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ISMP
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Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

Assessing medication safety in settings not designated solely for pediatric patients

Problem: Infants and children can arrive at any emergency department (ED) or healthcare facility seeking medical treatment, but some organizations (e.g., community hospitals, critical access hospitals) might not be properly equipped for the array of pediatric conditions that present. In an article published about Stanford Hospital's new ED, the pediatric emergency medicine director, Bernard Dannenberg stated, "All the large academic medical centers in the United States have free-standing pediatric emergency departments, because children are a special patient population that you shouldn't be mixing with adults. Adults have different illnesses…children need to be in an environment that not only looks physically different, but they have to be managed by a team that just deals with children" (www.ismp.org/ext/1143). Providing this specialized care outside of children's hospitals and large academic medical centers can be challenging.

As of 2019, there were 5,591 EDs but only 250 children's hospitals in the United States.[1,2] The 2015 *Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project* found that pediatric visits represented approximately 20% of all ED visits, with infants and children less than 5 years old accounting for more than 40% of all pediatric ED visits.[3] In addition, a national survey that was conducted to assess the availability of pediatric services in US EDs reported that in EDs that see both adults and children, only 10% had a separate pediatric ED. The 2013 study noted that only 17% of EDs had a designated physician or nurse coordinator for pediatric emergency care.[4]

Limited experience

Healthcare practitioners may not have the opportunity to take care of pediatric patients during their onboarding, yet could be "signed-off" to treat all patients without completing a pediatric-specific competency assessment. In addition, community hospitals experience seasonal fluctuations in the number of pediatric admissions or visits, with the volume declining during warmer months and peaking in the winter. In some organizations with variations in pediatric encounters, practitioners end up having mixed assignments (pediatric and adult patients) throughout the year, and the organization may struggle to maintain a core pediatric staff who are readily available in key locations (e.g., ED, inpatient, procedural areas).

Inadequately prepared

The 2022 ISMP article, *Survey results from pharmacists provide support to enhance the organizational response to codes* (www.ismp.org/node/41947), revealed that many of the respondents felt ill-prepared to participate in pediatric codes. Nearly one-third (32%) were concerned that they might dispense and/or administer an incorrect medication or dose. Of the pharmacists who work in hospitals that serve adult and pediatric patients, less than half (44%) had received training about pediatric doses and less than one-third (31%) were required to be certified in pediatric advanced life support (PALS).

A small community hospital reported to us that it transfers all pediatric patients who arrive in their ED to a nearby children's hospital. But, to stabilize the pediatric patient for transfer, they often need to consult with the children's hospital, especially to administer certain medications

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HIGH-ALERT

FDA authorizes CISplatin importation from China. Due to the critical shortage of **CIS**platin, the US Food and Drug Administration (FDA) has authorized Qilu Pharmaceutical, in conjunction with its distributor Apotex, to temporarily import **CIS**platin manufactured and marketed in China and not FDA-approved in the United States. On June 2, 2023, FDA posted a letter from Qilu dated May 24, 2023, with important prescribing information for healthcare professionals (www.ismp.org/ext/1190). As with other imported products, this medication has unique packaging and labeling characteristics that may contribute to confusion and errors.

Qilu's **CIS**platin is available as a 50 mg/50 mL injection in a preservative-free, multidose amber vial, similar to the FDA-approved product. However, it comes as a slightly viscous colorless to yellowish clear liquid, as opposed to a clear, colorless solution. Under "drug-drug interactions," the letter mentions that bisulfite, metabisulfite, sodium bicarbonate, and fluorouracil can affect stability. (We received clarification from Qilu that this is not related to an in vivo drug-drug interaction in a patient. The stability interaction noted is in relation to compatibility in solution.) The imported product has similar storage recommendations (i.e., store at 15-25ºC, protect from light, avoid refrigeration) to the US product. A sticker, applied to the carton and vial (**Figure 1**), contains the following information: translated name of **CIS**platin, the strength, the concentration, the US National Drug Code (NDC), a linear barcode that is readable by

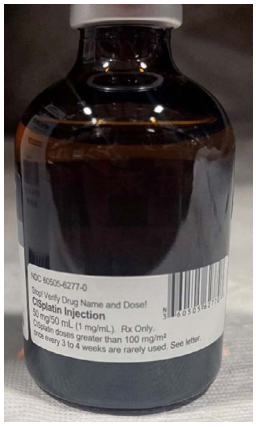

Figure 1. Sticker added to the vial on the imported **CIS**platin made by Qilu.

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such as vasopressors. The community hospital does not have access to syringe pumps and creates custom infusion concentrations that can be administered using their large volume parenteral (LVP) pumps. Practitioners worry they will make an error when calculating weight-based doses or might prepare an incorrect volume or concentration of a pediatric medication or solution. The simple misplacement of a decimal point can result in a 10-fold medication error, which could have devastating consequences for pediatric patients.

Understanding limitations

Given that pediatric patients are a unique and clinically diverse population, community hospitals, critical access hospitals, and other traditional adult-based settings should be equipped to manage these vulnerable patients. If your organization lacks pediatric-sized equipment, policies and procedures to ensure timely transfer of care, lacks standard pediatric concentrations/order sets and has limited awareness of pediatric guidelines/dosing references, or inadequately prepared staff,[5,6] these can be barriers to providing optimal emergency care for children.

Safe Practice Recommendations: Since pediatric patients often need to be treated in healthcare settings that are not designated solely for children, organizations should complete a gap analysis around current pediatric care and consider the following recommendations to safeguard against harm in this patient population.

Appoint pediatric coordinators. The American Academy of Pediatrics policy statement, *Pediatric Readiness in the Emergency Department* (www.ismp.org/ext/1141), recommends that a physician coordinator should be identified by the ED medical director, or a registered nurse coordinator identified by the ED nurse director, should serve as a designated pediatric emergency care coordinator (PECC). EDs should also proactively involve a pharmacist with pediatric competency to oversee critical safeguards built into systems and processes (e.g., pediatric dosing guidelines and order sets). These individuals should possess pediatric expertise and be responsible for addressing pediatric standards, implementing pediatric policies and procedures, preparing staff, and ensuring the availability of appropriate pediatric medications, supplies, and equipment (e.g., syringe pumps, oral liquid medication measuring devices).

Designate space. Determine if your ED, inpatient, and procedural areas can be structured in a way that separates pediatric patients from adult patients and can be staffed with competent practitioners depending on the pediatric census. Differentiating the environment where pediatric patients are treated can help orient practitioners to readjust their mindset for the population they are treating.

Create pediatric protocols and guidance. Collaborate with pediatric institutions and emergency medical services (EMS) agencies to adopt pediatric pathways, guidelines, algorithms, and checklists (e.g., confirm weight-based doses). Develop transfer protocols and partnerships with academic inpatient pediatric institutions for patients requiring specialized care.

Leverage the EHR. Evaluate how pediatric patients are differentiated from adults in the electronic health record (EHR). Some organizations have implemented a banner or alert to notify practitioners they are viewing a pediatric patient's medical record. If your hospital primarily treats adult patients, and only sees a few pediatric emergencies per year, it is critical to prebuild common pediatric medications and critical infusions (e.g., **EPINEPH**rine, **DOP**amine) in your computer systems. Implement clinical decision support (e.g., order sets, dose range checking) with pediatric-specific, weight-based (e.g., mg/kg) doses in your EHR, and link orders to the patient's age or weight. Check if your EHR can incorporate age-based percentile support which could help raise suspicion that a weight or height may be incorrect.

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US systems, and these warning statements, "Stop! Verify Drug Name and Dose!" and "**CIS**platin doses greater than 100 mg/m^2 once every 3 to 4 weeks are rarely used."

The imported product's carton and vial label state the lot number, production date, and expiration

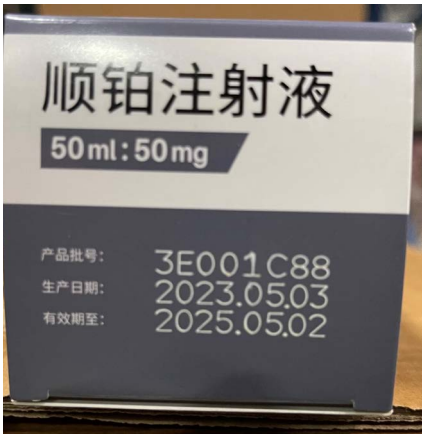

Figure 2. The carton label on the imported **CIS**platin made by Qilu lists the lot number (top), production date (middle), and expiration date (bottom) in Chinese.

date in Chinese characters (**Figure 2**), but this information has not been added to the sticker. Since there is both a production and expiration date, pharmacy staff may confuse the two dates. The manufacturer's letter provides a table with the lot number and expiration date, but it is unclear how organizations will be able to translate the information on the carton and vial unless this information is also added to the sticker or translated in the table. For now, organizations should consider creating a label that includes the translated lot number and expiration date and apply it to the carton and vial. Ensure master formulation records are updated to include product-specific instructions for compounding.

Because the product is slightly viscous, there is a statement in the manufacturer's letter about making the dosage accurate by injecting sodium chloride into the vial and shaking it to remove any drug that is adhering to the inner wall after initial drug removal. Unfortunately, questions remain about this step, which, presumably, would take place if one is unable to remove at least 50 mL from the vial. It may be difficult for practitioners to operationalize the washing process described to withdraw the expected amount of medication. This may also impact volume in the infusion bag,

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Standardize pediatric concentrations. Provide pediatric medication infusions in standard concentrations. When choosing standard concentrations, use the American Society of Health-System Pharmacists (ASHP) *Standardize 4 Safety* (www.ismp.org/ext/923) standard concentrations for pediatric patients as a reference. When possible, use commercially available, ready-to-administer syringes and premixed infusions.

Implement a pediatric code cart. Maintain a separate pediatric code cart, distinct from the adult code cart, that is clearly labeled for pediatric use and has pediatric equipment, supplies, medications, and formulations. Provide these in all locations where pediatric patients may be cared for, and ensure staff know where they are. Store medications in a standard configuration, with labels facing up, separating look-alike products. In the code cart, provide preprinted labels that specify the medication name, strength, and volume to assist in labeling practitioner-prepared medications and infusions in a standard concentration. Routinely review medications ordered during pediatric codes to ensure the drugs and doses used are evidence-based and readily accessible in the code cart.

Provide pediatric drug resources. Provide metric scales (e.g., infant, stretcher) in all areas where patients are admitted or encountered. Ensure that all pediatric code carts include emergency medication references specific to pediatric weight ranges based on the organization's standard concentration(s). Consider using a well-vetted, commercially available software system or phone application for drug information such as dosing, preparation instructions, and monitoring; alternatively, develop organization-specific weight-based emergency medication tables that are immediately available on all pediatric code carts (www.ismp.org/node/41947). Stock the most recent version of the Broselow Pediatric Emergency Tape on code carts and use it as a tool for determining the correct medication dose, based on the child's length, when the patient's weight is unknown, and they require emergency stabilization.

Educate staff. Healthcare educators should develop pediatric competency assessments for key staff (e.g., prescribers, nurses, pharmacists, pharmacy technicians) to complete during orientation and at least annually thereafter. Consider requiring current PALS certification for practitioners working in areas that see pediatric patients. Ensure staff are aware of and have easy access to pediatric protocols and guidance.

Use simulation. Conduct regularly scheduled interdisciplinary code simulations focusing on treating pediatric patients (e.g., entering pediatric weight-based orders in the EHR, calculating doses, compounding pediatric infusions, programming a pediatric infusion on a smart pump, responding to a pediatric code). Conduct post-simulation debriefings with participants so they can ask questions, share concerns, and review what went well and what could be improved to better approach pediatric-specific situations. For additional information, see our May 4, 2023 feature article, *The role of simulation when onboarding healthcare professionals—Part II* (www.ismp.org/node/75988).

Educate patients and caregivers. Parents serve as important advocates for their children and can help prevent errors, but in some cases may unknowingly contribute to errors as well. Be sure to review our June 16, 2011 feature article, *Parents can detect, contribute to, or be affected by critical events during a child's hospitalization* (www.ismp.org/ext/1177). Encourage parents to report any concerns or worries regarding their child's care and tell them to continue asking questions or voice concerns until they receive an answer that they are comfortable with and fully understand. At the same time, parents need to know what NOT to do. Educating parents and orienting them to the care setting can help avoid common issues like touching or even accidentally disconnecting tubes or drains.

Report errors. Encourage staff to share hazardous conditions, close calls, and actual errors that have occurred when treating pediatric patients both internally and externally. Create action plans and share the steps that the organization has taken to prevent incidents from happening again. If

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product compatibility with closed system transfer devices, or sterile compounding technologies (e.g., robotics, gravimetrics). ISMP is in communication with FDA and the manufacturer to better understand the amount of overfill in the vial and the need for this process. We will continue to provide updates.

The continuing crisis with drug shortages and supply chain disruptions has resulted in ongoing patient safety and cost concerns. FDA importation of drugs during dire shortages can be very helpful and is viewed as a much needed back-up plan without which we would not be able to treat many critically ill patients. However, FDA importation of drugs is not without its challenges. Imported products will continue to present certain risks, including, for example, issues with product packaging and labeling. It is imperative that institutions assess the risks of imported drugs and put in place mitigation strategies to proactively prevent errors and report any that occur.

Mix-ups between look-alike timolol eye drop formulations. Timolol maleate ophthalmic 0.5% solution is a beta-adrenergic blocker indicated for the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma. Organizations have reported mix-ups between generic once-daily and twice-daily formulations made by Bausch + Lomb due to the same generic name and similar-looking cartons (**Figure 1**) and dropper bottles. However, these products are not equivalent. While the product with the National Drug

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Figure 1. Generic formulations of 0.5% twice-daily timolol (left) and once-daily timolol (right) have similar-looking cartons.

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having to care for pediatric patients is uncommon, consider conducting retrospective case reviews to discuss what went well and what could be improved upon.

Measure performance improvement. When determining organization-wide quality improvement measures, remember to include pediatric-specific indicators (e.g., pediatric order set/drug library compliance rate, percentage of ED staff with PALS certification).

Seek expertise. Reach out to colleagues who work in children's hospitals to discuss pediatric medication safety challenges and how to best approach them. Establish routine check-ins with these colleagues to stay up to date on trends in pediatric medicine and continually assess pediatric readiness. Also, refer to resources on the Pediatric Pharmacy Association website (www.ppag.org), and pediatric topics posted on the Medication Safety Officers Society website (www.medsafetyofficer.org).

Consult resources. Review the following resources and use the additional tools/assessments provided.

- *Guidelines for Care of Children in the Emergency Department* (www.ismp.org/ext/1155)
- *Pediatric Readiness in the Emergency Department* (www.ismp.org/ext/1141)
- *National Pediatric Readiness Project (NPRP)* (www.ismp.org/ext/1157), which provides a readiness checklist and toolkit for download. This project developed a weighted pediatric readiness score (WPRS) based on a web-based assessment of ED readiness for children as measured by adherence to the above guidelines. For example, the study reported only two-thirds (67%) of respondents weighed children in kilograms only. Since pediatric doses are based on the patient's weight (e.g., mg/kg), this is a crucial part of the medication-use process.
- The ISMP ***Targeted Medication Safety Best Practices for Hospitals***, *Best Practice* #3, which calls for organizations to measure and document patient weights in metric units only (www.ismp.org/node/160). Significant medication errors have occurred when the patient's weight was communicated and/or documented in nonmetric units of measure (pounds and ounces) and was confused with kilograms or grams.
- *Pediatric Readiness Recognition Program*, which designates and verifies a hospital's ED capacity to provide care to children, and includes medical recognition programs (www.ismp.org/ext/1156) developed by some states. Of the 17 states that took part in a 2021 NPRP assessment, they found that EDs that participated in an ED readiness recognition program scored 24 points higher (on a scale of 0 to 100) on their WPRS than EDs that did not participate in the program (www.ismp.org/ext/1142).

Treating adults in pediatric settings. While this article focused on pediatric patients in healthcare settings not designated solely for children, some of the challenges and recommendations are applicable when treating adults in pediatric settings. Adults can also seek medical treatment at any ED or healthcare facility, including children's hospitals. In fact, during the coronavirus disease 2019 (COVID-19) pandemic, to meet the needs with the surge of adult patients, pediatric intensive care units were repurposed for adult critical care. However, pediatric-trained practitioners are not always prepared to care for adult patients. One challenge is that pediatric providers are so used to weight-based dosing that they may not take maximum doses into consideration when treating adults, which could lead to an overdose of medication especially in obese patients. In pediatric hospitals that treat adults, processes and systems (e.g., EHR clinical decision support, smart pumps) should be evaluated to support adult medication treatment and doses. For practitioners working in pediatric settings that occasionally see adult patients, require completion of competency assessments for common adult emergencies and disease states (e.g., heart disease, stroke) during orientation and annually. Also, consider requiring current basic life support (BLS) and advanced cardiovascular life support (ACLS) certification.

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Code (NDC) number 68682-0045-50 is indicated for once-daily dosing, the other product with the NDC number 68682-0813-05 is indicated for twice-daily dosing, although it may be decreased to once-daily if intraocular pressure is well-controlled. While the once-daily formulation outer carton states "Once Daily," this information is not displayed on the dropper bottle label itself (**Figure 2**).

Figure 2. The timolol dropper bottle (NDC 68682-0045-50) does not mention that it is for once-daily dosing.

The organization that identified this problem shared the concern with others in their health system and found that multiple hospitals had unknowingly purchased the once-daily formulation in error or purchased it when there was a shortage of the twice-daily formulation. The once-daily product was then erroneously linked in electronic health record (EHR) systems as equivalent to the twice-daily formulation and dispensed to both inpatients and outpatients. The manufacturer told us potassium sorbate was added to the once-daily formulation to enhance the ocular bioavailability. The concern is that if the once-daily formulation is used twice a day, this could lead to increased systemic absorption, with the potential risk of adverse cardiovascular events in vulnerable patients (although none have been reported to us so far). Also, if the twice-daily formulation is only used once a day, it may result in ineffective treatment of the patient's condition.

We have been in contact with the US Food and Drug Administration (FDA) and the manufacturer to recommend differentiation of the generic names, cartons, and dropper bottles. If your organization purchases timolol ophthalmic solution, review your purchase history, and check all storage locations (e.g., pharmacy, overstock area, automated dispensing cabinets [ADCs]) to determine which formulation and corresponding NDC is

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Special Announcements

FREE ASHP webinar

Pharmacists and pharmacy technicians—the American Society of Health-System Pharmacists (ASHP) is offering a **FREE** one-hour program on **June 21, 2023**, *Accelerating the Uptake of Safety Initiatives and Guidelines: Role of Implementation Science*. This webinar is the third in a series of three and will identify techniques to aid with improved uptake of the *Standardize 4 Safety* initiative and the ISMP ***Guidelines for Safe Medication Use in Perioperative and Procedural Settings***. Continuing education (CE) will be offered. Visit: www.ismp.org/node/79618.

Foundations in Medication Safety

ISMP's new online, interactive course offers healthcare organizations a standardized, cost-effective way to ensure staff involved in the medication-use process have the basic knowledge they need. For details, visit: www.ismp.org/node/74900.

Nominations open for CHEERS Awards

Each year, ISMP honors various healthcare disciplines that have demonstrated an exemplary commitment to medication safety through innovative projects with an ISMP **CHEERS Award**. Nominations for this year's **CHEERS Awards** are now open and will be accepted through **August 6, 2023**. For more information, visit: www.ismp.org/node/123.

Best Practices survey reminder

We are conducting a short survey to get a sense of the current level of implementation of the 2022-2023 ***Targeted Medication Safety Best Practices for Hospitals***. We would appreciate your participation in this survey. Please complete this survey online by **June 30, 2023**, by visiting: www.ismp.org/ext/1164. The findings will be described when introducing the 2024-2025 ***Targeted Medication Safety Best Practices for Hospitals*** in 2024.

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currently available. Verify that systems (e.g., EHRs, ADCs, pharmacy carousels) are linked to the appropriate formulation. Review order sentences or pre-populated dose frequency appropriateness (e.g., once daily, twice daily) and ensure the correct formulation is linked. Run a report to review past inpatient orders and outpatient prescriptions to identify potential errors, and determine if any patients need to be contacted. Evaluate how the once-daily product appears in your wholesaler's system. If you do not use that formulation, notify your pharmacy purchaser and consider placing a restriction so that it cannot be ordered. If the description is not clear on your vendor's software, ask them to change it. While it will not prevent ordering errors, ensure barcode scanning is used prior to dispensing and administration to identify any misfills.

Since the generic name of both the once-daily and twice-daily formulations is the same, organizations should only carry one of the formulations. During a drug shortage, when another formulation is brought in, do not allow both formulations to be stocked at the same time (e.g., wait until one formulation's stock is almost exhausted, remove residual stock from circulation and restock with the new formulation). Synchronize the change in the EHR, ADC, and other systems with the change of formulation. Wholesalers and distributors should take steps to differentiate the two formulations in the ordering system to prevent mix-ups (e.g., include once-daily [timolol maleate 0.5% (once-daily)] or twice-daily [timolol maleate 0.5% (twice-daily)] in the generic name of the drug).

During a drug shortage, organizations may purchase products that need to be added quickly to the medication-use system. Even so, plans should be in place to proactively consider product characteristics that might cause confusion and lead to errors, and strategies should be developed to prevent those errors. A sample format for a "mini failure mode and effects analysis (FMEA)" was included in our April 6, 2023 feature article, *Safety considerations during expedited product approval* (www.ismp.org/node/71465) that may help uncover potential safety gaps prior to introducing new products within your organization.