

# Acute Care ISMPMedication Safety Alert Educating the Healthcare Community About Safe Medication Practices

# Safeguard pediatric patients—Act upon the 2025 KIDs List



**PROBLEM:** Pediatric patients are vulnerable to higher rates of adverse drug events for a variety of reasons, including frequent off-label drug usage, individualized dose calculations, and age-related differences in drug disposition and effect. While children's hospitals often have pediatric-specific safeguards built throughout the medication-use process, most pediatric patients are treated in general hospitals, emergency departments (EDs), and other healthcare facilities. Practitioners who are completing the medication reconciliation must determine

if the drugs the pediatric patient has been taking at home require modifications in the care plan. Practitioners who are not specialized in pediatrics may be unfamiliar with a medication's use, maximum dose, contraindications, side effects, recommended monitoring parameters, or other safety concerns that could cause harm.

To create a standard of care for the safe use of medications in pediatric patients, the Pediatric Pharmacy Association (PPA) commissioned a group of pediatric pharmacists to evaluate the literature and compile a list of potentially inappropriate drugs for pediatric patients. The PPA KIDs List of Key Potentially Inappropriate Drugs in Pediatrics was published in the *Journal of Pediatric Pharmacology and Therapeutics* in 2020 and became the first list of drugs that should be "avoided" or "used with caution" in all or a subset of pediatric patients. It is akin to the well-known Beers Criteria for older adults, but it's for pediatric patients. ISMP served as a reviewer for the project. The KIDs List Collaborators were recognized with an ISMP Cheers award in 2021 for their passion to improve the safe use of medications in pediatric patients and inspire future medication safety research in children.

In 2025, twelve pediatric pharmacists reviewed and updated the KIDs List. For each potentially inappropriate medication, they evaluated primary, secondary, and tertiary literature; US Food and Drug Administration (FDA) pediatric safety communications; the UpToDate Lexidrug database; and product information. ISMP served as a reviewer for the updated list. After critical analysis and reorganization, the second edition of the KIDs List contains 39 medications and/or drug classes (refer to Table 1 in the journal article) and 10 excipients (refer to Table 2 in the journal article). There were several major updates, including those described below.<sup>2</sup>

#### **Examples of Updates from 2020**

- The first edition in 2020 provided recommendations based on age categories (e.g., newborn, infant, preschool child, child, adolescent). However, in the second edition, as no specific breakpoints between these groups consistently correlated with the available evidence, the panel opted to report specific ages (e.g., less than one year old) to avoid or use caution with the drug rather than age categories.
- Addition of the following drugs:
  - Angiotensin receptor blockers (caution in less than 1 month of age due to risk of renal tubular dysgenesis)
  - □ Mirabegron (caution in less than 3 years of age due to risk of increased blood pressure)
  - Molnupiravir (caution in 18 years of age and younger due to risk of bone and cartilage toxicity)

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Barcode scanning is crucial to prevent mix-ups with similar-looking heparin bags. A nurse went to remove a bag of heparin 1,000 units/500 mL from the automated dispensing cabinet (ADC) for a patient in the operating room (OR). She discovered bags of heparin 25,000 units/250 mL had been placed in the heparin 1,000 units/500 mL bin and notified the pharmacy. Both products by Hospira are supplied in clear bags with similar red fonts on the labels (Figure 1). This hospital had not yet implemented barcode medication administration (BCMA) scanning prior to administration in the OR.



**Figure 1.** Bags of heparin 25,000 units/250 mL (left) and heparin 1,000 units/500 mL (right) look similar.

Upon investigation, the hospital found that although pharmacy technicians were expected to scan medication barcodes and cabinet barcodes when restocking the ADC, scanning is not required by the system and could be bypassed. In addition, both heparin bags were stored near each other in the pharmacy. The pharmacy purchased Hospira's 1,000 units/500 mL heparin bags because their usual supplier experienced a supply chain interruption. After this event, due to the concern for mix-ups with Hospira's 25,000 units/250 mL bags, the pharmacy blocked staff from purchasing Hospira's 1,000 units/500 mL heparin in the ordering system.

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- □ Montelukast (caution in 18 years of age and younger due to risk of sleep disturbances)
- □ Ribavirin oral inhalation (caution in less than 2 years of age due to risk of sudden respiratory deterioration)
- Codeine and traMADol recommendations updated to reflect the latest FDA guidance (risk of respiratory failure and death)
- Revision of guanylate cyclase-c agonists recommendation based on updates to the package insert, which shows a risk of death from dehydration in patients less than 2 years of age (linaclotide) and 18 years and younger (plecanatide)
- **DAPTO**mycin was removed due to emerging case series describing safety
- Ivermectin (oral) was removed due to emerging case reports and series describing safe use in specific disease states in patients less than 15 kg
- Expansion of the tetracycline class with stratification of quality based on evidence regarding tooth discoloration
- Significant revision of **DOP**amine antagonists based on emerging evidence, along with reorganization as first-generation antipsychotics, second-generation antipsychotics, and other **DOP**amine antagonists
- Midazolam quality of evidence changed from high to low after reappraisal of cited evidence
- Revision of ethanol/ethyl alcohol, polysorbate 80, and propylene glycol recommendations due to emerging evidence/guidance

The KIDs List is a remarkable step forward for pediatric medication safety. To reduce harm, organizations and practitioners must understand how to operationalize this guidance in the clinical setting.

**SAFE PRACTICE RECOMMENDATIONS:** We encourage organizations that treat pediatric patients to review the updated KIDs List and implement safeguards into systems and processes by considering the following recommendations.

**Complete a gap analysis.** Review the updated KIDs List and conduct a gap analysis of drugs used within your organization. Evaluate whether the drug (or a drug with the excipient) is available on the organization's formulary and if any restrictions are needed based on the risk and recommendations provided. Recognize that pediatric patients may present to a variety of settings with a home medication list that includes a KIDs List drug that is not on the organization's formulary. If it is a nonformulary product with high usage, consider whether the drug is appropriate for formulary addition, so that system safeguards can be optimized.

**Safeguard medication reconciliation.** If the practitioner completing a pediatric patient's medication history determines that the child is taking a drug on the KIDs List and it has an applicable warning (e.g., avoid use in their particular age range), they must escalate this to the prescriber responsible for completing medication reconciliation. The prescriber responsible for completing medication reconciliation should then evaluate why the patient is taking the drug. Consider whether an alternative drug or formulation is appropriate and/or if additional monitoring should be done.

**Evaluate order sentences.** Review if there are order sentences and/or order sets available in the electronic health record (EHR) for the medications on the KIDs List. Consider if changes are needed, such as indication-based sentences with dosing guidance based on the child's age/weight, or additional monitoring parameters. Include discharge orders, order sets, and prescriptions in the review to assess if improvements are necessary.

**Use dose range checking.** Test your EHR settings to determine if it will generate a dose range checking (DRC) alert based on the KIDs List recommendations. For example, if a prescriber orders

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The hospital also reported that Hospira's magnesium sulfate 20 g/500 mL bags (**Figure 2**) look similar to the heparin bags involved in the close call. A similar concern was shared in our February 27, 2025 article, *Magnesium almost administered instead of heparin*, after bags of Hospira's magnesium sulfate 20 g/500 mL were restocked in the heparin 25.000 units/250 mL ADC bin.



**Figure 2.** Hospira's 20 g/500 mL magnesium sulfate is supplied in clear bags with red font on the labels.

We reached out to the manufacturer to recommend differentiating these heparin infusion bags by making the labels less similar. Use barcode scanning technology in the pharmacy to confirm that medications chosen for distribution to the ADC match the medications listed on the ADC fill report. Those loading the ADC should use barcode scanning to confirm the accurate placement of medications and confirm that each product is in the correct drawer, pocket, or bin. The ISMP Targeted Medication Safety Best Practices for Hospitals, Best Practice 18, calls for expanding the use of BCMA technology to short- and limited-stay locations such as perioperative areas.

When pharmacy receives a new product, conduct a review to identify potential risks with the product's design, including lookalike labeling and packaging. If risks are identified, consider purchasing the product (or one product of a problematic pair) from a different manufacturer. Store look-alike

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loperamide for a child less than 3 years old for acute infectious diarrhea, does the EHR warn the prescriber and/or pharmacist that this could result in ileus or lethargy? Ensure alerts are meaningful and easy to understand so practitioners can act upon them.

**Enhance clinical decision support.** Consider whether additional changes to clinical decision support (CDS) should be implemented (e.g., hard stop, contraindication warning). For example, if a prescriber orders a sodium phosphate solution enema rectally for a child less than 2 years old, what type of alert is generated? Is the warning a soft stop that can be easily overridden, or is it a hard stop that indicates this may result in electrolyte abnormalities, acute kidney injury, arrhythmia, and death?

**Review ADCs.** Evaluate if any medications on the KIDs List are stored in automated dispensing cabinets (ADCs) and determine if any formulations should be removed. Determine whether practitioners have access to KIDs List drugs via override, and if it should be removed.

**Optimize drug libraries.** Based on the EHR build (e.g., order sets, DRC, hard stops), align the smart pump drug library for applicable drugs on the KIDs List. Set soft dosing limits in the drug library that reflect the maximum expected dose and rate prescribed as well as a buffer for pediatric patients who may require more or less than the typical default doses and rates. Set hard dosing limits as a forcing function to prevent catastrophic errors, while considering patients who may clinically require atypical doses, to prevent end users from needing to program the infusion without engaging the dose error reduction system (DERS).

**Determine a risk-mitigation plan.** Use the information gathered from the gap analysis to create a comprehensive risk-mitigation plan. Understanding that there are quite a few medications and excipients on this comprehensive list, determine where the organization is most vulnerable, focusing on those drugs that present the highest risk to your patient population.

**Educate practitioners.** While practitioners may be more familiar with the Beers Criteria for older adults, they may be less familiar or even unaware that the KIDs List exists as a valuable safety resource. Educate practitioners about the KIDs List during orientation, annual competency assessments, huddles, staff meetings, and/or as a topic for grand rounds. Discuss how to safely use drugs on the KIDs List and what actions have been taken to protect pediatric patients from harm.

**Collaborate with outpatient practitioners.** Reach out to local outpatient pharmacies, compounding pharmacies, clinics, doctors' offices, urgent care locations, and EDs to spread awareness of the KIDs List. Share system changes that your organization has made to protect pediatric patients and encourage similar enhancements in their systems.

**Monitor.** Monitor patients for adverse drug events, including those involving drugs on the KIDs List, and evaluate if additional system changes are needed. Regularly review order sets, DRC settings, alerts generated through CDS and DERS, and corresponding actions taken. Frequent bypassing of dose limits or system warnings should prompt a review of their appropriateness.

**Collaborate with vendors.** Work with technology vendors to discuss the capability of the CDS for drugs and excipients on the KIDs List and provide feedback for upcoming enhancements.

**Report errors.** Report errors and close calls with medications, including those on the KIDs List, internally and to ISMP.

#### References

- 1) Meyers RS, Thackray J, Matson KL, et al. Key potentially inappropriate drugs in pediatrics: the KIDs List. *J Pediatr Pharmacol Ther.* 2020;25(3):175-91.
- 2) McPherson C, Meyers RS, Thackray J, et al. <u>Pediatric Pharmacy Association 2025 KIDs List of key potentially inappropriate drugs in pediatrics</u>. *J Pediatr Pharmacol Ther*. 2025;30(4):422-39.

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products separately and consider the use of signage or other warnings in storage locations and on infusion bags. Educate nurses to carefully review individual product labels after removing the medication from the ADC, when spiking an IV bag, prior to administration (before scanning), and when discarding or returning it to storage.

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#### Norepinephrine mistaken for similarlooking vials of multivitamin injection.

A pharmacy technician reported that they removed a vial of what they thought was **INFUVITE ADULT** (multiple vitamins injection) from a bin labeled as such in the refrigerator. The Infuvite adult product is supplied as two vials, labeled Vial 1 (5 mL) and Vial 2 (5 mL), which must be added to at least 500 to 1,000 mL of dextrose or saline solution prior to use. When the technician scanned what she thought was Vial 2 in the intravenous workflow management system (IVWMS), she was alerted that it was an incorrect product. Upon further inspection of the label, she identified it was actually a vial of 4 mg/4 mL norepinephrine injection—a good catch! Both products come as amber vials (Novaplus), are similar in size, and the labels look nearly identical (Figure 1). Norepinephrine is stored at room temperature, but a pharmacy technician had placed the similar-looking vial in the incorrect refrigerated bin in error.



**Figure 1.** Similar-looking vials of 4 mg/4 mL norepinephrine injection (left) and Infuvite Adult 5 mL injection (Vial 2) (right).

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# Another potentially contaminated calcium gluconate bag—now by Amneal

A hospital reported sterility concerns with a calcium gluconate 2,000 mg/100 mL injection bag manufactured by Amneal (NDC 80830-2363-1, lot number AH250052, expiration date 3/31/2027). A nurse went to remove a patient's dose from the automated dispensing cabinet (ADC) and, upon removing the overwrap, observed a black/brown substance resembling mold inside the sealed, unopened inner bag (Figure 1). The nurse never spiked or administered the product. It was immediately sequestered and reported to the pharmacy. The pharmacy removed the entire supply of 2,000 mg/100 mL calcium gluconate bags by Amneal from patient care areas.

In our August 14, 2025 article, Contaminated WG Critical Care calcium gluconate 2,000 mg/ 100 mL bag, we shared a similar concern with 2,000 mg/100 mL calcium gluconate bags made by WG Critical Care. In this case, WG Critical Care attributed the contamination to a microchannel defect at the seal between the tubing and the bag, compromising the product's sterility. According to instructions on the WG Critical Care bag label, practitioners should check for leaks by squeezing the container. WG Critical Care confirmed that the bag was contaminated with mold, and this was an isolated event.

We have reported this issue to the US Food and Drug Administration (FDA) and Amneal. At this point, we do not know if this is the same issue as the WG Critical Care bags. These incidents underscore how critical it is for end users to stay vigilant in reviewing



Figure 1. A black/brown substance was found inside a sealed, unopened bag of calcium gluconate 2,000 mg/ 100 mL manufactured by Amneal.

product integrity and to escalate potential safety issues. If your organization purchases calcium gluconate 2,000 mg/100 mL from Amneal or WG Critical Care, review your inventory and ensure end users are aware of this concern. If potentially impacted product is found, sequester it and report it to the manufacturer, FDA, and ISMP. Remind staff to visually inspect all medication injectable solutions for particulate matter, discoloration, and potential contaminants prior to use.



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We contacted the manufacturer to recommend differentiating these products by making the labels look less similar, and they informed us that they will investigate this concern. If your organization purchases these products, notify staff of this risk, and take steps to minimize mix-ups. Use barcode scanning when stocking and during preparation using an IVWMS. Store them so their labels are always visible. If possible, consider purchasing one of these medications from a different manufacturer.

# Special Announcements

#### Apply for a JUST CULTURE scholarship

Applications will be closing **September 30**, 2025 for the Judy Smetzer Just Culture **Champion Scholarships**. If you currently work in the healthcare field, have at least 5 years of full-time postgraduate experience, and commitment from executive leadership, apply now! For details and to submit an application, click here.

#### **Survey on IV push medications**

If you prepare, dispense, administer, or analyze errors related to IV push medications, we want to hear from you! Med Safety Board, an ISMP company, is conducting a short survey to reassess current practices and safety risks. Please take 5-10 minutes to complete the survey by September 30, **2025.** Thank you for your participation!

#### FREE ISMP webinar with CE

Join us on **October 9, 2025** for our webinar, Applying Best Practices to Prevent Wrong Drug Errors Associated with **Generic Names**. Pharmacy and nursing continuing education (CE) will be offered. This activity is supported by an educational grant from Azurity Pharmaceuticals. For more information and to register, click here.

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