MEDICATION SAFETY IN PEDIATRICS
Pharmacy practice involving pediatric medications requires special attention and cannot simply involve extrapolating practices from knowledge of adult medications. Pediatric is a unique population with characteristic and vulnerable practices in medication safety. In this article, we will examine the five-stage medication-use processes, namely: prescribing, order entry, dispensing, administration, and monitoring.

In the prescribing and order entry stages, weight-based dosing is required for many medications for pediatrics, thereby increasing the complexity of the prescription order. Furthermore, weights of growing children can change rapidly and hence requiring frequent re-calculations. In the dispensing stage, commercially available preparations are usually manufactured for adult dosing and therefore require dosage adjustments or dilution for children. In the administration or monitoring stage, neonates and toddlers often do not have the communication skills to express a potential adverse drug event, which may then defer the recognition of or even masking a potential medication error.

In addition, the pharmacokinetics and pharmacodynamics of a drug cannot be simply extrapolated to the pediatric population. For example, neonates have a less physiologic reserve (i.e. volume of distribution) with which to buffer an overdose. These unique features of the pediatric population may put them at distinguishing risks for medication incidents when compared to adults. Therefore, the administration of safe medication practices with pediatric medications requires special attention to unique areas and this article aims to highlight vulnerable practices in pediatric medication incidents.1, 2

AGGREGATE ANALYSIS OF PEDIATRIC MEDICATION INCIDENTS IN COMMUNITY PHARMACY PRACTICE

Using a search criterion of “0-28 days inclusive” or “>28 days to 18 years inclusive” for the age category of a medication incident, we retrieved a total of 454 reports for the period between April 2010 and August 2011, from the ISMP Canada Community Pharmacy Incident Reporting (CPhIR) Program.

Medication incidents occur due to failures in the system that places practitioners at heightened risk for committing an error. The result of a qualitative analysis of the above incidents revealed themes in pediatric medication incidents which are documented in the chart on the following pages.

The authors acknowledge support from the Ontario Ministry of Health and Long-Term Care for the development of the ISMP Canada Community Pharmacy Incident Reporting (CPhIR) Program. The CPhIR Program also contributes to the Canadian Medication Incident Reporting and Prevention System (CMIRPS). A goal of CMIRPS is to analyze medication incident reports and develop recommendations for enhancing medication safety in all healthcare settings.4 The incidents anonymously reported by community pharmacy practitioners to CPhIR were extremely helpful in the preparation of this article. 

See Chart on pages 16-17

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It is imperative that the weight of a child always be asked and the dosage is appropriate for the corresponding weight.
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<th>THEMES</th>
<th>WHAT</th>
<th>HOW</th>
<th>SAMPLE CASES</th>
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<tr>
<td>General order entry errors</td>
<td>Errors at the order entry stage. Examples include: unit errors, typing in the wrong number, look-alike or sound-alike drug names, errors while copying from a previous prescription, medication shortage, or a therapeutic substitution.</td>
<td>Identities last names leading to confusion and confirmation bias that multiple prescriptions from the same family are all for one family member (especially if the prescriptions are placed in the same baskets).</td>
<td>A mother brought in 3 prescriptions for herself and one for her daughter. All four prescriptions were accidentally processed under the mother’s name.</td>
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<td>Incorrect patient</td>
<td>Pediatric prescriptions are often dropped off by a family member (for example, parents), who may also be filling additional prescriptions for themselves or other members in the family. Hence, the order may contain prescriptions for multiple family members, who all have identical last names. This makes distinguishing the patient a challenge and therefore increases the chance of a prescription being filled for the incorrect patient.</td>
<td>Food allergies – Asking about drug allergies is an intuitive practice because drugs are dispensed in a pharmacy. Asking about food allergies may not seem to be a common practice, but certain pediatric medications contain food flavoring. Balance owing – Many pediatrics will be taking the prescribed medications for the first time. When an allergy is noted, the drug should be discontinued immediately but a loophole in the medication-use system is with balance owing, coupled with drug deliveries.</td>
<td>A child was allergic to bananas. The child was prescribed amoxicillin and the pharmacy staff missed the food allergy and dispensed the banana-flavoured amoxicillin oral solution. No harm was done as the error was caught before administration.</td>
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<td>Allergy</td>
<td>Pediatrics is at heightened risks for allergic reactions. Many of them may be new patients to a pharmacy, especially if it is the first time being sick and prescribed with a medication. New patients require an interview for thorough medication/medical records. If the allergies are missed, then the child may be at risk for an allergic reaction.</td>
<td>Food allergies – Asking about drug allergies is an intuitive practice because drugs are dispensed in a pharmacy. Asking about food allergies may not seem to be a common practice, but certain pediatric medications contain food flavoring. Balance owing – Many pediatrics will be taking the prescribed medications for the first time. When an allergy is noted, the drug should be discontinued immediately but a loophole in the medication-use system is with balance owing, coupled with drug deliveries.</td>
<td>A child was prescribed ranitidine but the mother noticed a bad reaction and informed the pharmacy. Ranitidine was discontinued but there was still a balance owing on file and no pharmacy staff noticed it. The remaining balance of ranitidine was delivered to the mother, at which time the mother sent back the drug.</td>
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| High alert medications | Certain medications, such as high alert medications, are more prone to errors when prescribed for a pediatric patient. These medications can also be prescribed for adults, but when processing for pediatrics, additional changes and cognitive processes by the pharmacy staff need to be made. These additional steps increase the likelihood of an error. Special attention should be directed to vulnerable characteristics of these medications. | Mix-up between the adult and junior formulations. The most common medications in this category are Biaxin® and Epipen®. Directions mix-up, for example, between Ventolin® and Flovent® metered-dose inhalers. These two puffers are often co-prescribed in asthmatic patients, thereby increasing confusion during order entry. Dispensing not-so-commonly used medication, such as, Concerta® that is expired. Concerta® may not be used as often as other pediatric medications; therefore the expiry date may not be checked as often, so it sits on the shelf for a longer period of time. Unlike antibiotics for adults, the pediatric formulation may need to be reconstituted, therefore requiring complex dilutions and unit calculations. A child prescribed the solution formulation of Biaxin® and amoxicillin requires additional steps in calculation, and hence increasing the possibility of an error. | Epipen® Junior was prescribed for a child. When checking the child’s age, it was unlikely that the child was less than 30kg (i.e. the upper limit for the Junior formulation). The weight of the patient was confirmed with the parent to be over 30kg and the adult formulation was prescribed instead. Ventolin® and Flovent® was prescribed for a child. The intended directions for Ventolin® was labeled on Flovent® and vice versa. This was caught during the pharmacist check and corrected. During a narcotic check in the pharmacy, it was discovered that Concerta® was expired. A subsequent report was generated to see if any patients had been dispensed Concerta® recently. A child was prescribed amoxicillin 75mg TID for 10 days. The stock solution was Novamoxin 125 SUSP 25mg/ml. A calculation error was made and the label reads “5 mL three times daily” when it should have been “3 mL three times daily.” An azithromycin solution prescription for a child calls for 250mg on day 1 and 175mg on days 2 – 4. The stock solution came in 250mg/5mL. The
Weight-based dosing is a unique challenge with pediatrics. The primary contributing factor to this type of error is the lack of confirmation of the appropriate dose according to a reference.

It is imperative that the weight of a child always be asked and the dosage is appropriate for the corresponding weight.

**HOW**

Increases the error risk. For instance, azithromycin is often prescribed with a loading dose on day 1 and then a lower dose on subsequent days (for example, 500 mg on day 1, then 250 mg on days 2-5). Furthermore, additional calculation may be required for liquid formulations, thereby creating an increased risk of medication error with pediatric prescriptions.

Certain pediatric medications that require reconstitution contain very specific instructions in the way reconstitution must be performed. For example, Suprax® (cefixime) 100mg/5mL oral solution requires reconstitution with 33 mL of water added in two portions. These minor variations in the reconstitution instructions may sometimes be difficult to remember because they are medication-specific.

Failure to reconstitute occurs when the pharmacy forgets to reconstitute the medication and dispense the powdered form.

Certain reconstituted medications are only stable for a defined period. While we traditionally focus on the expiry date of a medication, reconstituted oral suspension or solution requires the additional step for us to recognize the duration of stability after reconstitution.

Under dose – When dosing for pediatrics, clinicians tend to be more conservative and would rather under dose than overdose. However, this error can risk the child being treated with an ineffective therapy and may lead to complications.

Overdose – Pediatrics, because of their altered pharmacokinetics and pharmacodynamics, may have a smaller therapeutic window compared to an adult patient. Certain medications cannot be simply dosed by extrapolation of the adult dose, but requires deliberate guidance from a reference.

**SAMPLE CASES**

- A pharmacy staff member, after mixing Suprax® for another patient realized that he had mixed it incorrectly for an earlier patient. Instead of reconstituting it with 33 mL of water in two portions, he added 2 portions of 33 mL. The parent of the incorrectly prepared Suprax® prescription was contacted and returned the medication to the pharmacy.

- A mother dropped off two prescriptions of azithromycin for both her children (i.e. one prescription for each child). One bottle was reconstituted while the other remained as powdered form. When the mother went home, she inquired the pharmacy about the powdered form, in which the pharmacy exchanged it for a reconstituted bottle and apologized.

- A child was prescribed amoxicillin-clavulanate for 14 days. A bottle of Ratio-Aclavulanate 250F was mixed for the entire course of therapy but it is only stable for 10 days.

- A child was prescribed amoxicillin oral suspension 125 mg TID. When the pharmacist checked the reference dose according to the weight of the child, the dose should be 150 mg TID to 300 mg TID. The prescriber was notified and changed the original prescription to an appropriate dose.

- An 11.4 kg two-year-old child was prescribed Flovent® HFA 250 mcg BID. The pharmacist believed the highest recommended dose for the child is 350 mcg/day and verified this dose with two sources (Lexi-Comp and e-Therapeutics +). The prescriber was contacted about the possibility of an overdose, thereby decreasing it to 100mcg BID.