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**Actionable Patient Safety Solution (APSS) #3D:
PEDIATRIC ADVERSE DRUG EVENTS**

Executive Summary Checklist

Adverse drug events (ADEs) in pediatric patients (pADEs) are a common cause of serious morbidity and mortality.

- Create a multidisciplinary team specialized in neonatal and pediatric medicine, nursing and pharmacy that reports regularly to executive leadership, with a focus on pADE.
- Institute an effective software program for identifying, detecting, and reporting pADEs with analysis of the incidence and characteristics of pADEs and the near-misses.
- Deploy a closed loop medication administration system by implementing an electronic medication administration record (eMAR) and barcoding, or other auto identification technology with computerized provider order entry (CPOE) and pharmacy for medication administration.
- Institute proven interventional bundles for pADEs:
 - Standardized order sets and protocols for each admitting diagnosis;
 - CPOE with sophisticated decision support systems (DSS) including medication reconciliation, allergy checking, interaction checking, and dose range checking with alerts;
 - Enhanced pharmacy services including clinical pharmacists on rounds, implementing a double-check process as part of medication verification prior to dispensing high-risk medications, utilizing improved IV compounding tools such as bar code assisted medication preparation system (BCMP), and improving workforce skills to assure correct drug compounding and a pharmacy intervention database;
 - Ensure open communication and standardized medication handoff processes between healthcare teams at shift changes to verify medications are being administered correctly compared to the order, and that patient monitoring parameters for high alert medications are in place;
 - ‘Smart’ drug infusion pumps with drug libraries that are harmonized with order sets and enterprise formularies that include pediatric standardized drug concentrations addressing all weight ranges and are periodically updated based on review of an incident database, alert and override data;
 - Support tools to ensure that the correct concentration of drug in diluent is prepared, taking into account fluid balance for small patients and patients with fluid restrictions, and an infusion rate that is acceptable and within pump capabilities in all areas where children receive care.
- Select and implement new enterprise clinical information systems and electronic health records, verify and assess that the features of an organization’s healthcare IT system includes full support for best practices in age- and weight-specific prescribing, compounding, dispensing, and administration of pediatric medications.
- Consider relevant improvement initiatives and opportunities for collaboration in pADE reduction outside of the hospital system.
- Disseminate pediatric-specific assistive technologies such as eBroselow (or equivalent) to assure that basic capabilities to stabilize and treat acutely ill or injured children are present 24/7 throughout all environments of care.
- Ensure that the FDA Safety Communication: “Syringe Pump Problems with Fluid Flow Continuity at Low Infusion Rates Can Result in Serious Clinical Consequences” is reviewed and understood by the team.
- Utilize Continuous Quality Improvement (CQI) software from infusion pump manufacturers to monitor drug library parameters on a routine basis and to report the frequency of command overrides and alerts triggered for unsafe practices.



The Performance Gap

As reported by the Institute for Safe Medication Practices (ISMP), during a 5-year span between 2008 and 2012, there were over 45,000 adverse drug events (ADEs) reported to the US Food and Drug Administration (FDA) in children aged less than 18 years old. Of these, approximately 64% of ADEs (29,298) involved reports of a serious injury, which included 2,935 (6%) deaths, 10,032 (22%) cases that required hospitalization, 1,430 (3%) cases considered life threatening, and 816 (2%) cases of disability (ISMP, 2014). Preventing medication errors in pediatric patients poses unique challenges as children are particularly vulnerable to adverse outcomes from medication errors because of the need for weight-based drug dosing involving multiple calculations, dilution of stock drug solutions, immature renal and hepatic functions, and limited ability to communicate side effects (Kaushal et al, 2001; Poole et al., 2008). In addition, drugs not have an FDA specific indication for children. Greater than 70% of the drugs used in pediatrics have not been studied scientifically in age-specific populations to assess patient safety (Poole et al., 2008; Lindell-Osuagwu et al., 2009). Most medications used in the care of children are formulated and packaged primarily for adults. The available dosage forms and concentrations appropriate for administration to neonates, infants and children are limited. Therefore, medications often must be prepared in different volumes or concentrations to accommodate delivery modalities that take into account fluid balance for small patients and patients with fluid restriction, and, if an infusion pump is required, provide an infusion rate that is acceptable and within pump capabilities. When drugs are not prepared centrally in the pharmacy (i.e., extemporaneous compounding by frontline caregivers), computational errors and admixtures that do not account stability, compatibility, or bioavailability data may represent additional challenges (Joint Commission, 2008).

Studies showed that medication errors in pediatrics are up to three times more likely to be associated with a potential ADE compared to those reported in adults (Kaushal et al., 2001; Fortescue *et al.*, 2003). Compared to other pediatric patient groups, the neonatal ICU patient group has the highest error and potential ADE rate. Prioritizing strategies for preventing medication errors and adverse drug events in pediatric inpatients (Kaushal et al., 2001; Le et al., 2006). As reported in an earlier study, ADE rates in hospitalized children were substantially higher (15.7 per 1000 patient-days) than previously described. However, 22% of all ADEs could be preventable, and 17.8% could have been identified earlier (Takata et al., 2008).

In 2001, the ISMP and the Pediatric Pharmacy Advocacy Group (PPAG) collaborated to produce the nation's first set of guidelines to reduce pediatric medication errors (ISMP, 2001). The American Academy of Pediatrics (AAP) has also taken a lead in making recommendations to reduce errors (AAP, 2003).

Closure of performance gaps and “getting to zero” medication errors will require the constant vigilance from all healthcare professionals and the commitment of hospitals and healthcare systems to implement action in the form of specific leadership, practice and technology plans. This will lead to a decrease in medication errors and a reduction in the occurrence of preventable ADEs in pediatric patients.

Leadership Plan

The hospital board, executives and other senior administrative leadership (medicine, pharmacy and nursing) must fully understand the performance gaps in reducing pADEs at their own healthcare systems. Commitment from all the leaders and stakeholders is necessary for the successful closure of these performance gaps. Leaders should endorse a comprehensive pADE reduction action plan and ensure implementation across all providers and systems. Strategic and tactical approaches that hospital leadership should endorse include the following:

- Establish pADE reduction as a strategic priority by creating a clear metric and goal that are included on the hospital-wide dashboard reviewed by the board and senior executives.
- Invest and allocate funds to:
 - Develop and maintain continuous education programs for healthcare providers with respect to pediatric clinical updates, high alert medications, pADEs monitoring and proper use of drug infusion pumps (Manias et al., 2014; Cimino et al., 2004; Keiffer et al., 2015; Stump, 2000; Wolf, 2016).
 - Support clinical and research programs to develop an educational forum and “Best Practices” model for healthcare providers to expand the body of knowledge in pediatric medicine.
- Encourage and support the use of a simple, real-time pADE reporting system (Stump, 2000).
- Review accurate, up-to-date pADE data at least monthly (Stump, 2000).



- Charter a committee or task force to review the reported data at the hospital and unit levels, generate and implement strategies for improvement, analyze barriers and regularly report to executive leadership.
- Expect a comprehensive root cause analysis of all pADEs that involve serious patient harm. The analysis should include the root cause of the medication error, feedback to the individual linked to the error, implementation of time-bound and evidence-based changes to avoid similar pADEs, and widespread sharing of lessons learned (Stump, 2000).
- Support the development of a lessons learned program to raise awareness among providers across the spectrum of medication delivery about pADE events, risks and improvement efforts using longitudinal data, individual events and near misses.
- Assess staffing and ensure an adequate number of medical, nursing and pharmacy staff specially trained to prescribe, prepare, dispense, and administer medications to children (ISMP, 2003; Catlin, 2004)
- Promote and enhance collaborative communication among all disciplines participating in neonatal and pediatric patient care, including pharmacy staff, patients and families (Fortescue, 2003).
- Consider relevant improvement initiatives and opportunities for collaboration in pADE reduction outside of the pediatric hospital system such as ECLIPSE, FDA-ASHP Standardize for Safety (S4S) Initiatives and OCHSPS (Blandford et al., 2016).
- Implement and disseminate assistive technologies that support community practitioners as they stabilize, treat and transfer neonates and children in higher levels of care.

Practice Plan

- Standardize pediatric medication treatments and usage, as well as the processes for drug administration in pediatric patients. Some strategies include the following:
 - Establish and maintain a functional pediatric formulary system with policies for drug evaluation, selection and therapeutic use (Joint Commission, 2008; ISMP, 2003).
 - Develop and optimize a smart infusion pump drug library with explicit support for intravenous therapy for pediatric patients (Manrique-Rodriguez et al., 2012)
 - Prevent timing errors in medication administration by standardizing the number of days considered in all pediatric protocols upon deciding a treatment start date (e.g., Day 0 or Day 1) (Joint Commission, 2008).
 - Weigh all pediatric patients in kilograms at the time of admission or as soon as possible (i.e., within four hours of admission) in an emergency situation since weight is used to calculate most dosing for children (Joint Commission, 2008).
 - Standardize and limit the number of concentrations and dosage strengths of high alert medications to the minimum needed to reduce potential medication errors (Joint Commission, 2008; Irwin et al., 2008; Hilmas et al., 2009; Murray et al., 2014; Larsen et al., 2005). High alert medications for pediatric patients should be generated by individual hospitals based on their types of pediatric population, infrastructure and unique features (Doherty and Donnell, 2012; Glanzmann et al., 2015).
 - Establish and maintain a functional pediatric formulary system with policies for drug evaluation, selection and therapeutic use (Joint Commission, 2008).
 - Develop age-related treatment algorithms to guide providers to the correct dosing appropriate for the age of the pediatric patient.
 - Age- and weight-related developmental changes in pediatric patients affect the medication use process of specific drugs, and should be taken into consideration. The age-related treatment algorithms will be useful in preventing the use of medications outside the intended patient population.
 - Use reputable, reliable references and protocols to help standardize pediatric medication therapies.
 - Participate and track the progress of the FDA-ASHP Standardize for Safety Initiative.
 - Evaluate clinical guidelines and protocols on a routine basis for sustainability and safety, especially when limited safety and/or efficacy data are available in the pediatric population.
- Develop and implement a pediatric trigger toolkit that will electronically identify high risk medications based on the therapeutic levels, dosages and pADEs.
 - Alignment of the trigger toolkit with clinical protocols specific for the medication.
 - Utilization of an ADE trigger tool method to identify possible adverse events have been shown to ensure more patient safety events compared to voluntary reporting (Burch, 2011; Call et al., 2014).



- The pediatric trigger toolkit is effective at identifying ADEs and reducing the frequency of sentinel events for hospitalized pediatric populations (Takata et al, 2008).
- Create a pediatric multidisciplinary team. This team's responsibilities will include the following:
 - Achieve hospital-wide pADE reduction goals;
 - Monitor accurate, up-to-date pADE metrics;
 - Ensure outstanding event reporting systems, root cause analyses, lessons learned processes and improvement strategies for pADE reduction;
 - Benchmark the adequacy of the features of the individual hospital's medication safety practices and clinical information systems against the proven best practices, identify gaps, and make recommendations.
- Collaborate in a multidisciplinary team (e.g., physicians, pharmacists and nurses) to promote and endorse accountability and responsibility in reporting pADEs from all healthcare providers (Crowther et al., 2011; Stratton et al., 2004).
 - For example, a pharmacy-driven ADE reporting approach, embraced by nurses and physicians, was shown to improve ADE reporting and avoid inconsistency in the information gathered.
 - Develop and ensure comprehensive specialty training for all practitioners involved in the care of pediatric patients, as well as continuous education programs for healthcare providers to stay current and knowledgeable in medications and treatment of pediatric conditions, and be familiar with the ongoing pADE tracking and reporting systems (Joint Commission, 2008; ISMP, 2003).
 - Collaborate with the Informatics Technology team to develop and customize CPOE order sets to help standardize care and medication therapy for specific pediatric disease states (Potts et al., 2003).
 - Develop a team of experts (e.g., physician, pharmacist and nurse) to train healthcare providers at their hospital on how to use the smart infusion pumps with customized pediatric drug libraries (Manrique-Rodriguez et al, 2012).
 - Develop and standardize a smooth and effective communication process for hand-offs (e.g. using a checklist) upon patient transfer to a different unit within the hospital, and upon the transitions of care within and outside clinical settings (Robins and Dai, 2015; Halsyamani et al., 2006; Manias et al., 2015; Manias et al., 2009; Apker et al., 2007).
 - Ensure adequate pharmacy services for pediatric patients to reduce medication errors and ADEs (Manias et al., 2014). The strategies proposed by the American College of Clinical Pharmacy (ACCP) and PPAG include (Bhatt-Mehta et al., 2013):
 - Elevating the minimum expectations for pharmacists entering pediatric practice,
 - Standardizing pediatric pharmacy education,
 - Expanding the current number of pediatric clinical pharmacists,
 - And creating an infrastructure for development of pediatric clinical pharmacists and clinical scientists.
 - Develop and implement pharmacist-managed admission medication histories and medication reconciliation process for pediatric patients, which have shown to prevent potentially significant adverse drug reactions and have a positive impact on patient care (Provine et al., 2014).
 - Develop and implement a discharge prescription review program, led by a clinical pharmacist (with pediatric training preferred), to ensure the medication doses are equivalent to those prepared in the hospital. This is an effective method for reducing prescribing errors in pediatric patients during transition of care (Christiansen et al, 2008).
 - Implement pharmacist-driven processes, such as developing a double- and triple-check system for high alert medications to ensure the "5 Rights", appropriate medication selection, and accurate excipients, dose and concentrations of liquid medications prior to compounding and dispensing them.
 - Develop an education forum for community healthcare providers (e.g., physicians, pharmacists and nurses) about appropriate prescribing and dispensing medications for pediatric patients (Benavides et al., 2011).
 - Disseminate pediatric-specific assistive technologies such as eBroselow (or equivalent) to assure that basic capabilities to stabilize and treat acutely ill or injured children are present 24/7 throughout all environments of care (Damhoff et al., 2014)



Technology Plan

Suggested practices and technologies are limited to those proven to show benefit or are the only known technologies with a particular capability. As other options may exist, please send information on any additional technologies, along with appropriate evidence, to info@patientsafetymovement.org.

Technology has significantly advanced in the last decade within the healthcare setting with development of Electronic Health Records (EHR), CPOE, barcode medication administration (BCMA), bar code assisted medication preparation system (BCMP) and smart pump infusion technology. Multiple studies in pediatrics have demonstrated a decrease in both prescribing errors and ADEs after implementing these technologies (Manias, 2014; Laresen, 2005; Morriss, 2009; Tourel, 2012; Mason, 2014; Morriss, 2011; Hardmeier, 2014; King, 2003; Leung, 2015; Manrique-Rodriguez, 2016; Rinke, 2014). However, most of these systems are designed for use in adult patients and customization is often needed to ensure optimal use in pediatric patients (Ruano, 2016).

- Work with the multidisciplinary healthcare team to develop, improve and optimize the pADE-reporting systems to identify, target, track and monitor pADEs.
- Embed a pediatric trigger toolkit in the CPOE as an alert system for prescribers when medications are ordered out of range or are duplicate therapies (Takata, 2008; Burch, 2011; Call, 2014).
- Develop and optimize real-time surveillance systems to identify high risk/high alert medications and to optimize pediatric patient outcomes via mitigation of pADEs.
- Standardize equipment and measurement systems throughout the institution, such as smart infusion pumps and accurate weight scales for pediatric patients (Stucky, 2003).
- Ensure best practices are used for syringe pumps with medications requiring low infusion rates (<5 mL per hour) to prevent medication errors (FDA, 2016; Sherwin, 2014).
- Ensure that the FDA Safety Communication: “Syringe Pump Problems with Fluid Flow Continuity at Low Infusion Rates Can Result in Serious Clinical Consequences” is reviewed and understood by pharmacists who dispense drugs for use in programmable syringe pumps, by clinical engineers and technicians who maintain programmable syringe pumps, and by caregivers who use or who train users on programmable syringe pumps (FDA, 2016).
 - Promote eLearning modules on this topic, prepared by Massachusetts General Hospital, are freely available at syringeinfusionsafety.org as referenced by the FDA in the Safety Communication.
- Implement and optimize bar coded medication process for pediatric medication products (e.g., multi-dose or unit-dose vials, compounded, and/or repackaged) (ASHP, n.d.).
 - Use a bar code assisted medication preparation system (BCMP) for intravenous sterile compounding in pharmacy, such as Baxter’s DoseEdge Pharmacy Workflow Manager, BD’s Cato™ Medication Workflow Solutions, and Omnicell’s i.v.SOFT® Assist.
 - Use the eBroselow System (or equivalent) as an electronic aid to assist those who compound drugs extemporaneously, in achieving compliance with standardized concentrations that respect fluid balance considerations for small patients and patients with fluid restriction, and are compatible with the performance envelope of drug infusion pumps (Damhoff, 2014).
 - Use the Codonics Safe Label System, or the BD Intelliport Medication Management System, to assure correct source vial identification, container preparation, and Joint Commission- compliant labeling of drugs given by IV push or infusion in the perioperative environment (Nanji, 2016).
- Utilize Continuous Quality Improvement (CQI) software from infusion pump manufacturers to monitor drug library parameters on a routine basis and to report the frequency of command overrides and alerts triggered for unsafe practices (Ohashi, 2013; Bergon-Sendin, 2015).
 - Analyze and proactively respond to identified issues from smart pump data to minimize use of basic mode.
- Develop systems to perform gap and root cause analyses to improve patient and medication safety.
- With technology prevalent in healthcare, physicians, pharmacists and nurses should use both synchronous and asynchronous forms of communication to improve medication safety at the transitional points of care (Manias, 2009).
- Develop and optimize communication technology across healthcare settings, providers and caregivers of the pediatric patients via secured HIPAA-protected lines (e.g., telemedicine and apps).

Workgroup

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Conflicts of Interest Disclosure

The Patient Safety Movement Foundation partners with as many stakeholders as possible to focus on how to address patient safety challenges. The recommendations in the APSS are developed by workgroups that may include patient safety experts, healthcare technology professionals, hospital leaders, patient advocates, and medical technology industry volunteers. Some of the APSS recommend technologies offered by companies involved in the Patient Safety Movement Foundation that the workgroups have concluded, based on available evidence, are beneficial in addressing the patient safety issues addressed in the APSS. Workgroup members are required to disclose any potential conflicts of interest.

*This Workgroup member has reported a financial interest in an organization that provides a medical product or technology recommended in the Technology Plan for this APSS.

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