“Children are not little adults.”

If I had a nickel for every time I uttered those words to students, residents, and others unfamiliar with medication use in infants and children ... Pediatric patients are more vulnerable than adults and are at increased risk for adverse drug reactions. This is a dynamic patient population, displaying changing pharmacokinetic and pharmacodynamic parameters at various ages and stages of maturation and development. There is a relative lack of published information related to use of medications in infants and children, as well as FDA-approved labeling for this patient population. Most dosing is weight-based, obviously requiring individualized dosing calculations, and then requiring precise dosage measurement and delivery systems. In addition, there is also a lack of suitable dosage forms and appropriate concentrations for drug delivery to neonates, infants, and children.

Recent events involving neonatal deaths after administration of incorrect concentrations of heparin—10,000 units/mL instead of 10 units/mL—followed by other examples of the same scenario, which thankfully resulted in no apparent harm, should rock us to our very core. Preventing harm and death due to medication errors has been a topic of discussion for some time, but a true call to action was sounded when well-known actor Dennis Quaid and his wife spoke out on behalf of their twins, who were victims of this same preventable error in November 2007.

Pediatric Safety Resources
On April 11, 2008, The Joint Commission (TJC) issued a Sentinel Event Alert (SEA #39): Preventing pediatric medication errors, in which specific risk reduction strategies were presented. The expectation is that every health care organization that cares for infants and children will take action in response to this alert. In a collaborative effort, the Pediatric Pharmacy Advocacy Group (PPAG) and the Institute for Safe Medication Practices (ISMP) published Guidelines for preventing medication errors in pediatrics in 2001. This document presents specific recommendations that represent best practices in medication use in neonates, infants, and children. In July 2008, a summit on preventing patient harm and death from IV medications was held in Rockville, Maryland. Participants worked to identify safe IV medication practices across the medication-use continuum, potential barriers to implementing these safe practices, and specific actions to eliminate the barriers to safe practice. Short-term actions—those that could be accomplished within three years—and long-term actions, as well as primary stakeholder groups, were identified for subsequent action and follow-up. All patient populations were included in these discussions and actions, including stakeholders representing neonates, infants, and children. The proceedings from this summit have been published.

Every institution caring for neonates, infants, and/or children must perform an evaluation of systems and resources utilized in medication use processes, looking for opportunities to provide the safest possible environment for this vulnerable patient population. This is especially necessary in those institutions that care for both adults and pediatric patients. Staff must be educated and become competent in the age-related differences between pediatric and adult patients. Up-to-date and appropriate drug references must be readily available to all hospital staff caring for pediatric patients.

Available Drug Products and Concentrations
There should be a formulary process that is specific to pediatrics with a multidisciplinary approach to drug selection that encourages identification of potential risks prior to acceptance.
Ideally, organizations should limit the number of available concentrations for use in pediatric patients to minimize the risk of dosing errors due to wrong concentration selection. In institutions that care for pediatric and adult patients, care must be taken to clearly identify those concentrations intended for use in pediatric patients. Storage of designated pediatric concentrations must be separate and distinct from that of adult concentrations. If space constraints do not allow for a designated, pediatric medication storage area, creation of brightly colored cautionary signs or labels can be used to note the storage of those concentrations specific to pediatric use. Also, labeling adult concentrations can help staff avoid choosing the wrong concentration in dosage form preparation. In addition, highly concentrated solutions, such as electrolytes and heparin, should not be made available as floor stock in patient care units.

Concentrations of drugs for continuous infusions (i.e., “drips”) must also be available in limited concentrations. In 2003, included in TJC’s National Patient Safety Goals was the mandate to limit the number of different concentrations available for critical or high-risk medications. Further, TJC required that institutions eliminate calculation of infusions via rule-of-six. Because delivery of fluids over the course of the day requires weight-based calculations, so that harm due to fluid-overload is avoided, deciding which “standard concentrations” should be used is largely according to each institution’s preferences. Whenever possible, commercially manufactured, pre-mixed solutions should be used to eliminate preparation error and the potential for contamination. One of the short-term actions to come from the IV Safety Summit is to seek more timely processes for approval and marketing of new concentrations of existing medications so that national standards for neonatal and pediatric patients can be attained.
Prescribing

Protocols designating doses, concentrations, and monitoring parameters are good tools to help ensure safe drug delivery. Computerized physician order entry (CPOE) systems eliminate potential errors due to poor handwriting. In institutions not yet wired for CPOE, the use of pre-printed order sets can help assure appropriate dosing. Inclusion of the patient’s weight and allergy status in these order sets is vital, since dosing is generally weight-based.

Automated Dispensing Cabinets (ADCs)

The use of ADCs is common and provides more readily available medications in the patient care unit, while decreasing the staffing burdens associated with floor stock systems. Care must be taken, however, to ensure that medication safety is not compromised for the sake of convenience. An interface between the ADC and the pharmacy computer system is necessary. Once the medication order is reviewed by the pharmacist and entered into the pharmacy computer system, it is then available to be dispensed to the patient. TJC standard MM.05.01.01 specifically requires that a pharmacist review all medication orders prior to dispensing or removing of medication from floor stock or from an ADC. In emergent situations, an override can be used to obtain medication prior to pharmacist review and order entry; however, it is very important that this only occurs in truly emergent situations. Regular review of ADC reports, particularly override reports, is helpful to monitor whether medications are being removed emergently or as a matter of convenience and thus bypassing pharmacist review. Functions exist that require a response when medication is removed via override, such as, “is this medication needed for an ADE?” To limit overrides, collaboration between pharmacy and nursing staff is key. When override data is shared with nurses, discussion of reasons for using override can be surprising (e.g., missed order entry by pharmacy; verbal order for med received, but order was never committed to writing; medication routinely not interfacing appropriately; etc.). Improvement strategies for identified systems issues should be tackled in a collaborative fashion.

A pharmacist should check all medication replacements to the ADC. In many institutions, technicians refill the ADC after a pharmacist has checked the replacement stock. This does not prevent replacement of medication into the wrong drawer or cell within the drawer. This approach accounted for the heparin errors that occurred in Indiana, in which 10,000 units/mL heparin was inadvertently placed into the ADC bins reserved for 10 unit/mL heparin. Bar code technology can help minimize wrong-product placement both when restocking the ADC and when removing the dose for administration.

IV Medication Preparation

Except in emergent situations, all drug dosage and solution preparation should take place in the pharmacy, under conditions in compliance with USP<797>. Medications should be prepared in the most ready-to-use form prior to dispensing. Most often this means patient specific, unit-of-use packaging for pediatric patients.

IV Medication Administration

Accurate and safe IV drug and solution delivery requires the use of infusion devices, especially for pediatric patients. Use of intelligent infusion devices, or “smart pumps,” provides a mechanism for dose checking and infusion rates and/or volume limits through the creation of drug and solution libraries. Establishing dosing limits can help minimize dosing errors, potentially avoiding serious harm. For example, medications with a narrow therapeutic index, which are likely to cause serious harm if administered outside the usual dosing range, should be considered for hard limits, as they cannot be overridden.

When designing the drug library and its dosing limits, the relative risk of harm has to be weighed against the imposition of potential “nuisance alerts.” Given the wide range of ages and relative weights of pediatric patients, the best way to avoid large ranges of dosing is to divide the library into profiles that span a limited weight range (e.g., 0 to 3 kg; 3 to 10 kg; 10 to 20 kg; 20 to 40 kg; > 40 kg). Consider a medication that has an upper limit of 50 mg/kg per dose: the dose for the 4-kg infant.

Enforcing the use of the drug library is necessary. If the pump is capable of being programmed to bypass the drug/solution library, there is a risk that the dosing checks are not being used. It is critical that pump data is reviewed on a regular basis, as frequent limit overrides provide an indication that adjustment is necessary. If nurses routinely receive alerts for minor dosing issues, there is a real danger that they may get into the habit of overriding alerts without pausing to consider their value. Collating and analyzing override data on a regular basis is a time-consuming, but necessary and valuable activity.

A multidisciplinary approach to pediatric medication use often results in increased participation in “doing the right thing,” since the team has achieved agreement, or at least, consensus on safe medication use within the institution. Establishing an ongoing process to evaluate the medication use procedures throughout the institution is a very valuable tool to continuous improvement in pediatric patient safety.

Cynthia M. Dusik, BS Pharmacy, PharmD, is a clinical pharmacist specialist at the Toledo Children’s Hospital and a clinical assistant professor at the University of Toledo, College of Pharmacy in Toledo.
Ohio. She also serves as associate director of the PGY-1 Pharmacy Residency Program at the Toledo Hospital & Toledo Children’s Hospital, members of ProMedica Health System. Dr. Dusik obtained her bachelor of science in pharmacy and doctor of pharmacy degrees from the University of Illinois at Chicago. She completed an Advanced Specialty Residency in Pediatric Pharmacotherapy at the University of Illinois at Chicago. She is a member of the American Society of Health-System Pharmacists (ASHP) and the Pediatric Pharmacy Advocacy Group (PPAG). She is the immediate past-chair of PPAG and continues to serve on the board of directors as an ex-officio member. Dr. Dusik was a member of the Expert Panel for the ASHP IV Safety Summit in July 2008.

References

A Dozen Safety Maneuvers to Minimize IV Medication Risk for Pediatric Patients

- Ensure that all staff members are educated and competent to work on behalf of neonates, infants, children, and adolescents.
- Mandate that the patient’s weight and allergy status be included on all physician medication orders. Allow only metric units for weight and height (kg and cm) to avoid confusion and potential dosing errors.
- Provide medications in the most ready-to-use format, preferably in unit-of-use packaging.
- Use appropriate measuring devices to deliver pediatric doses.
- Have a formulary process in place that includes drug evaluation, selection, therapeutic use, potential risk, and any other issues to maximize safe medication use.
- Limit the number of concentration and dosage strengths available within the organization to minimize the risk of selecting the wrong concentration. Do not make concentrated electrolyte solutions available as floor stock in patient care areas.
- Standardize concentrations of medications that are delivered via continuous infusion. Eliminate the use of “rule-of-six” to calculate continuous infusions.
- Prior to dispensing and administration of medication, ensure that a pharmacist reviews all orders for appropriate indication, dosing regimen, potential allergy alerts, and potential drug and/or food interactions.
- Limit the availability of medications on override in ADCs to those that are needed in emergent situations. Discourage removal of medications prior to a pharmacist’s review. Regularly review override reports to identify trends.
- Use bar code technology when refilling ADCs and at the point of patient care to minimize wrong drug/concentration filling errors and administration errors. If bar code technology is not available, establish procedures of multiple checks when restocking ADCs to minimize wrong drug/concentration filling errors. In systems not utilizing ADCs, establish multiple checks when unit stock is replaced.
- Even the most thorough implementation of smart pumps does not guarantee compliance with their intended and appropriate use. Establish a practice of regular data review to determine compliance with drug library use and to determine if adjustments to dosing limits are warranted.
- Establish an ongoing method to review medication processes throughout the institution. Involve all disciplines to evaluate medication use processes and apply continuous quality improvement principles to identify and eliminate problematic practices.

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