

Medication Safety in Pediatrics

Pediatric patients are particularly vulnerable to medication errors

by Ann M. Ebert, PharmD

Medication safety continues to be a topic in the forefront of health care today. Since the release of the report "To err is human," by the Institute of Medicine in 1999,¹ the topic of medication safety and the extent of medication errors in health care has become a universal topic. Very recently we have heard of multiple mishaps with medications, specifically in pediatric patients, including the headlines of the Quaid twins who received the wrong concentration of heparin in a peripheral intravenous catheter or a similar situation at a hospital in Indiana that resulted in devastating consequences for the infants involved. In many cases, medication errors are caught before they reach the patient, however, when medication errors reach the patient, the results can cause significant harm or death. Medication error prevention should be a fundamental expectation for any health care system or patient entering the health care system. Despite this fact, we continue to have problems daily with medication errors that occur.

EXTENT OF THE PROBLEM

Takata, et al recently published a study in which a new pediatric-focused trigger tool to identify medication errors was tested in 12 pediatric hospitals.² Nine hundred sixty charts were randomly selected for review, representing 6,806 patient-days. In this study, a medication error rate of 11.1% was found in pediatric patients evaluated. Only 3.7% of the errors had a voluntary hospital occurrence report generated. This is consistent with the 2-3% error rate reported in similar studies that rely on traditional methods of error reporting including voluntary self-reporting by



75% of drugs marketed in the U.S. lack pediatric use information, yet continue to be used routinely to treat children.

staff. Of the errors that were noted, the authors found that 22% were preventable, and 97% resulted in mild, temporary harm (classified as category E or higher by the National Coordinating Council for Medication Error Reporting and Prevention).

Data from USP's MedMarx[®] database, a voluntary medication error reporting system, during the years 2006 and 2007 found that 2.5% of pediatric medication errors led to patient harm.³ Further breakdown of the data revealed that the most frequent type of error was improper dose or quantity occurring 37.5% of the time

followed by errors of omission at 19.9%, unauthorized/wrong drug at 13% and prescribing error at 9.4%. The most common causes of the errors were classified as performance deficit (43%), knowledge deficit (29.9%), procedure/protocol not followed (20.7%), and miscommunication (16.8%). MedMarx[®] has also compared the rates of pediatric errors to adult errors in the operating room and found that pediatric patients were twice as likely to experience a medication error than an adult or geriatric patient (32% vs. 15%).⁴

VULNERABILITY OF PEDIATRIC PATIENTS

Pediatric patients are more susceptible to errors that result in harm for many reasons. In general, medications that are available today are formulated and packaged to meet adult needs. Added steps are frequently required in reformulation of these products to meet the needs of children either by dilution or compounding of oral solids into liquid dosage forms. Additionally, many health care settings are built around the needs of adult patients where pediatric-specific protocols, safeguards and references may be lacking. In many cases practitioners, including pharmacists, lack pediatric specific education and training, making it difficult to manage the needs of this population of patients. A case reported in *Pediatric Nursing* very poignantly illustrated the need for pediatric trained staff and systems that are set up to intercept potential errors.⁵ The report described the case of a 14-month-old who received an overdose of digoxin. In this situation, as in many, multiple missteps allowed the error to perpetuate and ultimately reach the patient. Prescribing errors, transcribing errors and lack of system safety checks all played a part in this fatality.

Even if we were able to control these system issues, significant differences in physiology between infants, children and adults may limit the child's ability to handle medication errors especially in those who are ill or very young. The differences in pharmacokinetics and pharmacodynamics of young infants, especially those who are premature, compared to their adult counterparts makes medication dosing challenging at times. Lack of pediatric-specific clinical trials places

PEDIATRIC - SPECIFIC RISK REDUCTION STRATEGIES

Standardize

- Establish and maintain a functional pediatric formulary system with policies for drug evaluation, selection and therapeutic use.
- Use weight-based dosing for all medications.
- To prevent timing errors in medication administration, standardize how days are counted in all protocols (e.g., start date = Day 0 or Day 1).
- Limit the number of concentrations and dose strengths of high alert medications.
- For pediatric patients who are receiving compounded oral medications and total parenteral nutrition at home, ensure that the doses are equivalent to those prepared in the hospital.
- Use oral syringes to administer oral medications.

Pharmacy Oversight

- Assign a practitioner trained in pediatrics to any committee that is responsible for the oversight of medication management.
- Have a pharmacist with pediatric expertise available or on-call at all times.
- Provide ready access to up-to-date pediatric-specific information for all hospital staff including research study data, growth charts, normal vital sign ranges, emergency dosage calculations, and drug reference materials with information about minimum effective doses and maximum dose limits.
- Orient all pharmacy staff to specialized neonatal/pediatric pharmacy services in your organization.
- Independent double-checks of the calculations should be performed by a pharmacist, nurse or both.
- Provide a dosage calculation sheet for each pediatric critical care patient, including both emergency and commonly used medications.
- Develop preprinted medication order forms and clinical pathways or protocols to reflect a standardized approach to care.
- Create pediatric satellite pharmacies or assign pharmacists and technicians with pediatric expertise to areas or services such as neonatal/pediatric critical care units and pediatric oncology units.
- Pediatric medications should be stored and prepared in areas separate from those where adult medications are stored and prepared.

Technology

- Use methods to ensure the accuracy of technology that measures and delivers additives for intravenous solutions, such as for total parenteral nutrition.
- Use dose and dose range checking software programs to provide alerts for potentially incorrect doses.
- Medications in automated dispensing cabinets that do not undergo appropriate pharmacist review should be limited to those needed for emergency.
- Recognize that the use of infusion pumps, or smart pumps, is not a guarantee against medication errors. Appropriate education for nurses, pharmacists and other caregivers regarding these technologies is important for all institutions caring for pediatric patients.
- Use age- and size-appropriate monitoring equipment and follow uniform procedures under the guidance of staff appropriately trained in sedation, monitoring and resuscitation.
- Use bar-coding technology with pediatric capability. A pediatric bar-coding solution must be able to provide readable codes for small-volume, patient-specific dose labels.

Adapted from The Joint Commission: Preventing pediatric medication errors. Sentinel Event Alert #39, April 11, 2008.

children and the people who treat them at a significant disadvantage. In 2002, the American Academy of Pediatrics Committee on Drugs issued a statement regarding the off-label use of medications.⁶ In this statement, they point out that 75% of drugs currently marketed in the United States lack pediatric use information. Despite this fact, medications are used routinely to treat children. In some cases, the treatment is backed up with sound evidence. In other cases, it may be simply expert opinion. In either case, the lack of Food and Drug Administration (FDA)-approved labeling can leave children as therapeutic orphans in the medical community, increasing their vulnerability to medication errors.

Additionally, communication barriers can also play a role in the vulnerability of the pediatric population. Children, especially infants, are limited in their ability to clearly express how they are feeling to their parents or a health care provider, particularly as it relates to adverse effects that a medication may be causing.

RECOMMENDATIONS TO PREVENT MEDICATION ERRORS

The Pediatric Pharmacy Advocacy Group (PPAG) in conjunction with the Institute for Safe Medication Practices (ISMP) published guidelines for preventing medication errors in pediatric patients.⁷ This paper describes, in depth, the necessary steps that need to take place in order to provide a safe medication environment for children. Recommendations in this paper are divided into three general categories: 1) organizational/systems, 2) educational systems, and 3) manufacturing and regulatory systems. The guideline also urges all health care professionals involved in the care of children to accept responsibility for their own continuing education, active participation on a medical team and involvement in all aspects of the medication use process as it pertains to the patients with whom they are working.

Recently, The Joint Commission released a sentinel event alert which outlines several strategies for reducing the risk of medication errors in children.³ Many of these strategies mimic those outlined by ISMP and PPAG in 2001. These strategies are divided into three broad categories: standardization, pharmacy oversight, and

use of technology. Some of the strategies are relatively easy to achieve, such as standardizing concentrations of medications, utilizing standard protocols for treatment, establishing a pediatric formulary and use of oral syringes for oral medications. Others may be more difficult to achieve in some practice environments. Having pediatric-specific trained personnel available at all times may not be economically feasible in a smaller practice setting. Uses of technology such as syringe pumps for small volume intravenous medications, bar-coding for medication administration, smart pumps, and CPOE with decision support are all tools that are available and need to be implemented in all settings to help prevent errors. Anything that we can do as health care practitioners to eliminate the risk of error is beneficial for our patients.

CONCLUSIONS

Pediatric patients are particularly vulnerable to medication errors for a variety of reasons. The rate of errors identified in the pediatric population appears to be relatively high and in some cases higher than that reported in the adult population. Adopting the recommendations put forth by organizations such as ISMP or PPAG to reduce medication errors in pediatric patients is an important step in reducing the risks. It is important that all health care providers work together to make medication errors an exceedingly rare event. ●

Ann Ebert is perinatal clinical specialist in the Department of Pharmacy at Meriter Hospital in Madison.

REFERENCES

1. Kohn LT, Corrigan JM, Donaldson MS. To err is human. Building a safer health system. Washington DC: National Academy Press, 2000.
2. Takada GS, Mason W, Taketomo C, et al. Development, testing and findings of a pediatric-focused trigger tool to look at medication-related harm in US children's hospitals. *Pediatrics* 2008; 121:e929-935.
3. The Joint Commission: Preventing pediatric medication errors. Sentinel Event Alert #39, April 11,2008. Available online: http://www.jointcommission.org/sentinelalerts/sentineleven-talerrt/sea_39.htm (accessed 4/21/2008)
4. Hicks RW, Becker SC, Cousins DD: MedMarx® Data Report: a chartbook of medication errors: findings from the perioperative settings from 1998-2005, 2006 Rockville, MD, United States Pharmacopeia Center for Advancement of Patient Safety.
5. Dowdell EB. Pediatric Medical Errors Part 1: The case – a pediatric drug overdose. *Pediatr Nurs* 2004; 30:328-330.
6. American Academy of Pediatrics Committee on Drugs. Uses of drugs not described in the package insert (off-label uses). *Pediatrics* 2002; 110:181-183.
7. Levine SR, et al. Guidelines for preventing medication errors in pediatrics. *J Pediatr Pharmacol Ther* 2001; 6:427-443.

Announcements

Ann Ebert, PharmD, clinical pharmacy specialist in perinatology at Meriter Hospital in Madison, was inaugurated as president of the Wisconsin Association for Perinatal Care at their annual meeting held at the Radisson Paper Valley Hotel in Appleton on April 15, 2008. Formed in 1970, the Wisconsin Association for Perinatal Care (WAPC) is the largest perinatal care organization in the country, providing leadership and education for improved perinatal health outcomes of women, infants, and their families.

Somerset, Wisconsin's newest pharmacy, Somerset Drug opened for business in May. The community pharmacy, owned by PSW Board member Ken Nelson, offers prescription and OTC medications and limited home health products.

Women's Health America's specialized pharmacy, Madison Pharmacy Associates, is the first pharmacy in Wisconsin to earn the prestigious Pharmacy Compounding Accreditation Board's Seal of Accreditation. The accreditation was awarded after Madison Pharmacy Associates (MPA) met or exceeded the rigorous standards created by the eight national professional pharmacy organizations that make up the PCAB, and confirms that MPA consistently meets the highest quality and safety standards in its profession.

Thomas S. Thielke, MS, FASHP, vice president of professional and support services at the UW Hospital and Clinics in Madison and a clinical professor at the UW School of Pharmacy, has been named the 2008 recipient of the prestigious John W. Webb Lecture Award.

A recipient of numerous awards and honors, Thielke was honored with the Donald E. Francke Medal in 2006 and the Harvey A.K. Whitney Lecture Award in 2005. He also received the McKesson Medication Safety Leadership Award and the Winston J. Durant Lecture Award.

The Webb award honors health-system pharmacy practitioners or educators who stand apart from others because of their extraordinary dedication to fostering excellence in pharmacy management and leadership.

Thielke will present his award lecture at the ASHP Conference for Leaders in Health-System Pharmacy and as visiting professor in hospital pharmacy at Northeastern University. ●

Share Your Experience with Electronic Prescribing on New NASPA/SureScripts Online CQI Portal

The National Alliance of State Pharmacy Associations (NASPA) and SureScripts have announced a collaborative effort to gather direct input from practicing community pharmacists and technicians about the experiences that they have had with electronic prescriptions. This initiative, which compliments the patient safety focus of NASPA's ongoing Pharmacy Quality Commitment program, is designed to allow the two organizations to gather suggestions for improvement as well as detailed, actionable, non-PHI data about issues that may have been encountered with electronic prescriptions so that said issues can be traced, analyzed, and if appropriate, remediated. It is hoped that the widespread use of the Pharmacy E-prescribing Experience Reporting Portal (PEER Portal) will lead to continuous innovation and quality improvement within e-prescribing processes on a national basis.



Pharmacists and technicians are encouraged to complete the brief questionnaire on the PEER portal whenever they have suggestions for improvement to, or constructive criticisms about, e-prescribing processes that they have encountered. ●