



How-to-guide Pediatric supplement High Alert Medications

Pediatric Affinity Group



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Working in concert with the following leadership hospitals: Arkansas Children's Hospital, Cincinnati Children's Hospital, Johns Hopkins Children's Center, Children's Hospitals and Clinics in Minnesota, Children's Hospital of Philadelphia, Lucille Packard Children's Hospital at Stanford, Primary Children's Medical Center and acknowledges the contribution of the ISMP and IHI in the development of this work.

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These documents are recommendations and the user is responsible for implementation and ultimate outcome

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I. Scope of Problem and Description of Need in Pediatrics

Goal: To prevent harm from high-alert medications by implementing the changes in care recommended in the IHI Guide and this supplement for pediatric clinical settings.

Medication administration in pediatrics is a complex process. The Institute for Safe Medication Practices identified several factors in the medication system that contribute to error and increased risk for adverse drug events in children. There is a lack of published information or FDA approved labeling regarding dosing, pharmacokinetics, safety, efficacy and clinical use of drugs in the pediatric population. Pediatric clinicians often must perform complicated calculations for individual doses based on age, weight, body surface area and clinical condition. Dosage forms and concentrations appropriate for administration to neonates, infants, and children are not always available and dosage formulations are often extemporaneously compounded. This requires nurses and pharmacists to calculate and prepare dilutions from adult unit-dose packages for intravenous medications as well as provide precise dose measurement and appropriate drug delivery systems.

Furthermore, because of the different and changing pharmacokinetic parameters between patients at various ages and stages of maturational development, children are at increased risk for adverse drug reactions. Young children cannot serve as a check on the medication administration system. They cannot recognize if a preparation of a medication is different from previously prescribed or describe side effects that might serve as an early warning sign of potential harm. Pediatric patients are therefore especially vulnerable for adverse events from high alert medications.

The Institute for Healthcare Improvement (IHI) elected to focus on High Alert Medications as one component of their 5 Million Lives Campaign. As defined by the Institute of Safe Medication Practice, high-alert medications are “drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error with these medications are clearly more devastating to patients.”

Although evidence documenting harm from high alert medications is somewhat limited in pediatrics, the Pediatric Affinity Group recommends pediatric clinical teams focus improvement efforts in this area based on the following data:

- During a Collaborative of pediatric hospitals led by the Child Health Corporation of America (CHCA), participating hospitals identified a rate of 5.2 narcotic-related ADEs for every 100 patients.
-CHCA Improvement Case Study

- In a descriptive study from the MEDMARX data from January 1, 1999 through December, 31, 2003, eleven medications accounted for more than one third of reported errors (n=261 or 34.5%) in children. Wrong dosing and omission errors were common and were associated with therapeutic classes such as opioid analgesics, antimicrobial agents and diabetic agents.
 - Hicks, R, Becker, S. Cousins, D. Harmful medication errors in children: a 5-year analysis of data fro the USP's MEDMARX program. *Journal of Pediatric Nursing* 2006, 21 (4): 290-298.
- Although sedation studies vary in reported rate of complication, the risk is overall moderate at 5-20% (Waterman). Risk varies by age, drug choice, sedation provider, and underlying co-morbid conditions (Waterman, Heistein, Cravero). Most common complications are desaturations, emesis, increased secretions, and apnea (Cravero).
- In a study of sedation of children, 239 (20.1%) experience adverse events related to sedation, including inadequate sedation in 150 (13.2%) and decrease in oxygen saturation in 63 (5.5%). Five of these children experienced airway obstruction and two became apneic.
 - Malviya S. Adverse events and risk factors associated with the sedation of children by non anesthesiologists. *Anesthesia Anal.* 1997; 85: 1207-1213.
- Adverse sedation events were frequently associated with drug overdoses and drug interactions, particularly when 3 or more drugs were used. Of the events associated with opioids, 61% resulted in death or permanent neurologic injury. Adverse outcome was associated with all routes of drug administration and all classes of medication, even those (such as chloral hydrate) thought to have minimal effect on respiration. (also cite Heistein here; though their conclusion was that chloral hydrate is "safe", the complications are listed and statement made that <6mo olds have higher rate of complications). Combinations of sedatives with narcotics such as morphine have been associated with increased complication rate, thought to be due in part to the elimination of the noxious stimulus (pain) that may stimulate respiration (Waterman).
 - Cote, CJ, Karl, HW, Notterman, DA, Weinberg, JA & McCloskey, C. Adverse sedation events in pediatrics: analysis of medications used for sedation. *Pediatrics*2000; 106 (4): 633-644.
- Multiple sedative use accounted for 42% of preventable ADE's in the intervention group.
 - Computerized Order Entry on Inpatient Services Reduces Adverse Drug Events. Department of Pediatrics and Communicable Diseases, University of Michigan Health System.

II. Evidence for Initial Selection of Dopamine, Insulin and Morphine

Drug classes associated with pediatric medication errors mirror those from the adult literature, yet have age, weight-based, and calculation-related specific variations of importance. For children, calculation errors are common and often result in 10-fold errors (AAP Policy Inpt Med Errors statement 2003). A number of studies have reported on frequent errors with use of insulin, narcotics, and vasoactive drips (Kaushal 2001; Rothchild 2005; Wang 2007). One large recent study performed by Medmarx of 53 member institutions reviewed almost 20,000 pediatric medication errors (Hicks JPN 2006). Improper dose and prescribing error were 2 of the top 3 reasons for error commitment in this study. Narcotic opioid analgesics morphine and fentanyl were the most commonly reported products to be associated with errors, cited in 11.5% of the records reviewed. Insulin was the third most commonly cited drug (4.5%), with the inotrope dopamine listed in the 6th most common therapeutic class associated with harmful errors.

Specifically for *insulin*, the Medmarx study found errors were due to miscalculation of the amount to be withdrawn from the vial, unclear sliding scale insulin orders, and misprogramming of infusion pumps used for insulin drips. Insulin is available in various formulations (IV, subcutaneous, inhaled), requires calculation and administration of different formulations often at the same time, and frequently includes transition from one method of administration to another. It is commonly used in many hospital units and the outpatient setting. Errors may be associated with significant morbidity or even mortality. These areas of risk, coupled with the added need to invest families in the inpatient and discharge medication education process, make insulin a logical choice for a pediatric-specific high alert medication example.

Morphine is a commonly prescribed analgesic used in outpatient, emergency, inpatient and operative/post-operative settings. It can be delivered by multiple routes (IV, oral, inhaled, intrathecal, nurse/patient controlled analgesia infusions) and has different formulations including extended release. Pediatric-specific issues are many, and include varying volume of drug distributions, severity and frequency of respiratory depression and hypotension (Cucchiaro 2003, Brown 2006, Enders 2006, Ganesh 2007, Viscuzi 2007). All of these issues, combined with the increasing performance of sedation for painful procedures outside the operating suite and risk of significant morbidity and mortality with even a single mis-dose make morphine a model high alert drug for children.

Infused drips such as inotropic medications still may be associated with errors despite use of 'smart pumps' (Lehman 2006, Larsen 2005). Use of standard dosing concentrations has been recommended by the Joint Commission for Accreditation of Hospitals and Organizations (JCAHO National Patient Safety

Goal 3B- ref). Issues still remain around system enhancements needed for effective implementation (pumps, pharmacists, other), fluid volume restrictions (particularly for neonatal patients), and bedside patient-specific tables needed for safe rapid rate adjustments. *Dopamine* is a constant infusion inotrope commonly used in critically ill pediatric patients of all ages and sizes, and thus suitable for use as the template drug for infused high alert medications.

III. How and where to get started

General principles for reducing harm from high alert medications in pediatrics

As described in the IHI How to Guide, pediatric hospitals and pediatric inpatient services should employ the following general principles of a safe system:

- Design processes to prevent errors and harm – e.g. ensure standardization
- Improve methods to identify errors and harm when they – e.g. ensure adequate monitoring
- Design methods to mitigate harm that may result – e.g. partner with patients and families (we should discuss this); develop protocols to administer antidotes

Specific adaptations and modifications for pediatrics are:

a. Methods to prevent errors and harm:

- Standardize concentrations and dose strengths to the minimal few needed to provide safe care (**See Appendix A**)
- Develop order sets, preprinted order forms and clinical pathways or protocols to reflect a standardized approach to care (**See Appendix B**)
- Include reminders and information about monitoring parameters in order sets, protocols, and flow sheets
- If using smart pump technology, consult with expert colleagues who have already developed the drug libraries for preset limits – this is a high-risk transition unless done carefully.
 - Continue to use double-check technique for medication bag selection before administration

Smart pumps are IV pumps that have software that checks programmed doses against preset limits specific to a drug and clinical location. --- Depending on preset limits, the clinician may either override an alert (soft limit) or not be allowed to continue at all (hard limit);

- If not using smart pump technology, ensure an independent double-check by nursing and/or pharmacy or a combination on drug product, dose, and infusion pump settings for all high-alert medications

- Review organizational policies and procedures for independent nurse check during the selection of high alert medications for bag selection unless using bar code technology
- Require weight based dosing, in kilograms, with upper limits for dosing; address special considerations for morbid obesity and drug-drug interactions
- Separate products that look alike
<http://www.ihl.org/IHI/Topics/PatientSafety/MedicationSystems/Changes/IndividualChanges/Separate%20Drugs%20that%20Look%20or%20Sound%20Alike>
- Have pharmacy prepare, ready-to-use doses, to minimize risk for errors during drug selection and preparation by nursing staff

Drug specific recommendations:

Dopamine

- Standardize dopamine infusions to the fewest needed to provide safe care

Insulin

- Standardize insulin infusion orders
- Prepare all infusions in the pharmacy and standardize to a single concentration of IV-infusion, if possible. The aim is to get to the fewest number of concentrations with the goal of getting to one concentration.
- If more than one concentration, build error proofing techniques to minimize mix up of available concentrations
- Eliminate the use of sliding insulin dosage scales if possible; if a sliding scale is used, standardize it through the use of a protocol and preprinted order form that clearly designates the specific increments of insulin coverage
- Require an independent double-check of the drug, concentration, dose, and pump settings
- Separate types of insulin by labeling, by time, and by distance
- For neonates
 - Use insulin 100 units/mL for doses 5 units or greater using a U100 insulin syringe.
 - For doses less than 5 units, have pharmacy prepare and label a 10 units/mL concentration and use a 1 mL tuberculin syringe with 0.01 mL graduations (1 unit equals 0.1 mL).
 - Otherwise, consider IV infusion for insulin delivery – from the ISMP;

Narcotics

- Standardize pain management protocols that includes documentation of vital signs and pain score following each dose
- Engage patient/family in plan for pain management to establish mutual expectations between family and care team

- Consult a pain specialist if the patient is not reaching the sedation/pain management goals set by the care plan. *The goal is to provide appropriate pain relief and minimize harm associated with this group of medications*
- Increase the use of non-pharmacologic intervention for pain and anxiety

b. *Methods to identify errors and harm:*

- Ensure that critical laboratory information is available to those who need the information and can take action
- Ensure timely response to event reports involving high alert medications

Drug specific recommendations:

Dopamine

- Ensure appropriate cardiovascular and respiratory monitoring during administration

Insulin

- Monitor blood sugar with more rapid testing of blood sugar
- Include monitoring parameters in order sets

Morphine

- Ensure appropriate cardiovascular and respiratory monitoring during administration
- Develop order sets and standard monitoring procedures and documentation to ensure appropriate monitoring occurs

c. *Methods to mitigate harm:*

- Develop protocols for the administration of reversal agents without having to contact the physician prior to their administration
- Ensure antidotes and reversal agents are readily available
- Engaging patients and families in reducing harm from high-alert medications
- Include family in medication reconciliation process at admission, transfer and discharge
- Ensure patients/family always have an accurate list of all medications
- Encourage parents to ask questions about medication names and side effects and ensure that prescriptions are legible
- Encourage parents to report differences in colors of medications, changes in their child that could reflect an early side effect or any other question/concern they have about medications
- Engage parents in monitoring process and procedures
- Encourage patients/families to question doses, timing, and administration of all medications

- Use *Ask Me* Initiative (See Appendix C)
- Use dry erase board in room to identify parent/guardian questions about medications and other care issues

IV. Tips for Getting Started

1. Getting organized

- Identify project champion from the physician group, nursing, and pharmacy
- Engage key stakeholder groups; P&T committee, medical staff, nursing pharmacy committee, parent advisory group
- Complete an institutional assessment; options include:
 - Flow chart existing prescribing process particularly for non-standard concentrations
 - Ask pharmacy what high alert medications are most commonly used
 - Review all preprinted forms for concentrations used; count the number of concentrations for all high alert medication
 - Complete ISMP self-assessment and retrospective review to monitor the reliability of existing care processes (at www.ismp.org)
- Ask yourself, if you have standardized process, how often are they used? “How reliable are our processes?”
 - Is the protocol or order set being used; if yes, how often. If used less than 95% of the time, ask “Why?”
 - Is the protocol or order set being used, as designed?
 - Do you use dose-conversion charts to minimize errors when changing from one medication to another? If yes, how often are they used?
- Ask yourself, “How robust are our detection systems?”
 - Do you have methods to intercept errors? Such as, total volume, flow and lockouts
 - Review your data from smart pumps, if available
 - Evaluate the reliability of your independent double check system using a MAR chart audit
- Link this initiative with larger system issues; use links that are high value for the organization such as reconciling medications
- Use data from a variety of sources to assess opportunities for improvement
 - Pharmacy database – e.g. pharmacy intervention reports with frequency of rewrites, near misses, calls about errors
 - Incident reporting forms – did or did they not reach the patient?

2. Pick one high-alert medication, to get started

- Reduce the number of concentrations of high alert medications

- If necessary, start making changes in small increments rather than attempting a larger change to existing systems

3. Plan your measurement strategy

- Consider measuring harm experienced by patients in your institution by using the trigger tool methodology
[http://www.ihl.org/IHI/Topics/PatientSafety/MedicationSystems/Tools/Trigger%20Tool%20for%20Measuring%20Adverse%20Drug%20Events%20\(IHI%20Tool\)](http://www.ihl.org/IHI/Topics/PatientSafety/MedicationSystems/Tools/Trigger%20Tool%20for%20Measuring%20Adverse%20Drug%20Events%20(IHI%20Tool))
- Use drug specific trigger tools, if focusing on harm from one class of high-risk medications
- Apply efforts direction toward issues and specific harmful events to global improvement efforts
- If unable to use trigger tool on a regular basis, consider a pre-post methodology following improvement efforts; repeat measurement as needed
 - a. Examples of recommended process measure:
 - Percent of patients receiving [high alert medication] with a protocol in place
 - Percent of patients receiving [high alert medication] with treatment managed according to protocol
 - b. Examples of recommended outcome measure:
 - Adverse Drug Events (ADE) related to [high alert medication] per 100 admissions with [high alert medication] administered

V. Appendices:

- A. Standard concentration sheet - University of Maryland
Calculation tools
- B. Sample order sets
Lucille Packard
Rady Children's Hospital
- C. Ask Me initiative
<http://www.askme3.org/iom.asp>
http://www.askme3.org/pdfs/4970J_Eng_FH.pdf
- D. San Diego Patient Safety Consortium – Getting Started Kit
San Diego Patient Safety Consortium. Getting Started Kit: Safe Administration of High-Risk IV Medications. Intra-and Inter-Hospital Standardization: Drug Concentrations and Dosage Units. How to Guide. (2005).

VI. Helpful Guidelines

- The USP** - Error Avoidance Recommendations for Medications Used in Pediatric Populations
<http://www.usp.org/hqi/patientSafety/resources/pedRecommnds2003-01-22.html>
- The American Academy of Pediatrics** - Prevention of Medication Errors in the Pediatric Inpatient Setting.
http://www.guideline.gov/summary/summary.aspx?ss=15&doc_id=4253&nbr=3253
- The Institute for Safe Medication Practices** - Pediatric Pharmacy Medication Safety Guidelines Seen as Important Step in Reducing Medication Errors
<http://www.ismp.org/pressroom/PR20020606.pdf>
- Pediatric Critical Care Website** – Pediatric Emergency Medications Drip Sheet Calculator
<http://www.supermagnus.com/med/drips/>

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<http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/>.
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