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Improving Pediatric Medication Safety
Part I: Research on Medication Errors and Recommendations from the Joint Commission

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On April 11, 2008, the Joint Commission issued a Sentinel Event Alert (SEA) calling on all health care facilities caring for infants and children to implement new strategies for medication error prevention.[1] The Joint Commission, previously known as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), is an independent, non-profit organization that evaluates and accredits more than 15,000 health care institutions across the United States. An SEA is one of the methods for the Joint Commission to call attention to an issue or area that requires further investigation by health care organizations. Although complete compliance with SEA recommendations is not a requirement for accreditation, an institution's response is accessed as part of the Joint Commission's review process.[2]

This SEA, *Preventing Pediatric Medication Errors*, is the first time the Joint Commission has specifically focused on the care of infants and children. It was triggered, in part, by continued reports of serious medication errors within pediatric institutions, including two cases involving neonatal heparin overdoses. In both incidents, vials of 10,000 unit/mL heparin were used in place of 10 unit/mL heparin flush solution.[3] The SEA has prompted all children's hospitals to re-evaluate their approach to preparing, administering, and monitoring medications.[1,4] The next two issues of *Pediatric Pharmacotherapy* will provide an overview of the SEA and describe new research on medication errors and methods for improving the safety of pediatric medication delivery.

Medication Error Rates in Infants and Children

The Joint Commission cited data collected from a national voluntary medication error reporting system, the USP MEDMARX® project, as evidence of the significance of pediatric medication errors. In the past two years, the MEDMARX® database revealed a 2.5% incidence of medication errors resulting in harm to children. Thirty-eight percent of the documented errors involved an incorrect dose or quantity. Medication order omissions made up 20% of the errors, followed by use of an unauthorized drug or wrong drug in 14%.[1]

In a 2007 issue of *Cancer*, Rinke and colleagues used the MEDMARX® database to evaluate the frequency and characteristics of errors associated with pediatric chemotherapy.[5] The authors examined the database from 1999 to 2004, which contains 829,492 adverse event reports involving 29,802 patients. A total of 310 events involved children receiving chemotherapy. Although rare, these errors were often significant. Eighty-five percent of these errors were not detected prior to administration, and 16% were serious enough to require additional medical intervention. Approximately half of the errors occurred during drug administration, with another 23% involving the wrong dose. By performing this analysis, the authors hoped to call attention to the risks of chemotherapy administration in children and prompt pediatric clinicians to develop new strategies to minimize errors.

In addition to these reports from the MEDMARX® database, a number of other papers have been published in the medical literature examining the incidence or severity of medication errors in children. One of the most frequently cited studies of medication error prevention was published by Folli and colleagues in 1987.[6] The authors used clinical pharmacists to evaluate and record medication errors at two children's hospitals over a 6-month period. The overall error rates in the two hospitals were 4.9 and 4.5 errors per 1,000 medication orders. Of these, 5.6% were considered by the investigators to have been potentially lethal. The majority of the errors (64.3%) occurred in children under 2 years of age. The most common type of error was incorrect dosage. The authors concluded that pharmacy intervention can prevent significant medication errors, a finding which

resulted in the expansion of pediatric clinical pharmacy services in many institutions and is highlighted in the current SEA.

Following the Institute of Medicine's 1999 report, *To Err is Human: Building a Safer Health System*, the number of studies evaluating medication errors greatly increased. In 2001, Kaushal and colleagues at Boston's Children's Hospital and Brigham and Women's Hospital conducted a prospective cohort study of 1,120 pediatric patients admitted to their institutions during a 6-week period.[7] The authors found 616 medication errors in 10,778 orders, giving an error rate of 5.7%. Of these errors, there were 115 potential adverse events and 26 actual adverse events. Most of the errors resulting in a potential adverse event (79%) occurred during ordering. More than half of the errors (54%) involved intravenous (IV) medications. The authors' estimates, while higher than the rates reported by Folli, are similar to studies conducted in adults and have been replicated by other investigators in pediatric institutions.

Earlier this year, Takata and colleagues evaluated a total of 960 medical records from 12 children's hospitals to test the efficacy of their pediatric-focused trigger tool designed to identify adverse drug events.[8] The tool was designed to help researchers identify adverse events during chart review by providing a list of items which should trigger further investigation, such as the onset of unexplained hyperglycemia, rising creatinine, or administration of antidotes such as flumazenil or naloxone. The authors found an adverse drug event rate of 11.1 per 1000 patients, or 1.23 per 1000 medication doses. The majority (97%) were categorized as a minor or temporary effect, such as nausea. Only 2.8% were considered severe, leading to prolonged hospitalization. The drug classes most often involved were analgesics and antibiotics. Twenty-two percent of the events were considered preventable. Of those, most were errors during ordering or in patient monitoring. The authors concluded that using their tool for retrospective chart review may provide more accurate data on medication errors than voluntary reporting.

Infants and children in intensive care units may be at even greater risk, due to the more frequent use of IV medications and drugs with a narrow dosing range.[9] The rate of medication errors in pediatric intensive care units (PICUs) has ranged in the literature from 2 to 6%.[7,10,11] In 2007, Buckley and coworkers conducted a prospective direct-observation study to detect medication errors and adverse drug events in their 16-bed PICU.[11] The authors shadowed one nurse selected at random for each of twenty-six 12-hour observation periods. They reviewed 357 medication orders and observed 263 doses being administered. Of the 58 incidents they identified, 52 involved errors in medication orders. Of those 42 (81%) were classified as being clinically significant. Based on their assessment, there were 3.6 actual adverse drug events and 9.8 potential adverse drug events per 100 orders, similar to other reports, however the number of potentially serious errors was much higher.

While a smaller number of drugs are routinely used in the neonatal intensive care unit (NICU), compared to a PICU, the potential for dose calculation errors is often much greater.[7,12,13] In the study by Kaushal, there were 91 errors per 100 NICU admissions.[7] Using previous studies for comparison, the authors suggested that errors with the potential to cause patient harm were eight times more likely to occur in the NICU than in adult patient care areas. In a recent study of the voluntary reports submitted to the Vermont Oxford Network, a collaborative multicenter database, 47% of the medical errors reported by the member institutions involved medications.[13] Thirty-one percent of the errors occurred during drug administration, 25% during dispensing, and 16% during ordering.

High rates of medication errors have also been reported in pediatric emergency departments. In a 2002 study, Kozer and colleagues identified prescribing errors in 10% of patient charts.[14] These results were confirmed by Rinke and colleagues in a study published in the January 2008 issue of *Pediatric Emergency Care*.[15] The authors conducted two retrospective reviews, finding errors in 47 of the 377 medication orders evaluated (12.5%) and in 37 of the 191 charts reviewed (19.4%). In addition, they found at least one error in 30 of the 696 (4.3%) ambulatory prescriptions written by emergency department personnel to be filled by outside pharmacies. As in previous studies, the most common drugs involved were antibiotics and analgesics.

<u>The Joint Commission Recommendations</u>

The SEA groups the Joint Commission's recommendations into three primary areas: standardization, pharmacy oversight, and use of technology, followed by a list of general comments.[1] The remainder of this issue summarizes the contents of the document and provides tools for implementation.

<u>Standardization</u>

The recommendations in the first section focus on methods to minimize variation throughout the

medication ordering, preparation, and administration process. All organizations providing pediatric care should:

- Develop a pediatric formulary system which includes specific policies for evaluating, selecting, and using medications in the health system.
- Standardize the start date in all protocols (Day 0, Day 1, etc) in order to improve patient tracking and minimize confusion among health care providers.
- Limit the number of concentrations and strengths of high-alert medications. A list of these medications is available from the Institute for Safe Medication Practices (ISMP) at www.ismp.org/Tools/highalertmedications.pdf
- Ensure that home doses of compounded medications or solutions are equivalent to the doses dispensed.
- Use oral syringes to improve the accuracy of administering liquid medications.

Utilizing staff expertise

The second section of the SEA highlights the need to ensure pharmacy staff oversight in the verification, dispensing, and administration of medications for infants and children. It also calls attention to the need to separate pediatric medication storage and preparation from areas used for adult medications. Institutions are advised to:

- Assign a practitioner with training in pediatrics to all committees involved in oversight of medication management.
- Provide ready access to current pediatric-specific information, including recent study results, growth charts, normal ranges for vital signs, emergency dose calculations, and drug references. The use of web-based resources is encouraged.
- Orient all pharmacy staff to the institution's pediatric pharmacy services.
- Provide a dosage calculation sheet for each pediatric critical care patient which includes both emergency and common medications.
- Develop medication orders, clinical pathways, and protocols to reflect a standardized approach to patient care. The Joint Commission recommends including specific information on monitoring.
- Create pediatric satellite pharmacies or assign specific pharmacists and technicians with pediatric expertise to high-risk areas, including critical care and oncology. If a separate satellite pharmacy cannot be created, pediatric medications should be stored and prepared in areas separate from those used for adult medications.

Using technology judiciously

In this section, the Joint Commission calls attention to the benefits of incorporating new technology, while acknowledging the limits and potential risks of excessive reliance on these systems. The recommendations in this section include the need to:

- Ensure that all IV pumps can accurately deliver the intended fluid volumes.
- Use dose-checking software during order entry to provide alerts for doses outside of the desired (programmed) dosing range.
- Require all orders for medications placed in automated dispensing machines (e.g. PYXIS) undergo verification by a pharmacist prior to being accessible. Exceptions to this process would be those drugs needed in an emergency or those that remain under the control of a licensed independent prescriber at all times.
- Educate all clinicians in the appropriate use of programmable infusion pumps (smart pump technology). Health care providers should be aware of the potential for errors remaining within the administration process when this equipment is being used.
- Provide consistent monitoring of children requiring procedural sedation, including pulse oximetry. Pediatric procedural sedation should only be undertaken by staff members trained in the use of these medications, as well as pediatric resuscitation.
- Implement bar-coding technology using systems that have been evaluated in children. These systems must be able to function on small labels or wrist-bands appropriate for neonatal patients.

Additional Suggested Actions

In addition to the three focus areas already described, the Joint Commission included several other specific suggestions for health care institutions in this SEA:

- All patients should be weighed (in kg) at admission. No high risk medication should be dispensed or administered without an accurate patient weight to allow for dose-checking, unless it is needed in an emergency.
- Prescribers should include dosage calculations (mg/kg, mg/m^2, etc) on all orders and prescriptions. Exceptions include topical, otic, or ophthalmic products or other drugs not dosed according to patient size.
- Whenever possible, pediatric-specific commercial products should be used. All extemporaneous formulations should be provided in single doses.
- When adult preparations must be used for pediatric patients, a warning label should be applied. Adult products, such as concentrated heparin vials, should not be stored in pediatric areas.
- Institutions should develop a comprehensive, on-going program for educating all health care practitioners who provide care for children. Training programs should include instruction on how to report adverse medication reactions.
- Families should be involved in the medication use process. Health care providers should discuss the child's medications, including potential adverse effects, with the family. Parents and children should be encouraged to ask questions and to verbalize their understanding.
- A pharmacist with pediatric expertise should be available as a resource for prescribers at all times.
- The institution should establish a formal process for reviewing the pediatric medication use process. In the event of a serious error, a root cause analysis should be performed, followed by development of a corrective action plan. Transparency in this process, with both the family and staff, is encouraged.

Summary

Over the past decade, there has been an increasing awareness of the risk for medication errors in infants and children. The recent Joint Commission SEA, triggered by recent research and several widely publicized medication errors, provides a detailed list of suggestions for improving medication safety. Using these recommendations, along with recent research in medication safety, health care institutions can evaluate their current medication management process and identify areas for improvement.

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Formulary Update

The Pharmacy and Therapeutics Committee did not meet in October. Their next meeting will be held on 11/14/08.

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