INTRODUCTION

The pediatric patient population can be considered in the developmental subcategories of preterm neonates (less than 36 weeks’ gestation), full-term neonates (birth to 30 days of age), infants (1 through 11 months of age), toddlers (1 through 4 years of age), children (5 through 11 years of age), and adolescents (12 through 17 years of age). These young patients have not only some unique diseases and medical conditions but also an increased risk of adverse drug events, for several reasons:

- Pharmacokinetic parameters are different at various developmental stages.\(^1\)
- Multiple calculations are needed to individualize doses on the basis of age, weight (mg/kg), or body surface area (mg/m\(^2\)).\(^1\)
- Most medications used in the care of children are formulated and packaged primarily for adults. Therefore, extemporaneous preparation is common because of the lack of available dosage forms and concentrations for pediatric and neonatal patients.\(^1\)
- Precise dose measurement and appropriate drug delivery systems are necessary; many medication delivery systems are not designed for pediatric patients.\(^1\)
- Children, especially young, small, or sick children, are usually less able to physiologically tolerate a medication error because renal, immune, and hepatic functions are still maturing.\(^5\)
- Many children, especially very young children, cannot communicate effectively to providers regarding adverse effects of medications.\(^5\)
- There is a lack of published information and US Food and Drug Administration (FDA)-approved product labeling addressing the dosing, pharmacokinetics, safety, efficacy, and clinical use of some medications in pediatric patients.\(^1\)

In addition, a 100-fold difference can exist between a medication dosage for an adolescent and that for a preterm neonate. A pediatric dose could be one-tenth of an adult’s dose but still be 10 times the appropriate dose for a preterm neonate. All of these challenges could easily contribute to medication errors in this population.

Pediatric inpatients may experience three times as many medication errors as adult inpatients, and these errors are frequently harmful.\(^6\) For children, 1% of all medication errors carry significant potential for harm, with 0.24% of errors causing actual harm.\(^6\) Takata et al. were the first to develop and evaluate a trigger tool to detect adverse drug events in an inpatient pediatric population, which identified an 11.1% rate of adverse drug events in pediatric patients.\(^7\) Their study also showed that 22% of those adverse drug events were preventable, 17.8% could have been identified earlier, and 16.8% could have been mitigated more effectively.

Stockwell et al. also developed and pilot-tested a trigger tool that would identify the most common causes of harm in pediatric inpatient environments; in evaluating 600 patient charts, 240 harmful events (“harms”) were identified, resulting in a rate of 40 harms per 100 patients admitted and 54.9 harms per 1,000 patient-days across the six academic children’s hospitals.\(^8\) At least one harm was identified in 146 patients (24.3% of patients). Of the 240 total events, 108 (45.0%) were assessed to have been potentially or definitely preventable.

The United States Pharmacopeial Convention’s MEDMARX database showed that almost 2.5% of pediatric medication errors in 2006 and 2007 led to patient harm.\(^9\)
The most common types of harmful medication errors were improper dose or quantity (37.5%), omission error (19.9%), unauthorized or wrong drug (13.7%), and prescribing error (9.4%).

The Joint Commission published a Sentinel Event Alert in 2008 to address the prevention of pediatric medication errors and noted that most healthcare settings are primarily built around the needs of adults.5 Many settings lack trained staff oriented to pediatric care, pediatric care protocols and safeguards, and/or up-to-date and easily accessible pediatric reference materials, especially with regard to medications. Emergency departments (ED) may be particularly risk-prone environments for children. Based on these concerns, as well as the aforementioned unique challenges of this population, this article specifically focuses on medication errors involving patients younger than 18 years of age that took place in general acute care hospitals not focused on pediatrics (i.e., pediatric hospitals were excluded) in Pennsylvania.

METHODS
Analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for events reported to the Pennsylvania Patient Safety Authority from January 1, 2013, through October 31, 2014, in which the patient age was less than 18 years and the event took place in a general acute care hospital that does not specialize in pediatrics. The query yielded 4,065 medication error reports, which analysts reviewed and categorized by error according to interpretation of the event. If an event fit into more than one category, the analysts determined, when possible, the primary reason for the event, using only information provided within the report. Analysts also identified events involving high-alert medications, based on the ISMP List of High-Alert Medications in Acute Care Settings.10

RESULTS
Categorization of the reports by harm score, which is adapted from the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) harm index,11 shows that 74.1% (n = 2,983 of 4,065) of the events reached the patient (harm score = C through I); almost 18% (n = 715, 17.8%) of the events were reported as harm score D or greater, which indicates that many pediatric patients required extra monitoring or intervention to preclude harm; and only 0.4% (n = 15) of the events resulted in patient harm (harm score = E through I). The distribution of harm scores reported by pediatric hospitals compared with general acute care hospitals is skewed toward higher, or more serious, harm scores in the general acute care hospitals (see Figure 1).

While review of any event involving a pediatric patient, including a near miss or close call, may provide clues to the multifactorial reasons why an error occurred, further analysis focused on those events that required at least extra monitoring or intervention to preclude harm as well as those events that resulted in harm to the patient (events with harm scores of D through I, n = 715).

Overall, 54 unique care areas were associated with events that required extra monitoring or intervention or that resulted in harm involving the pediatric population. The most common units implicated in these events were neonatal intensive care units (21.2%, n = 152 event reports), pediatric units (15.9%, n = 114), and EDs (8.5%, n = 61). Intensive care unit settings accounted for 30.2%, (n = 216) of the cited locations and 31.8%, (n = 228) of the locations were not pediatric-specific care areas (e.g., ED, medical-surgical unit).

When looking at the age ranges of patients involved in events, 28.0% (n = 200) of the reports with harm scores of D through I involved neonates, and 60.1% (n = 430) involved patients younger than five years of age (see Figure 2).
REPORTS & ANALYSES

Figure 2. Medication Events with Harm Scores of D through I, by Pediatric Sub-population, January 2013 through October 2014, as Reported to the Pennsylvania Patient Safety Authority (N = 715)

Note: Neonates (birth to 30 days of age), infants (1 through 11 months of age), toddlers (1 through 4 years of age), children (5 through 11 years of age), and adolescents (12 through 17 years of age)

The most common classes of medications cited were antibiotics (14.7%, n = 105), opioids, (8.1%, n = 58), intravenous (IV) fluids (5.9%, n = 42), and vaccines (4.7%, n = 34). Almost 25% (n = 176, 24.6%) of the reports involved at least one high-alert medication. Among reports involving high-alert medications, the three classes most commonly cited were opioids (e.g., morphine) (33.5%, n = 59), parenteral nutrition (22.7%, n = 40), and insulin (11.9%, n = 21); combined, these represented roughly 68% (n = 120) of the events involving a high-alert medication.

**DISCUSSION**

Wrong-Dose Scenarios

Based on the event types selected by reporting hospitals, more than half of all reports with harm scores of D through I (51.7%, n = 370) involved patients receiving the wrong dose of a medication. Roughly 22% (n = 161) of the reports indicated that the patient received too much medication (i.e., wrong-dose/overdosage and extra-dose events), 16.3% (n = 117) stated that patients received an insufficient dose (i.e., drug omission and wrong-dose/underdosage events), and 12.8% (n = 92) involved wrong rates, wrong duration, or the wrong strength/concentration, which all could have resulted in either an over- or underdose of the drug. When analyzing the overdose events, analysts identified that 5.4% (n = 39 of 715) of the events resulted in patients receiving medication overdoses ranging from 2-fold to 100-fold in scale.

Following are examples of reports of multiple “fold” errors occurring during the administration process:

* The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

During nursing report and the confirmation of drips, I noticed that the midazolam drip was running at an alarming rate of 1 mg/kg/hr for a total of 12.3 mg of midazolam per hour in a [less than 3 year old] patient. I asked the nurse if she indeed intended to run it at such a high rate and she confirmed. I then checked the order and it had been ordered as such. I immediately contacted the physician and informed him of the rate and he came to the room. The dose was decreased to 0.1 mg/kg/hr.

The prescriber was entering medication for conscious sedation for the procedure. He inadvertently entered into the computer 230 mg instead of 23 mg. The nurse prepared the medication and had it checked by another nurse. Neither nurse realized the dose was wrong. This medication is not used frequently in the ED. The medication was administered. After the procedure, when it took longer for the patient to awaken from sedation, the error was discovered.

An infant was delivered and admitted to the ICN [intensive care nursery]. The infant was intubated and on a ventilator. The infant was administered a morphine sulfate infusion at the rate of 17 mL/hr instead of 0.17 mL/hr for approximately one and a half hours. The physician was notified, and the infant was monitored with every-five-minute vital signs and additional laboratory studies.

Non-Patient-Specific Dosage Forms

Healthcare professionals often cannot use a commercially available formulation to prepare and administer the appropriate medication dose for a pediatric patient.\(^\text{12}\) For example, because small children cannot swallow tablets and capsules, suspension or solutions may need to be compounded or tablets may be crushed and capsules opened so they can be mixed with food (e.g., applesauce) or beverages (e.g., juice, formula). Such manipulation can not only cause solubility and bioavailability problems but can increase the potential for error. Analysis of reported events (n = 715) reveals that this specific situation was the most commonly (4.3%, n = 31) mentioned pediatric-specific problem.

Following are examples of reports of errors involving the provisions of non-patient-specific doses:

- A [less than six months old] male was ordered morphine sulfate 0.24 mg oral solution [10 mg/5 mL] via a NGT [nasogastric tube] every six hours. The nurse gave 0.24 mL (0.48 mg) via NGT, a double dose. No adverse event to patient.

Nursing was about to give a dose of morphine and realized that the syringe pharmacy brought up was not...
wasted to the appropriate dose. Nursing then realized that the previous dose that the patient received was an overdose. The syringe was never wasted prior to administration, as evidenced by looking back at the bag the medication came up in. It was assumed by nursing that pharmacy had already made the waste.

While there were some reports that mentioned the unique challenges associated with medication use with the pediatric population, most reports described scenarios similar to the normal challenges described in earlier Pennsylvania Patient Safety Advisory articles—for example, breakdowns associated with information about patients, mix-ups due to similar drug names or packaging, and errors associated with the use of IV pumps and IV lines.

**Insufficient Patient-Specific Information**

To guide appropriate drug therapy, practitioners can obtain pertinent demographic and clinical information, including the patient’s name, age, weight, medical conditions, medication allergies, medication lists, and laboratory results, in order to select the appropriate medications, doses, and routes of administration as well as to monitor the effects of the medications. In a prospective cohort study of nonobstetric adult patients at two tertiary hospitals, which involved a systems analysis of events, inadequate availability of patient information was associated with 18% of events.

Previous Advisory articles addressed issues associated with inaccurate patient information, including errors involving patient weights (e.g., mix-ups between pounds [lb] and kilograms [kg]), patients prescribed medications to which they were allergic, breakdowns obtaining accurate medication lists during reconciliation, and wrong-patient errors. From this analysis of events that required additional monitoring or caused harm, 9.4% (n = 67) of reports mentioned a breakdown with information about the pediatric patient.

Following are examples of reports of errors associated with breakdowns with patient information:

**Patient was ordered ibuprofen 10 mg/kg by mouth (PO).** The patient weighs 23 lb (10.45 kg), and the dose of ibuprofen was calculated at 10 mg/lb, not 10 mg/kg. The patient was administered 230 mg of ibuprofen PO. Physician assistant and mother of patient notified immediately. Mother instructed not to give ibuprofen to child again for the next 24 hours.

A patient was given a prescription for amoxicillin 500 mg 1 tablet TID (three times a day) x 10 days. An allergy was listed in the computer for Augmentin® (amoxicillin/clavulanate potassium). The patient’s parent called after discharge to advise [about the] rash and requested we add amoxicillin as an allergy.

**Similar Medication Names and Similar Packaging**

A similarity of characters in brand drug names, generic names, and brand-to-generic names can lead to confusion, with similar-sounding drug names adding to those problems. These similarities are compounded by practitioners attempting to keep up with the vast array of new products introduced to the marketplace, illegible handwriting, orally communicated prescriptions, similar labeling or packaging of medications, and proximity for look-alike names (e.g., Zyprexa® [OLANZapine] and ZyrTEC® [cetirizine]) to one another in electronic order entry systems. In fact, research has identified that a frequent (29%) cause of pharmacy drug dispensing errors is failure to accurately identify drugs, usually due to confusion between look-alike or sound-alike drug names. Due to similarity in the manufacturer’s provided package or pharmacy-prepared package, significantly contribute to the risk of medication errors.

Analysis of events reported to the Authority involving the pediatric population with harm scores of D though I shows that 6.0% (n = 43) of reports specifically cite or allude to wrong-drug errors with similar naming or packaging contributing to the event. When looking specifically at errors involving vaccines (n = 35), over 33% (n = 12) of these events were categorized as wrong-drug errors.

Following are examples of reports of errors associated with similar medication names and packaging:

The patient was to be given 650 mg of Tylenol® (acetaminophen) but was erroneously given 10 mg of Haldol® (haloperidol). Provider was notified immediately and ordered a one-time dose ofCogentin® (benztropine) 1 mg, which was given right away. [The cause of the error cited in the actual report was similar package and labeling.]

The patient was ordered eyedrops—tropicamide and phenylephrine. I went into his medication basket and grabbed the two eyedrop containers. After “dropping the eyes,” I had discovered that I had grabbed and administered phenylephrine and atropine in error.

**Patient ordered tetanus and diphtheria toxoids absorbed (Decavac®), but tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine, absorbed (Boostrix®) was selected upon removal from the automated dispensing machine; the nurse documented that Boostrix was administered.**

**IV Pump and IV Line Mix-Ups**

The most common issue mentioned in reports involving medication errors in the
had been infused. The nurse read the pump and it read “Volume Infused 122 mL,” meaning that 39 mL had infused. The rate was set at 38 mL/hr, not 3.8 mL/hr. Reported incident to the doctors, and repeat glucose was 474 mg/dL.

A 31-year-old female post–Cesarean section requested IV ketorolac for pain. Dose ordered was 30 mg IV. Ketorolac syringe was inadvertently connected to infant’s IV while patient was holding the infant for feeding. Nurse administered unknown amount of ketorolac to the infant (estimated 0.1 mL to 0.2 mL before error was discovered). Patient monitoring was conducted on the advice of Poison Control. Patient was transferred to tertiary care.

**RISK REDUCTION STRATEGIES**

The medication events reported to the Authority involving patients younger than 18 years of age in general acute care organizations reveal the complex nature and large variety of factors that contribute to errors. Some of those factors were an extension of the unique challenges associated with providing medications to a younger age group. However, many of the factors were the same as seen in events associated with adults. Unfortunately, most of the reports did not describe the errors in great detail or include the causes and contributing factors linked to the errors; however, these reports, observations from the Institute for Safe Medication Practices, and recommendations in the literature do offer strategies that healthcare facilities may consider to decrease risk in the medication-use process for the pediatric population.

**Pediatric-Specific Strategies**

**Prescribing node.** Analysis of the events reported to the Authority revealed that at least 13.1% (n = 94) of the events originated in the prescribing process, with 20.2% (n = 19 of 94) of those resulting in an overdose to the patient. Thus, the use of a computerized prescriber order entry (CPOE) system with an effective clinical decision support system may help to catch prescribing errors that could result in an overdose. In addition, during the prescribing process, the following strategies may help to prevent these types of events:

- Confirm that the patient’s actual weight, in kg, is correct, as this will be used for weight-based dosing.
- Include weight, dose basis (e.g., mg/kg/dose), and total dose on orders and prescriptions.
- Check that the weight-based dose does not exceed the recommended dose.
- For handwritten orders, avoid use of a terminal zero to the right of the decimal point (e.g., use 5 rather than .5) and use a zero to the left of a dose less than 1 (e.g., use 0.1 rather than .1) to minimize 10-fold dosing errors.
- Stay current and knowledgeable concerning changes in medications and treatment of pediatric conditions.
- Consult a pharmacist if possible, particularly when there is a need to adjust a dose or dosing interval for neonates (e.g., renal impairment) or for calculations based on body surface area.

**Patient-specific doses.** The following strategies may assist organizations in reducing the risk associated with manipulating medications to provide an accurate dose of medication to pediatric patients:

- Dispense medications for individual patients in a patient-specific, ready-to-administer form whenever possible. When this is not possible, provide clear preparation instructions prior to administration.
- Utilize standardized protocols, approved by the pharmacy and therapeutics (P&T) committee, for commonly prescribed pediatric medications (e.g., amoxicillin, acetaminophen) to more easily facilitate pharmacy dispensing of patient-specific, ready-to-administer doses.
- For those medications that will be stored in an automated dispensing cabinet (ADC), consider the following:
  - Stock only pediatric concentrations of oral liquids and injectable medications in pediatric and neonatal ADCs.
  - Limit the variety and quantity of medications in ADCs.
  - Require an independent double check before administration of a high-alert medication obtained from an ADC.

**Administration node.** The following strategies can help reduce the risk of
To prevent mix-ups between the units of measures of lb and kg, standardize the measurement and communication of patient weight to metric units of measure (kg). Official product labeling for medications provides weight-based dosing using only the metric system (e.g., mg/kg).

**Patient drug allergies.** Upon admission to a facility, list patient allergies, a description of the reaction to the allergen, and if possible, the date that the reaction took place on all admission order forms. Review all paper and online data collection forms to determine the location (e.g., front of medical record, on the top of order forms, designated MAR locations, computer screens, resident assessment forms) in which practitioners will document and retrieve complete allergy information, including descriptions of the reaction(s). Standardize the location of this information throughout the organization, including the ED, operating room, imaging services, and general medical/surgical care areas.

**Patient identification.** While the Joint Commission has a National Patient Safety Goal to improve the accuracy of patient identification, the proper use of two patient identifiers may still not be performed at all times. Consider verification processes using at least two patient identifiers for all patient-associated tasks, including prescribing, reporting of test results, and communication of medication information among providers. A proper identification check not only consists of confirmation with the patient but also requires confirmation with the MAR or patient chart, patient armband, patient-specific medication labels, and/or other records.

**Look-Alike Medication Names and Packaging**

Perform a failure mode and effects analysis (FMEA). Before adding a medication that could be used in the pediatric population to your organization’s formulary, consider gathering an appropriate interdisciplinary team (e.g., P&T committee) to perform an FMEA to determine potential hazards with that medication. Evaluation of the look-alike potential of product names and containers in all possible areas of storage throughout the organization, not just the pharmacy, may be necessary.

The P&T committee may also verify that drugs are appropriate for use in the pediatric population (e.g., concentrations, dosage forms, inactive ingredients) as well as approve clinical pathways, protocols, preprinted orders/CPOE order sets, and dose calculation forms. The committee could appoint and oversee a multidisciplinary team for this purpose.

**Product storage and listings.** Separate products with lookalike names on storage shelves, computer screens, and any printed prescriber or stock order forms.

**Product differentiation.** Modifying look-alike drug names by using mixed-case letters and bolding to draw attention to the letters that differ in their names can help distinguish similar drug names. This strategy is commonly referred to as “tall man lettering” (e.g., hydrALAZINE and hydrOXYzine). This strategy may be considered to differentiate drug names on product labels, on storage bin labels, and in computer pick lists or drop-down menus.

**IV Line Mix-Ups**

Set up infusions completely and one at a time. When preparing to administer multiple infusions to a pediatric patient, ensure that the line for the first medication is inserted into the pump prior to preparation of the second medication. Physically tracing the line can help ensure that the correct channel and the correct IV line have been used to program the injections.

Label IV lines. Affixing the name of the drug being infused to each IV line (at the end closest to the patient) and above each channel on the pump may help prevent IV line mix-ups. This practice may also help prevent errors if tubing has to be detached from patients during procedures, imaging, or transfer.
CONCLUSION

Analysis of medication error events reported to the Authority from non-pediatrics-specific acute care organizations revealed some causes or contributing factors that are unique to the pediatric population, such as 10- and 100-fold over- or underdoses. Yet most of the reports showed that the challenges in providing appropriate medications to pediatric patients are actually similar to those encountered for adult patients. Organizations may consider providing medications in a patient-specific dose as often as possible while also applying other strategies, including many that work for adults, for pediatric patients.

NOTES

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