PATIENT SAFETY MOVEMENT

First, Do No Harm. ZERO by 2030

Pediatric Adverse Drug Events

How To Use This Guide

This guide gives actions and resources for creating and sustaining safe practices for reducing pediatric adverse drug events (pADEs). In it, you'll find:

- Executive summary checklist
- What we know about pediatric adverse drug events
- Leadership plan
- Action plan
- Technology plan
- Measuring outcomes
- Conflicts of interest disclosure
- Workgroup
- References

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Executive Summary Checklist

Pediatric adverse drug events (pADEs) are harm and injury caused by medication in children. During 2008 to 2012, the Institute for Safe Medication Practices (ISMP) reported there were over 45,000 adverse drug events (ADEs) in children less than 18 years old and 64% of the ADEs (29,298) involved a serious injury, including:

- 2,935 (6%) deaths
- 10,032 (22%) hospitalizations
- 1,430 (3%) life threatening cases
- 816 (2%) cases of disability (ISMP, 2014)

Create an action plan

- ☐ Create a multidisciplinary team specialized in neonatal and pediatric medication, nursing, and pharmacy that reports regularly to executive leadership
- ☐ Use a software program to identify, detect, and report pADEs with analysis of the incidence and characteristics of pADEs and the near-misses
- ☐ Set up a closed loop medication administration system with an electronic medication administration record (eMAR) and barcoding, or other technology with computerized provider order entry (CPOE)
- ☐ Collaborate in pADE reduction among all hospital systems during inpatient care and transitions of care

Ensure best patient care

- ☐ Standardize order sets and protocols for each admitting diagnosis
- ☐ Use a CPOE with decision support systems (DSS) including medication reconciliation, allergy checking, interaction checking, and dose range checking with alerts
- ☐ Use a double-check process of medication verification before dispensing high-risk medications
- ☐ Ensure open communication and standardize medication handoffs between healthcare teams at shift changes
- ☐ Use 'smart' drug infusion pumps with drug libraries that include pediatric standardized medication amounts for all weight ranges

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Engage staff and use data to find areas for improvement

- ☐ Use pediatric-specific technologiesto assure that basic resources to treat acutely ill or injured children are present 24/7
- ☐ Ensure that the healthcare team reviews and understands the FDA Safety Communication: "Syringe Pump Problems with Fluid Flow Continuity at Low Infusion Rates Can Result in Serious Clinical Consequences"
- ☐ Use Continuous Quality Improvement (CQI) software from infusion pump manufacturers to routinely monitor drug library parameters and report the frequency of command overrides and alerts
- ☐ Use patient stories – in written and video form – to teach and inspire change in your staff

What We Know About Pediatric Adverse Drug Events

Preventing ADEs in pediatric patients poses unique challenges because children are particularly vulnerable to adverse outcomes from medication errors (preventable adverse events due to wrong medication use). However, it can create a safety culture, which is a culture that promotes patient safety and quality of care while reducing preventable risks and harm.

Children are especially vulnerable to pADEs due to these factors:

- The need for weight-based drug dosing involving multiple calculations
- Series dilution of stock medication solutions
- Immature renal and hepatic functions
- Limited ability to communicate side effects (Kaushal, 2001; Poole and Carleton, 2008)
- Some medications do not have an FDA-specific indication for children - more than 70% of the medications used in pediatrics have not been studied in age-specific populations to assess patient safety (Poole and Carleton,2008; Lindell-Osuagwu et al., 2009)

Problems with the standard treatment

Most medications used in the care of children are made and packaged primarily for adults. There are limited dosage forms and amounts for newborns, infants, and children. Therefore, healthcare professionals must often prepare medications in different volumes or amounts for pediatric patients. Also, if an infusion pump is needed, they must provide an infusion rate that is acceptable and within pump capabilities. When medications are not prepared in the pharmacy, calculation

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errors and admixtures that do not account stability, compatibility, and bioavailability data may pose additional challenges (Joint Commission, 2008).

Studies show that:

- Medication errors in pediatrics are up to 3 times more likely to have a potential pADE compared to those in adults (Kaushal, 2001; Fortescue et al., 2003)
- Compared to other pediatric patient groups, the neonatal ICU patient group has the highest error and potential pADE rate
- pADE rates in hospitalized children are as high as 19.1 per 1000 patient-days (Stockwell et al., 2018)
- 22% of all pADEs could be prevented and 17.8% could have been identified earlier (Takata et al., 2008)
- pADE rates were substantially higher in teaching hospitals, as well as in patients with more chronic conditions (Stockwell et al., 2018).

Preventing pediatric adverse drug events (pADEs)

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, 2018). The American Academy of Pediatrics (AAP) has also taken a lead in making recommendations to reduce errors (AAP, 2003).

To reduce medication errors and preventable pADEs, all healthcare professionals, hospitals, and healthcare systems need to create specific leadership, action, and technology plans. This is especially important for community and rural hospitals, which usually treat a low numberof pediatric patients. The limited experience, infrastructure deficiency, and highly variable training in pediatric prescribing and pharmacotherapy may place patients at increased risk of medication errors (Benjamin et al., 2018; Marcin JP et al., 2007; Dharmar M et al., 2013).

The evidence for reducing pADEs

Research has found that use of an ADE trigger tool that is aligned with clinical protocols specific for a medication can:

- Ensure more patient safety events compared to voluntary reporting (Burch, 2011; Call et al., 2014)
- Identify ADEs and reduce the frequency for hospitalized pediatric populations (Takata et al., 2008)
- Global Assessment of Pediatric Patient Safety (GAPPS) Trigger Tool developed by the

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Center of Excellence for Pediatric Quality Measurement (CEPQM) consists of both the manual approach and the automated approach (for automated screens of EHRs).

- The GAPPS Trigger Tool is shown to reliably identify pADEs and can be used for monitoring quality improvement in healthcare facilities (Landrigan et al., 2016).

Studies in pediatrics have found a decrease in both prescribing errors and ADEs after using technology, including:

- Electronic Health Records (EHR)
- Computerized provider order entry (CPOE) system (York et al., 2019)
- Barcode medication administration (BCMA)
- Bar code assisted medication preparation system (BCMP)
- Smart pump infusion technology (Manias, 2014)

Leadership Plan

Hospital governance, senior administrative leadership, clinical leadership, and safety/risk management leadership need to work collaboratively to reduce pADEs.

To achieve a goal of zero preventable deaths, leaders need to commit to taking these key actions.

Show leadership's commitment to pADEs

- The hospital board, executives, and other senior administrative leadership (medicine, pharmacy, and nursing) must fully understand the performance gaps (the difference between the safety measurements and the ideal) in reducing pADEs at their own healthcare systems
- Leaders should endorse a comprehensive pADE reduction action plan and ensure it's applied across all providers and systems
- Create a clear metric and goal to make pADE reduction a strategic priority - include the metric and goal on the hospital-wide dashboard reviewed by the board and senior executives
- Invest and assign funds to:
  - Create and maintain continuous education programs for healthcare providers about 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 create "Best Practices" in pediatric medicine

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Engage staff

- Promote communication among all disciplines involved in pediatric patient care, including pharmacy staff, patients, and families (Fortescue, et al., 2003)
- Use patient stories – in written and video form – to teach and inspire change in your staff

Make policy changes

- Review pADE data at least monthly (Stump, 2000) – create a committee or task force to review the reported data at the hospital and unit levels, create strategies for improvement, analyze barriers, and report to executive leadership
- Expect a root cause analysis of all pADEs that involve serious patient harm that includes:
  - Root cause of the medication error
  - Feedback to the individual linked to the error
  - Time-bound and evidence-based changes to avoid similar pADEs
  - Sharing of lessons learned (Stump, 2000)
- Support lessons learned programs to raise awareness about pADE events, risks, and improvement efforts among providers
- Assess staff and ensure an adequate number of medical, nursing, and pharmacy staff specially trained to prescribe, prepare, dispense, and give medications to children (ISMP, 2018; Catlin, 2004)

Create the infrastructure needed to make changes

- Encourage and support the use of a simple, real-time pADE reporting system (Stump, 2000)
- Consider opportunities for collaboration in pADE reduction both among and outside of the pediatric hospital system, such as:
  - The Exploring the Current Landscape of Intravenous Infusion Practices and Errors (ECLIPSE)
  - DA-ASHP Standardize for Safety (S4S) Initiatives
  - Ohio Children's Hospitals' Solutions for Patient Safety (OCHSPS) (Blandford et al., 2016)
- Use and share technology that supports community practitioners as they treat and transfer infants and children

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Action Plan

Ensure accountability

- Create and maintain a pediatric formulary system with policies for medication evaluation, selection, and use (Joint Commission, 2008; ISMP, 2018)
- Create a smart infusion pump drug library with support for intravenous therapy for pediatric patients (Manrique-Rodriguez et al., 2012)
- Create a pediatric multidisciplinary team to:
  - Achieve hospital-wide pADE reduction goals
  - Monitor 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
- Ensure adequate pharmacy services for pediatric patients to reduce medication errors and ADEs (Manias et al., 2014) based on strategies proposed by the American College of Clinical Pharmacy (ACCP) and the Pediatric Pharmacy Advocacy Group (PPAG) (Bhatt-Mehta et al., 2013), and the guidelines for providing pediatric pharmacy services in hospital and health systems developed by American Society of Health-System Pharmacists (ASHP)-PPAG (Eiland et al., 2018):
  - Elevate the minimum expectations for pharmacists entering pediatric practice
  - Standard pediatric pharmacy education
  - Expand the current number of pediatric clinical pharmacists
  - Create an infrastructure for training of pediatric clinical pharmacists and healthcare professionals.
  - When possible, 24-hour pharmacy services should be available for the pediatric population, especially in specialized, high-risk units (e.g., pediatric intensive care units, neonatal ICU, hematology-oncology unit, operating rooms, and emergency department)
- Create pharmacist-driven processes, such as:
  - Admission medication histories and reconciliation process for pediatric patients (Provine, Simmons, and Bhagat, et al., 2014)

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- Discharge prescription review program, led by a clinical pharmacist (with pediatric training preferred), to ensure the doses are the same with those prepared in the hospital (Christiansen, Hilmas, Morgan, and Shepardson, et al., 2008)
- A double- and triple-check system for high alert medications to ensure the "5 Rights", appropriate medication selection, accurate excipients, dose, and concentrations of liquid medication prior to compounding and dispensing them
- Managing drug product shortages including development of strategies for identifying alternative therapies, working with suppliers, collaborating with physicians and other healthcare providers as well as the Pharmacy and Therapeutics P&T committee for specific clinical changes affecting pediatric patient care (Eiland et al., 2018). For more information about mitigating drug shortages please refer to APSS #3F: Drug Shortages.

- Standardize equipment and measurement systems throughout the institution, such as smart infusion pumps and weight scales for pediatric patients (Stucky, E.R., 2003)
- Ensure best practices are used for syringe pumps with medications that require low infusion rates (<5 mL per hour) (USFDA, 2016)

Create protocols

- Prevent timing errors in medication administration by:
  - Using a standard number of days in all pediatric protocols for treatment start date, such as Day 0 or Day 1 (Joint Commission, 2008)
  - Standardizing and limiting the number of concentrations and dosage strengths of high alert medications to the minimum needed (Joint Commission, 2008; Irwin et al., 2008; Hilmas, Sowan, Gaffoor, and Vaidya, 2009; Murray et al., 2014; Larsen et al., 2005)
- Weigh and record all pediatric patients in kilograms only at the time of admission, or as soon as possible (i.e., within four hours of admission) in an emergency situation - weight is used to calculate most dosing for children (Joint Commission, 2008)
- List high alert medications for pediatric patients based on your types of pediatric population, infrastructure, and unique features (Doherty and Donnell, 2012; Glanzmann, Frey, Meier, and Vonbach, et al., 2015)
- Create age-related treatment algorithms to guide providers to the correct dose for the child's age
- Use reliable references and protocols to standardize pediatric medication therapies
- Create CPOE order sets to help standardize care and medication therapy for specific pediatric disease states with embedded dosing range maximums (Potts et al., 2003)

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- 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) – it should electronically identify high risk medications based on the therapeutic levels, doses, and pADEs
- Create 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, Mallack, and Gibson, 2007

Provide training in pediatric medication safety

- Create and integrate dedicated training in pediatric medication safety in the core curricula of professional training programs in medical, nursing, and pharmacy schools (Mueller et al., 2019; Benjamin et al., 2018; Szymusiak et al., 2018). For more on the curriculum training, see AEBP #17)
- Create specialty training for all practitioners involved in the care of pediatric patients,
- as well as continuous education programs for healthcare providers to stay current in medications and treatment of pediatric conditions, and be familiar with the ongoing pADE tracking and reporting systems (Joint Commission, 2008; ISMP, 2003)
- Create 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., 2012b)
- Have a dedicated pharmacist who is specifically trained or certified in pediatrics pharmacy practice to oversee the pharmacotherapy of pediatric patients
- Create an education forum for community healthcare providers (e.g., physicians, pharmacists, and nurses) about appropriate prescribing and dispensing medications for pediatric patients (Benavides, Huynh, Morgan, and Briars, 2011)
- Have all staff and caregivers who use programmable syringe pumps review and understand the FDA Safety Communication: "Syringe Pump Problems with Fluid Flow Continuity at Low Infusion Rates Can Result in Serious Clinical Consequences" (FDA, 2016) - use Massachusetts General Hospital eLearning modules on this topic, that are free at http://patient.sm/PGP6Zu

Track and analyze your progress

- Take part in 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, AEBP especially when there is limited safety and efficacy data in the pediatric population

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- Use Continuous Quality Improvement (CQI) software from infusion pump manufacturers to routinely track drug library parameters and to report the frequency of command overrides and alerts triggered for unsafe practices (Ohashi, 2013; Bergon-Sendin, 2015)
- Analyze and respond to identified issues from smart pump data

Report outcomes inside your organization and share best practices outside your organization

- 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, Buck, McCarthy, and Barton, 2011; Stratton, Blegen, Pepper, and Vaughn, 2004)
- Work with the multidisciplinary healthcare team to create, improve, and optimize reporting systems to identify, target, track, and monitor pADEs
- Create real-time surveillance systems to identify high risk/high alert medications and avoid pADEs
- Share 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, Kuhn, and Baker-Justice, 2014)

Technology Plan

These suggested practices and technologies have shown proven benefit or, in some cases, are the only known technologies for certain tasks. If you know of other options not listed here, please complete the form for the PSMF Technology Vetting Workgroup to consider: http://patient.sm/2sopQK

SYSTEM OR PRACTICE	AVAILABLE TECHNOLGY
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following abilities: • Computerized Provider Order Entry (CPOE) • Drug-drug interaction check • Drug-allergy interaction check • Clinical Decision Support tools (CDS)	

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Standardized measuring tools for liquid pediatric oral medication	• Oral syringes with better accuracy (Yin et al., 2016) • Provide measuring tools closely matched to prescribed dose (Yin, et al., 2017)
Enhance the accessibility of tertiary care for children, especially in rural and underserved areas	• Using telemedicine consultations in rural ED to reduce physician-related ED medication errors and to improve patient safety among seriously ill and injured children (Dharmar et al., 2013; Yang et al., 2015) o Secure electronic communications, information exchange, or other methods that meet applicable state and federal requirements. • Implementing a telepharmacy services to provide round-the-clock medication order review by pharmacists to reduce prescribing errors (Wakefield, Ward, Loes, O'Brien, & Sperry, 2010)
Bar coded medication process for pediatric medication products (e.g., multi-dose or unit-dose vials, compounded, and/or repackaged) (ASHP, 2013.; Eiland et al., 2018)	• Use a bar code assisted medication preparation system (BCMP) for intravenous sterile compounding in pharmacy, • Use an electronic aid to help those who compound parenteral medications on their own to standardized concentrations for fluid balance considerations for small patients and patients with fluid restriction (Damhoff, Kuhn, and Baker-Justice, et al., 2014) • 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).

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Measuring Outcomes

The most appropriate metric is the measure of adverse drug events. For more on this measurement, see AEBP #3A.

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 APSSs recommend technologies that are offered by companies involved in the Patient Safety Movement Foundation. The workgroups have concluded, based on available evidence, that these technologies work to address APSS patient safety issues. Workgroup members are required to disclose any potential conflicts of interest.

Workgroup

Co-Chairs

Ron Jordan	Chapman University School of Pharmacy
Jerika Lam	Chapman University School of Pharmacy
Nathaniel Sims	Massachusetts General Hospital
Sun (Coco) Yang	Chapman University School of Pharmacy
Christopher Jerry	The Emily Jerry Foundation

Members

This list represents all contributors to this document since inception of the Actionable Patient Safety Solutions.

Hania Alim	Patient Safety Movement Foundation
Peter Antevy	Handtevy
Steven Barker	Masimo; Patient Safety Movement Foundation

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***Linda Beneze**	Monarch Medical Technologies
Michel Bennett	Patient Safety Movement Foundation (formerly)
Laressa Bethishou	Chapman University School of Pharmacy
***Jim Broselow**	eBroselow
John Burnam	Louise H. Batz Patient Safety Foundation
Mitchell Goldstein	Loma Linda Medical Center
Kari Hamlin	Hackensack Medical Center
Helen Haskell	Mothers Against Medical Error
Soojin Jun	Quorum Health
Edwin Loftin	Parrish Medical Center
Ariana Longley	Patient Safety Movement Foundation
Jacob Lopez	Patient Safety Movement Foundation (formerly)
Olivia Lounsbury	Patient Safety Movement Foundation
Anne Lyren	Children's Hospitals' Solutions for Patient Safety
Brendan Miney	Talis Clinical
Sidney Morice	Lee Health
Lisa Morrise	Consumers Advancing Patient Safety
Steve Mullenix	National Council for Prescription Drug Programs
***Flannery Nangle**	Monarch Medical Technologies
Donna Prosser	Patient Safety Movement Foundation
Talia Puzantian	Keck Graduate Institute
Judith Reiss	Advocate
Claire Roy	Patient Safety Movement Foundation
Rochelle Sandell	Patient Advocate
Enrique Seoane-Vasquez	Chapman University School of Pharmacy
Alex Shaffer	Advocate
David Shane Lowry	Rosalind Franklin University of Medicine and Science
Robin Shannon	The T System

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Deeba Siddiqui	Hackensack Medical Center
Charles Simmons	Cedars-Sinai Medical Center
Nat Sims	Massachusetts General Hospital
Robert Stein	Keck Graduate Institute
Laura Townsend	Louise H. Batz Patient Safety Foundation
Kimberly Won	Chapman University School of Pharmacy
Jason Yamaki	Chapman University School of Pharmacy

Metrics integrity

Robin Betts	Kaiser Permanente, Northern California Region

*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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