordered as micrograms per kilogram per hour were programmed into the pump as milligrams per kilogram per hour.

Potassium Chloride Incidents

A total of 204 detailed incident reports were received for potassium chloride, 7 of which were associated with patient harm. None of the reported incidents involved the use of concentrated potassium chloride vials. Almost half of all potassium incidents involved the incorrect selection of premixed bags of potassium chloride (either the incorrect infusion solution or the incorrect concentration of potassium chloride). For example, an infusion of dextrose 10% and 0.2% sodium chloride with 20 mmol of potassium chloride per litre was inadvertently administered when dextrose 5% and 0.2% sodium chloride with 20 mmol of potassium chloride per litre was ordered. The complexity of paediatric IV fluid regimens was identified as one of the main contributing factors in these incidents.

Insulin Incidents

A total of 41 detailed incident reports involving insulin were received and analyzed, 8 of which were reported as resulting in patient harm. Of the 8 reports of harm, 6 were due to wrong dose errors. The wrong dose was also the most commonly reported incident type among all detailed reports (18/41 reports); this problem occurred with both IV infusions and subcutaneous administration of insulin. A mix-up of IV lines was an important contributing factor to incidents involving IV infusion of insulin. A common contributing factor in incidents involving subcutaneous administration of insulin was misinterpretation of orders.

Fentanyl Incidents

A total of 30 detailed incident reports involving fentanyl were analyzed, 5 of which were reported to have resulted in patient harm. The majority of fentanyl incidents, and all those resulting in harm, involved wrong-dose errors. Contributing factors to these wrong-dose incidents included misinterpretation of the order, in particular misreading of the decimal place during dispensing and administration. For example, in one case an order for fentanyl 550 micrograms to be admixed in 50 mL normal saline and infused at 0.5 mL per hour was misinterpreted, and fentanyl 55 micrograms was admixed resulting in an underdose. In addition, various problems related to IV pump programming were reported to have contributed to fentanyl overdose incidents.

Salbutamol Incidents

A total of 31 detailed incident reports involving salbutamol were received, 5 of which were reported as resulting in patient harm. Salbutamol is frequently used as a rescue medication for asthma exacerbations, and dose omissions led to patient harm in 3 instances. Misinterpretation of the order was a significant contributing factor. Wrong-dose incidents constituted the majority of all of the detailed reports, 2 of which were reported to have caused harm. Contributing factors included mix-ups between units of measurement (e.g., 5 mL versus 5 mg), dose miscalculations because the wrong patient weight was used, and miscommunication between disciplines (e.g., miscommunication between a nurse and a respiratory therapist led to the duplicate administration of a patient's inhaler medication, resulting in overdose).

Next Steps

Phase 2 of this project on medication safety in paediatrics, now underway, will focus on identifying system solutions for enhanced opioid safety. The risk of harm to children from medication incidents involving opioids has previously been reported,[6] and the analysis reported here emphasizes that enhancing opioid safety can enhance medication safety in paediatrics. Next steps will utilize human factors expertise and will identify practices and medication system safety strategies to be included in a resource toolkit for Canadian paediatric opioid safety.

Acknowledgements

Reporting is the first step in enhancing medication safety. ISMP Canada and CAPHC express sincere appreciation to the many healthcare professionals for their initiative, efforts, and demonstrated support for a culture of safety, exemplified by their willingness to share information about medication incidents and related findings.

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Report of Incorrect Glucose Tolerance Testing Product Received and Administered

A healthcare organization received bottles of glucose solution containing 75 grams of glucose, rather than solutions containing 100 grams of glucose as ordered from the distributor. The following information is shared:

A laboratory staff member was preparing to carry out a glucose tolerance test for an adult patient. Upon retrieving the glucose beverage, the staff member noticed that the incorrect strength was stocked. The organization always purchased and stocked only bottles containing 100 gram of glucose solution; laboratory staff members then gave each adult patient the amount of beverage required for the specified dose, according to the glucose tolerance test to be done. The product distributor confirmed that the incorrect product had been shipped, and an inventory count indicated that the product had been in use for about 10 days. The organization contacted 30 patients who might have received an incorrect dose, and retesting was recommended for 19 of these patients.

The organization is now conducting a review to determine underlying causes of the error. Preliminary information suggests that labelling and packaging may have played a part, since the 50 gram, 75 gram, and 100 gram doses are packaged in the same size of bottle, with similar labels (Figure 1).

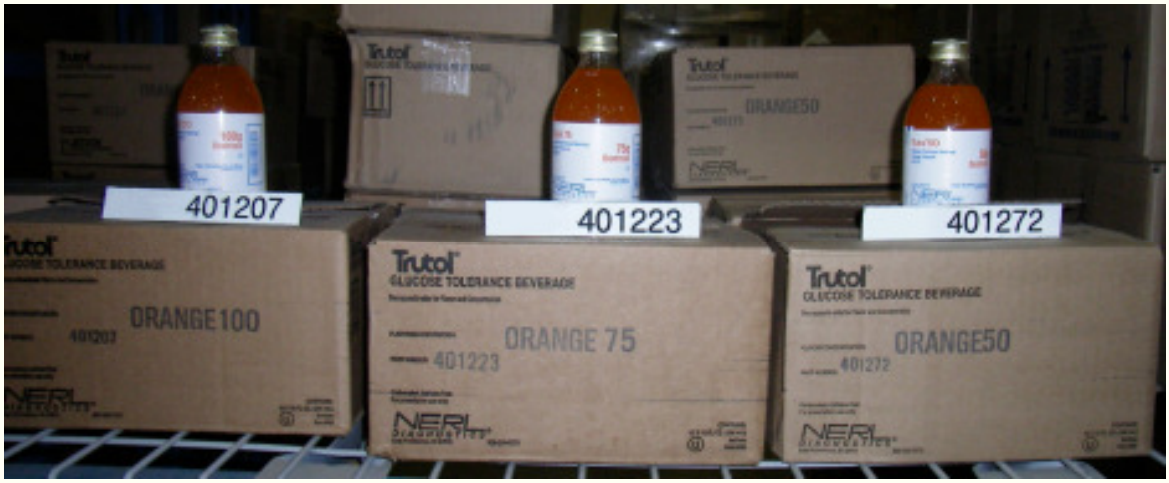

Figure 1: Three products of orange-flavoured Trutol available from the manufacturer (from left to right, bottles containing 100 grams, 75 grams, and 50 grams), atop their respective shipping cartons. The bottles, which are identical in size, all contain an orange liquid. The labels for all 3 products have a white background with blue and red print, the red print specifying the product name and dose.

Ultimately, an automated checking system, such as bar coding, at all stages of the process (ordering, shipping, receiving, stocking, and administration) may assist in preventing such incidents. In the interim, ISMP Canada suggests that healthcare organizations and professionals review their procedures for glucose tolerance testing and for managing oral glucose beverages to ensure that, in addition to the name and strength of the solution, the product number is double-checked against the purchase order and inventory requirement.

ISMP Canada has informed the manufacturer and Health Canada of this report.

A Reported Concern that Xarelto Looks and Sounds Like Xatral

ISMP Canada has received a report of concern about the look-alike, sound-alike potential between the newly marketed Xarelto[1] (brand name for rivaroxaban) and Xatral (brand name for alfuzosin hydrochloride). Rivaroxaban is an anticoagulant, specifically a direct factor Xa inhibitor, and is indicated for the prevention of venous thromboembolic events in patients who have undergone elective total hip replacement or total knee replacement surgery.[2] Alfuzosin hydrochloride is an alpha-1-adrenoreceptor antagonist indicated for the treatment of signs and symptoms of benign prostatic hyperplasia (BPH) and as adjunctive therapy with urethral catheterization following acute urinary retention related to BPH and management following catheter removal.[3] Both products are available in 10 mg tablets, and both have a recommended daily dosage of 10 mg once daily.[2,3] The reporter expressed concerns about the possibility of a mix-up.

ISMP Canada has notified Health Canada and the manufacturers of this reported concern. The following strategies are suggested as measures to reduce the risk of a mix-up:

- use the generic name in addition to the brand name where applicable;
- physicians are encouraged to include the indication for the medication when prescriptions are communicated;
- verify the indication for the drug with the patient whenever possible;
- clearly distinguish the 2 drugs in the product selection screen of computerized order entry systems; and
- add a warning where these drugs are stored.

References

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Education Announcement

Analyzing Medication Incidents Effectively to Enhance Medication Safety

ISMP Canada, in collaboration with the United States Pharmacopeial Convention (USP), is pleased to offer a one-day interactive program on September 21, 2009, providing vital information on how to improve safety in our healthcare institutions. The workshop is designed specifically for pharmacy directors, risk managers, patient safety officers, medication safety officers, and other healthcare professionals seeking to enhance their ability to analyze medication incident data and choose effective system improvements.

During the session, you will learn the current best practices and most effective strategies for reducing risk, based on proven medication safety principles, rather than human vigilance alone. Structured, logical approaches will assist in meaningful interpretation of medication incident data, which will in turn allow you to prioritize the issues and appropriately direct your medication safety efforts. During the workshop, you will have an opportunity for hands-on practice under the guidance of USP and ISMP Canada experts. You will also receive a variety of take-home materials and tools.

To learn more about this program, please visit: http://www.ismp-canada.org/education/download/amieems.pdf or call ISMP Canada at 1-866-544-7672.

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.

Medication Incidents (including near misses) can be reported to ISMP Canada:
(i) through the website: http://www.ismp-canada.org/err_report.htm or (ii) by phone: 416-733-3131 or toll free: 1-866-544-7672.

ISMP Canada can also be contacted by e-mail: cmirps@ismp-canada.org. ISMP Canada guarantees confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications.

A Key Partner in the Canadian Medication Incident Reporting and Prevention System