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CMIRPS Canadian Medication Incident Reporting and Prevention System
SCDPIM Système canadien de déclaration et de prévention des incidents médicamenteux

ISMP Canada Safety Bulletin

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Pediatric Medication Errors in the Community: A Multi-Incident Analysis

This bulletin highlights the findings from a multi-incident analysis of harmful medication incidents involving pediatric patients in the community and identifies opportunities to improve pediatric medication safety.

METHODOLOGY

Reports of medication incidents involving harm to pediatric patients in the community setting were extracted from 3 ISMP Canada databases* (National Incident Data Repository for Community Pharmacies, Individual Practitioner Reporting, and Consumer Reporting) over the 5-year period from June 1, 2016, to May 31, 2021.

Key terms used to search the free-text fields in the databases included "infant," "pediatric," "child," and "adolescent." Of the 68 incidents identified, 62 were included in the analysis. The analysis was conducted according to the multi-incident analysis methodology outlined in the Canadian Incident Analysis Framework.[1]

Most of the incidents were reported as being associated with a mild level of harm, with 16% reported as causing severe harm or death (Figure 1).[2] About two-thirds of the reported incidents involved an error during order entry and dispensing (Figure 2). It is recognized that many clinical concerns and prescribing errors[3] may be managed through pharmacist intervention before harm can occur.

FIGURE 1. Reported medication incidents according to level of harm

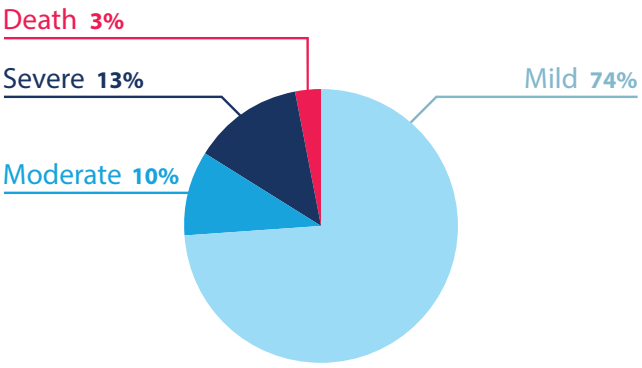
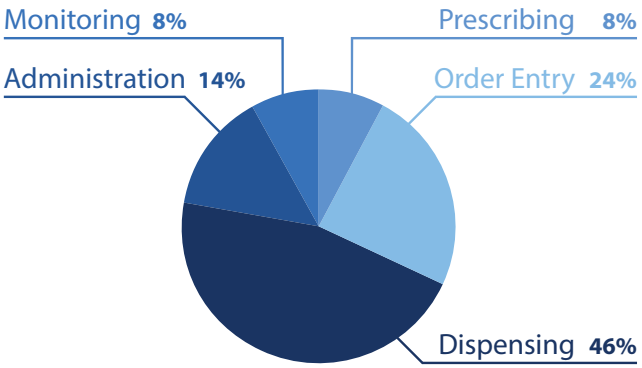


FIGURE 2. Reported medication incidents according to stage of the medication-use process

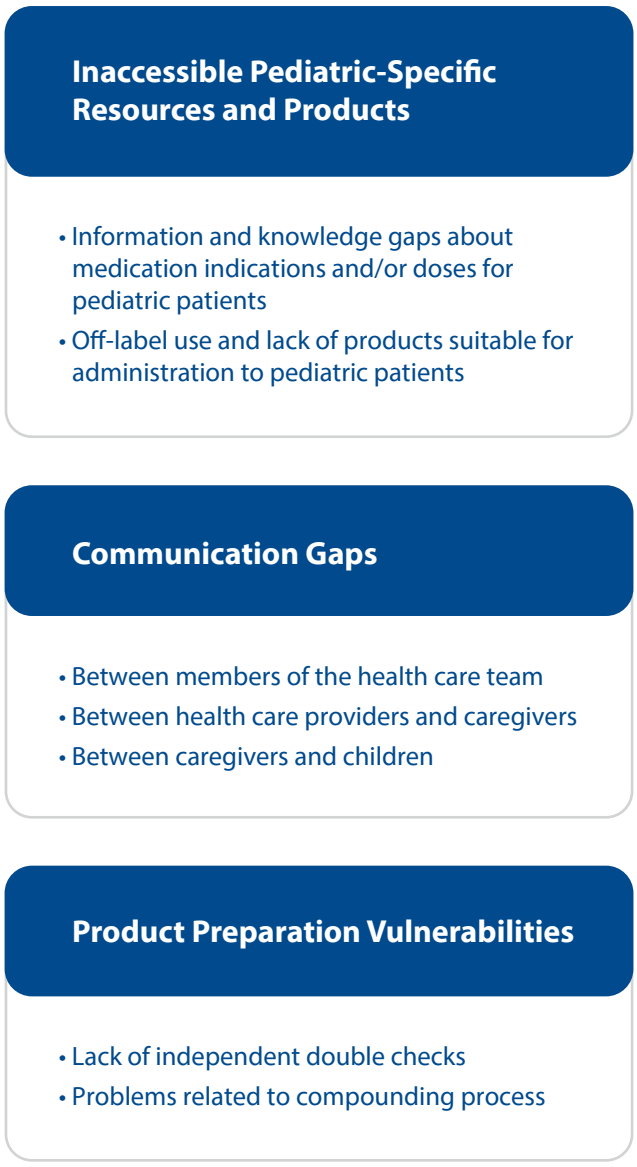


* The databases are components of the Canadian Medication Incident Reporting and Prevention System (CMIRPS). More information about the databases is available from: http://www.cmirps-scdpim.ca/?p=12.

QUALITATIVE ANALYSIS FINDINGS

The analysis identified numerous factors contributing to the medication errors. These factors were categorized under 3 main themes, each with multiple subthemes (Figure 3).

Figure 3. Main themes and subthemes



THEME: Inaccessible Pediatric-Specific Resources and Products

Considerations for medication management in pediatric patients often include weight-based dosing, age-related pharmacokinetic differences, and limited product choices (e.g., to accommodate inability to swallow tablets or capsules). This analysis identified gaps in readily accessible information to confirm indications for pediatric use and pediatric dosing, in addition to off-label use, and lack of appropriate pediatric product formulations, as key contributors to medication errors.

Incident Example

Amoxicillin/clavulanic acid 90 mg/kg/day (based on the amoxicillin content) was prescribed for an infant. The formulation containing a higher ratio of clavulanic acid to amoxicillin was dispensed. The infant was admitted to hospital a week later because of gastrointestinal (GI) problems. The pharmacist who dispensed the medication was unaware that high doses of clavulanic acid can cause GI intolerance in infants and that a different formulation containing a lower ratio of clavulanic acid should have been provided.

TIP: Perform an independent calculation to confirm the prescribed dose.

If working alone, a drug information centre or a colleague at a different pharmacy can support the double check process.

TIP: Verify supporting evidence for pediatric off-label use.

It is estimated that 75% of medications for pediatric patients are prescribed on an off-label basis.[4] It is important to contact the prescriber if more information about the prescribed medication and dosage would be helpful for the pharmacy order verification process.

THEME: Communication Gaps

Reporters attributed many errors to a lack of communication, including (i) between members of the health care team, (ii) between a health care provider and the caregiver(s), and (iii) between a caregiver and the child. Some examples were prescriptions for which pharmacists did not seek clarification from the prescribing physician (where such clarification was needed), lack of follow-up or monitoring by health care providers, and communication barriers between children and their caregivers.

Incident Example

An adolescent diagnosed with diabetes weaned themself off insulin. The specialist was aware of the change to metformin monotherapy and follow up was to be continued by the primary care physician. There were multiple visits to the hospital for varying reasons over several years, and glucose levels and diabetes management were not documented despite the diagnosis on the patient record. The patient passed away at home; the cause of death was determined to be diabetic ketoacidosis. An analysis of the glucometer post-mortem demonstrated high glucose readings in the previous month.

TIP: Optimize continuity of care between primary care providers and acute or specialist care providers.

TIP: Encourage conversations with patients and families about medications, including when to follow up with the doctor.

The "5 questions to ask about your medications" and "5 questions to ask about my medicine – for kids" can be helpful resources.

Engaging pediatric patients and their caregivers in the circle of care is critical to support safe and effective medication use. When educated about their medical condition(s) and medication(s), pediatric patients can also help convey valuable information at transitions of care.

THEME: Product Preparation Vulnerabilities

Many of the errors made during product preparation were deemed preventable through improved workflow and checking processes. Numerous incidents stemmed from calculation errors during compounding and preparation of liquid formulations, which led to dispensing of an incorrect concentration or provision of incorrect directions for use (e.g., the incorrect volume to be administered).

Incident Example

Cefuroxime 250 mg/5 mL was prescribed for a patient, to be administered as 4 mL (200 mg) twice daily. The prescribed product was not available, so the pharmacy dispensed cefuroxime 125 mg/5 mL instead, but mistakenly left the directions as "4 mL twice daily". As a result, the dispensed dose was only 100 mg.

TIP: Conduct an independent double check of every calculation performed and final amounts included during product preparation.

If working alone, the independent double check process can be supported virtually using video technology, if needed.

TIP: Confirm the prescribed dose by checking a reliable pediatric resource.

Ideally, prescribers can select a medication based on what is commercially available and in a format suitable for pediatric use. However, in many cases, a prescription for a compounded product may be required to meet the needs of the patient.[5] Compounding introduces additional risks for errors, especially during dose calculation, ingredient selection, and ingredient weighing. Strategies to reduce or eliminate compounding errors include the use of standardized, validated master formulas published by organizations with pediatric expertise and the implementation of technology (e.g., bar code scanning) to support correct product identification.[6]

CONCLUSION

This multi-incident analysis highlights factors contributing to harmful incidents involving pediatric patients in the community. Several opportunities exist to improve medication safety for this population including bringing more pediatric formulations to the commercial market.[6] Including children and adolescents in conversations about their medications can help to empower them as partners in their own care. Because specialized knowledge is required, it is essential that practitioners review medication indications and weight-based doses when prescribing or dispensing medications for the pediatric patient population.

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Preventing Pediatric COVID-19 Vaccine Errors at Mass Vaccination Sites

ISMP Canada received reports of the inadvertent administration of adult COVID-19 vaccine doses to children eligible for a pediatric vaccine. Vaccination sites have implemented various strategies to prevent this type of error.

A successful initiative of one hospital that has hosted several hospital- and community-based clinics is shared. The approach is based on clear, segregated processes for dose preparation, patient registration, and dose administration, as well as the consistent use of a distinctive colour to differentiate the pediatric dose from the adult dose. At this hospital, the chosen colour was green. (Figure 1).

Figure 1. Overview of the process and colour differentiation strategy implemented to differentiate pediatric doses from adult doses at a mass vaccination clinic.

Dose Preparation
- Designate staff to prepare only pediatric doses
- Store pediatric vaccines in foam coolers with green labels
- Use electronic templates to print green pediatric syringe labels; apply these labels as soon as pediatric vaccine doses are drawn up

Patient Registration
- Check child's eligibility for pediatric dose (i.e., age, dose interval)
- Apply a green wristband to signify that a pediatric dose is required
- Lead the patient through the green-signed pediatric dosing stream at the clinic

Dose Administration
- Designate staff to administer only pediatric doses
- Independently double check each pediatric patient's eligibility
- Remove tab from patient's green wristband to give to site leader (to confirm a pediatric patient is seated); retrieve green-labelled pediatric syringe

Mass vaccination sites are encouraged to incorporate strategies to clearly distinguish between adult and pediatric COVID-19 vaccine dosing, in terms of designated areas for dose preparation and administration, distinctly labelled vials and syringes, and clearly outlined check processes.

Acknowledgement

ISMP Canada extends appreciation to Michael Garron Hospital for allowing details of its organizational actions to be shared, with the goal of preventing COVID-19 vaccine dosing errors in children eligible for the pediatric dose.

Sharing Matters! Incident Spurs Implementation of Child-Resistant Closure

ISMP Canada's consumer reporting program, SafeMedicationUse.ca, described a report of a young child who drank amoxicillin suspension directly from the bottle, in the absence of caregivers. This was possible in part due to the lack of a child-resistant closure.[1]

ISMP Canada contacted Apotex (manufacturer) and Health Canada to inform them of the incident and the need for improved packaging, specifically a child-resistant cap. Apotex has recently confirmed that their product is now available in a container with a child-resistant closure (Figure 1). The last lot of products with the regular cap will be available until its expiry date of 19 August 2022.

ISMP Canada is grateful to the consumer for sharing the incident and thanks Apotex for their commitment to advancing medication safety.

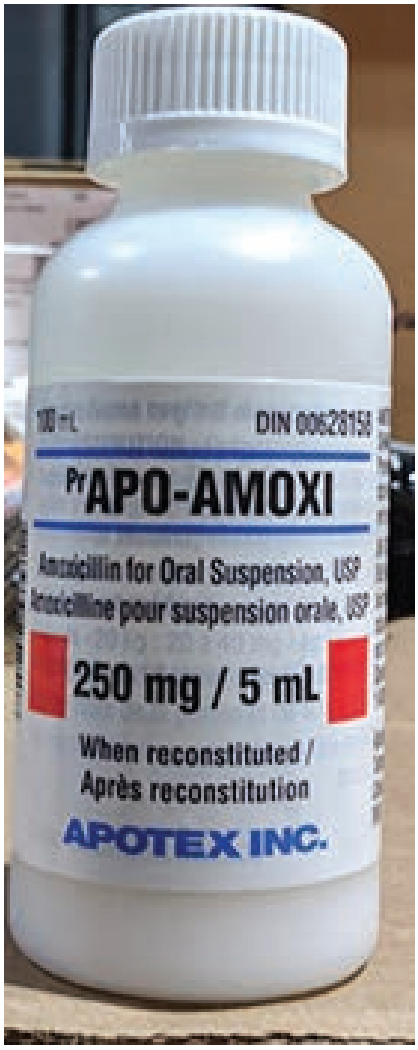

Figure 1. New amoxicillin suspension bottle with child-resistant closure

Reference

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The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and Healthcare Excellence Canada (HEC). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.

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

ISMP CANADA

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.

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