Ensuring Medication Safety in Pediatrics

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Objectives

Describe unique risk factors of pediatric patients that make them prone to medication errors.

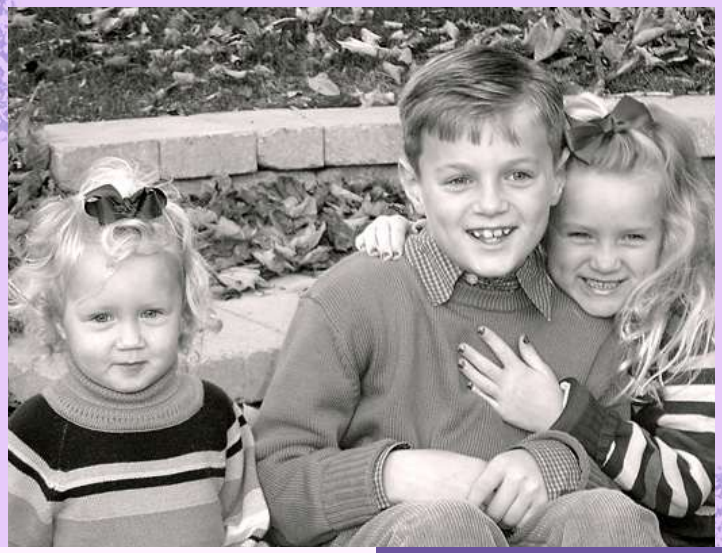
Identify evidence-based medication safety strategies in prescribing, dispensing, and monitoring pediatric medications.

Recognize the pharmacist's role in pediatric medication safety.

What is a medication error?

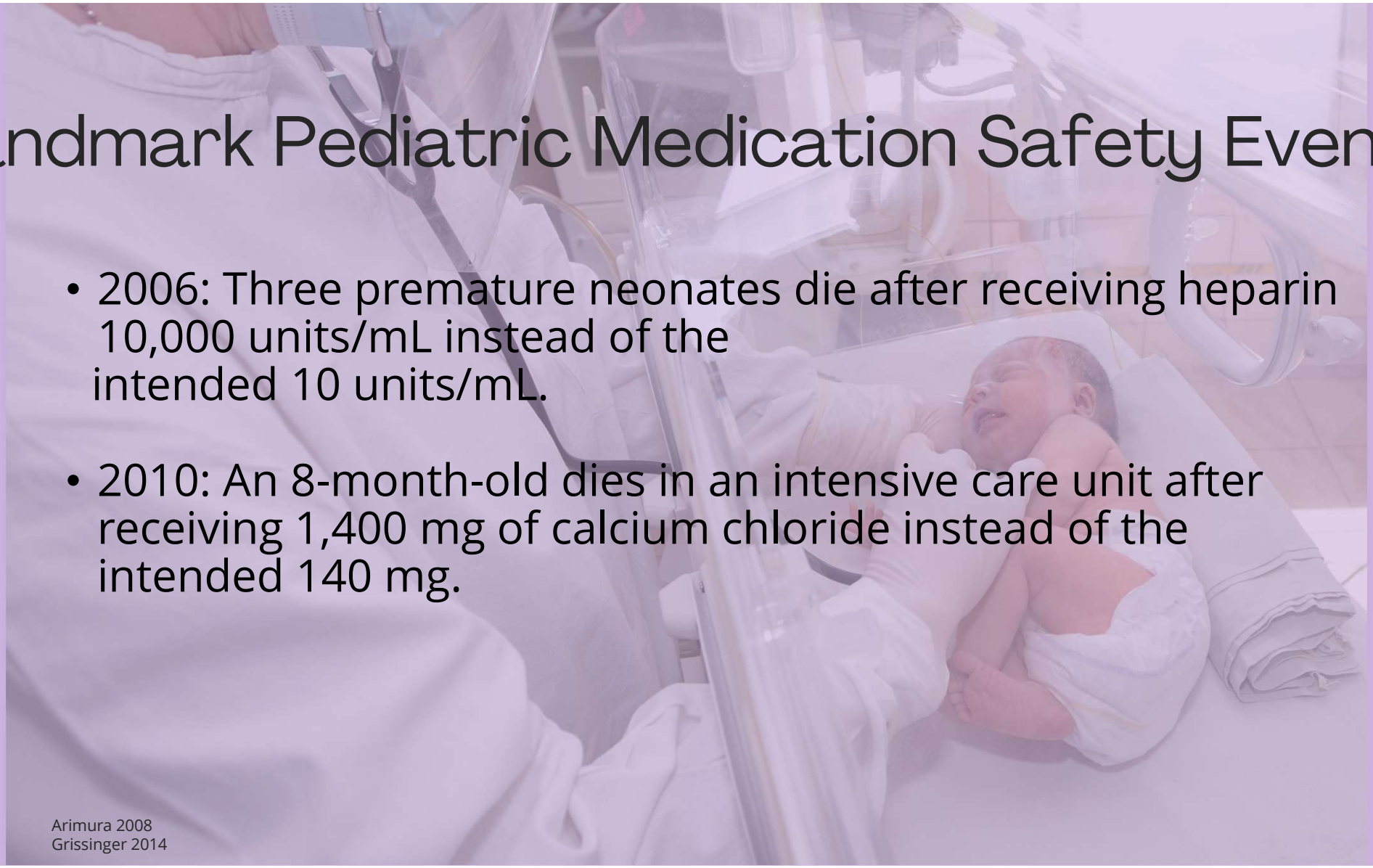
"A medication error is any **preventable** event that may cause or lead to **inappropriate medication use** or **patient harm** while the medication is in the control of the health care professional, patient, or consumer."

NCC MERP 2026
Josie King Foundation 2026
Joint Commission 2026



Emily Jerry

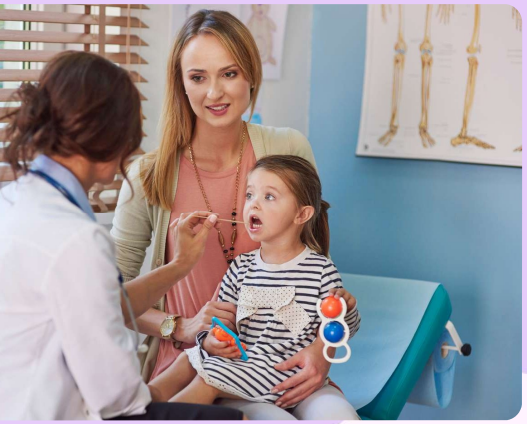
Landmark Pediatric Medication Safety Events



- 2006: Three premature neonates die after receiving heparin 10,000 units/mL instead of the intended 10 units/mL.
- 2010: An 8-month-old dies in an intensive care unit after receiving 1,400 mg of calcium chloride instead of the intended 140 mg.

Arimura 2008
Grissinger 2014

Why Pediatric Medication Safety Matters?

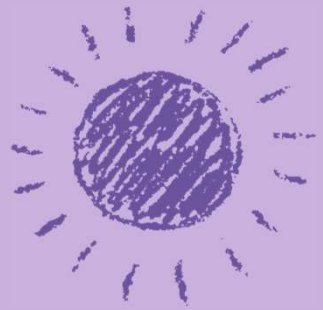


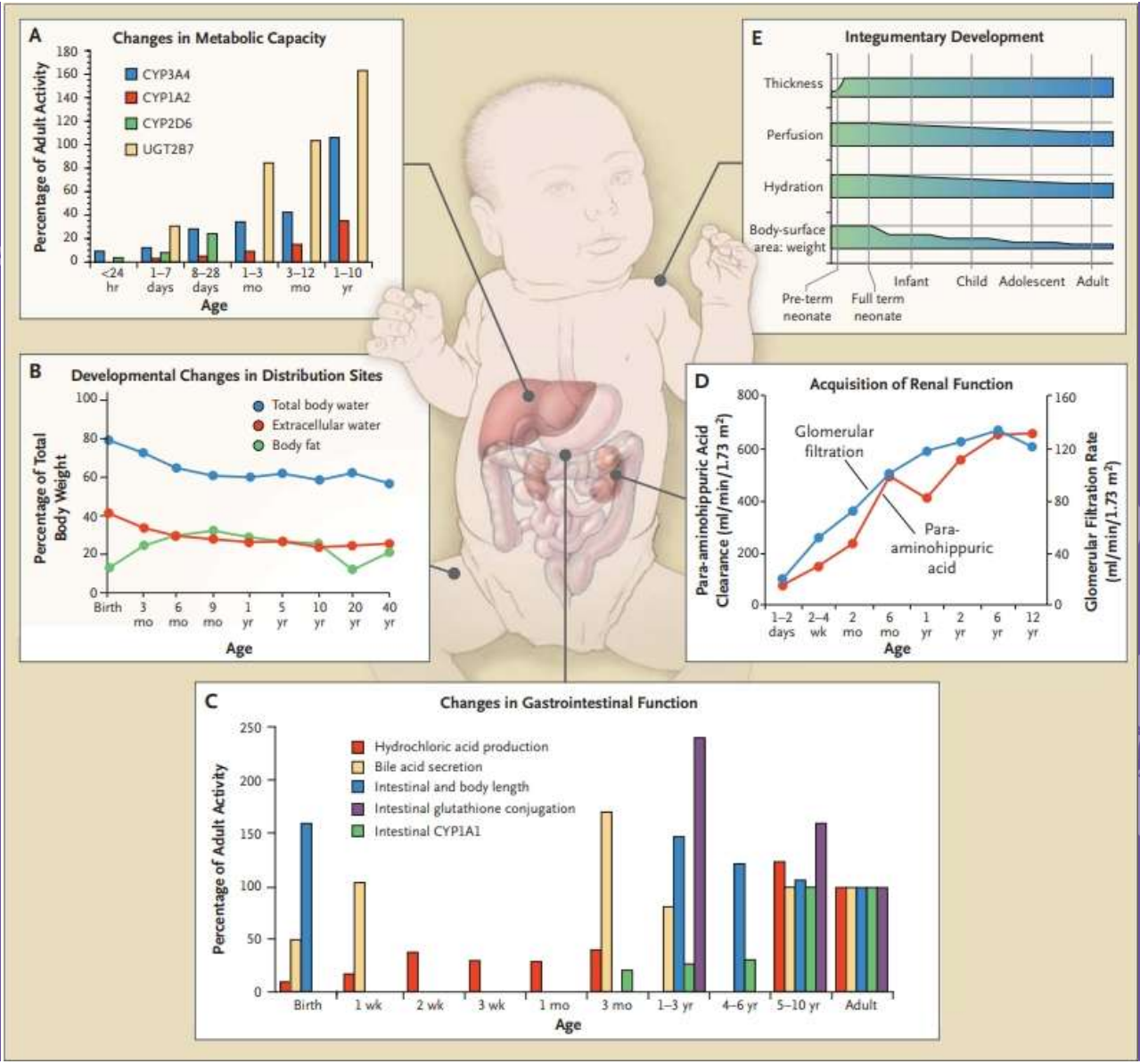
- Medication error rate ~ 5.7 per 100 medication orders
  - Potential ADE rate 3 times higher than adult patients
  - Significantly higher potential ADE rate in neonates
- Improper dose/quantity is the most common error type
  - 79% ADEs occurred in prescribing phase and involved:
    - incorrect dosing
    - anti-infectives
    - intravenous medications

Kaushal 2001
Gates 2018
Alghamdi1 2019
Arimura 2008

What makes Pediatric Patients Unique?

- Age-dependent pharmacokinetics
- Weight-base dosing and calculations
- Limited ability of pediatric patients to identify or communicate medication errors
- Frequent off-label medication use in children
- Availability and use of appropriate measurement devices




A
Changes in Metabolic Capacity
Percentage of Adult Activity
CYP3A4
CYP1A2
CYP2D6
UGT2B7
<24 hr
1–7 days
8–28 days
1–3 mo
3–12 mo
1–10 yr
Age
E
Integumentary Development
Thickness
Perfusion
Hydration
Body-surface area: weight
Pre-term neonate
Full term neonate
Infant
Child
Adolescent
Adult
B
Developmental Changes in Distribution Sites
Percentage of Total Body Weight
Total body water
Extracellular water
Body fat
Birth
3 mo
6 mo
9 mo
1 yr
5 yr
10 yr
20 yr
40 yr
Age
D
Acquisition of Renal Function
Para-aminohippuric Acid Clearance (ml/min/1.73 m²)
Glomerular Filtration Rate (ml/min/1.73 m²)
Glomerular filtration
Para-aminohippuric acid
1–2 days
2–4 wk
2 mo
6 mo
1 yr
2 yr
6 yr
12 yr
Age
C
Changes in Gastrointestinal Function
Percentage of Adult Activity
Hydrochloric acid production
Bile acid secretion
Intestinal and body length
Intestinal glutathione conjugation
Intestinal CYP1A1
Birth
1 wk
2 wk
3 wk
1 mo
3 mo
1–3 yr
4–6 yr
5–10 yr
Adult
Age

Kearns 2003

Table 1. Examples of Age-Specific Usual Doses of Drugs Commonly Used in Pediatric Medicine.*

Drug	Average Dose				Primary Determinants of Difference in Age-Related Doses
	Neonates	Infants	Children	Adults	
Gentamicin	2.5 mg/kg every 12 hr	2.5 mg/kg every 6–8 hr	2.5 mg/kg every 8 hr	1–2 mg/kg every 8 hr	Pharmacokinetic: apparent renal clearance and apparent volume of distribution
Ceftazidime	50 mg/kg every 12 hr	50 mg/kg every 8 hr	50 mg/kg every 8 hr	14–28 mg/kg every 8–12 hr	Pharmacokinetic: apparent renal clearance and apparent volume of distribution
Clindamycin	15 mg/kg every 8 hr	10 mg/kg every 6–8 hr	10 mg/kg every 6–8 hr	8–12 mg/kg every 8–12 hr	Pharmacokinetic: apparent hepatic clearance
Carbamazepine	Not established	3–10 mg/kg every 8 hr	3–10 mg/kg every 8 hr	5–8 mg/kg every 12 hr	Pharmacokinetic: apparent hepatic clearance
Phenytoin	2.5–4.0 mg/kg every 12 hr	2–3 mg/kg every 8 hr	2.3–2.6 mg/kg every 8 hr	2 mg/kg every 12 hr	Pharmacokinetic: apparent hepatic clearance
Phenobarbital	3–4 mg/kg every 24 hr	2.5–3.0 mg/kg every 12 hr	2–4 mg/kg every 12 hr	0.5–1.0 mg/kg every 12 hr	Pharmacokinetic: apparent hepatic clearance, followed by apparent volume of distribution
Theophylline	0.5 mg/kg/hr	0.6–0.7 mg/kg/hr	1.0–1.2 mg/kg/hr	0.5–0.7 mg/kg/hr	Pharmacokinetic: apparent hepatic clearance
Digoxin	4–8 μg/kg every 24 hr	7.5–12.0 μg/kg every 24 hr	3–8 μg/kg every 24 hr	1.4–4.0 μg/kg every 24 hr	Pharmacokinetic (apparent renal clearance followed by apparent volume of distribution) and pharmacodynamic
Captopril†	0.01–0.05 mg/kg every 8–12 hr	0.15–0.3 mg/kg every 8–12 hr	0.2–0.4 mg/kg every 12–24 hr	0.2–0.4 mg/kg every 8–12 hr	Pharmacokinetic: apparent hepatic clearance
Ranitidine	0.75–1.0 mg/kg every 12 hr	0.75–1.0 mg/kg every 12 hr	1 mg/kg every 6–12 hr	0.7 mg/kg every 6–8 hr	Pharmacokinetic: apparent renal clearance, followed by apparent volume of distribution

Kearns 2003

Absorption Distribution Metabolism Elimination

	Neonates / Infants	Pediatrics	Adults	Elderly
Renal elimination	↓	↔	↔	↓
Cytochrome P450 metabolism	↓	↑	↔	↔
Uridine diphosphate glucuronosyl transferase metabolism	↓	↔	↔	↔

Kearns 2003

Self-Assessment Question #1

A 2-day old neonate is prescribed a hydrophilic medication that is primarily eliminated unchanged by the kidneys. Compared with an older child or adult, which pharmacokinetic difference most increases this neonate's risk of drug accumulation and toxicity?

a. Increased hepatic enzyme activity leading to faster metabolism
b. Larger total body water resulting in a smaller volume of distribution
c. Immature renal function resulting in reduced drug clearance
d. Increased plasma protein binding reducing free drug concentration

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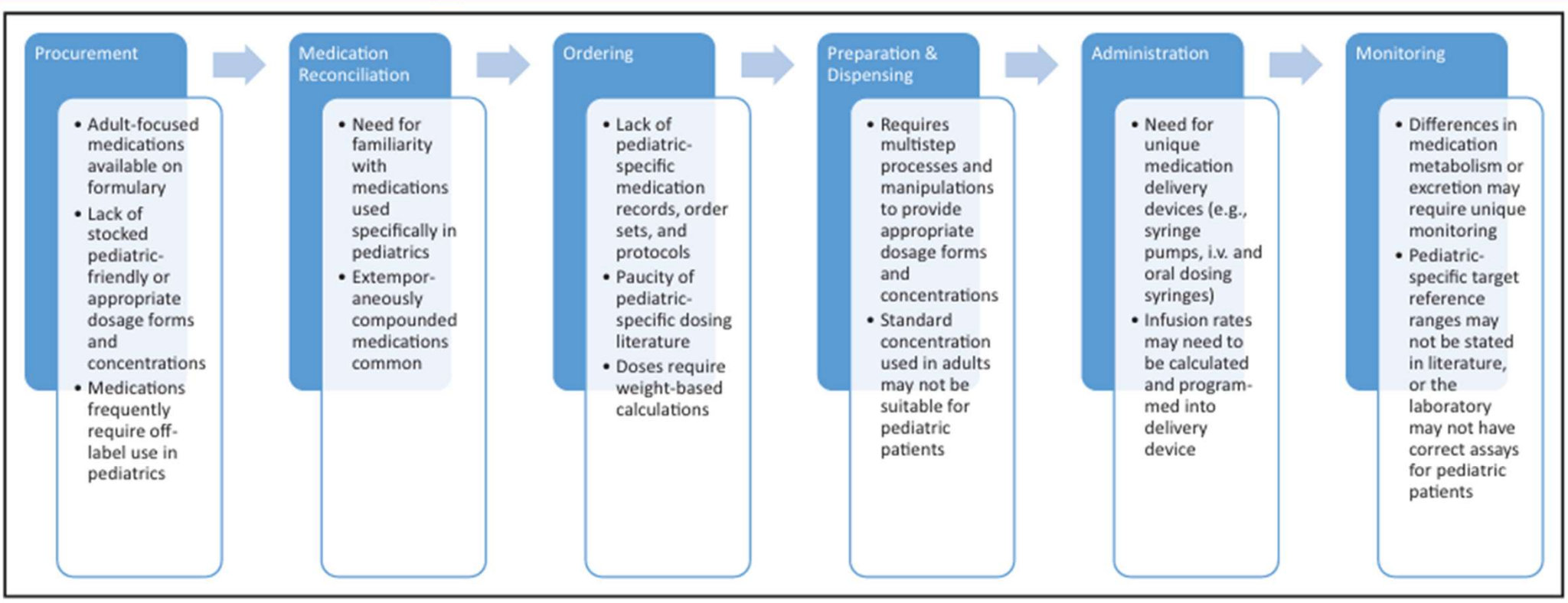
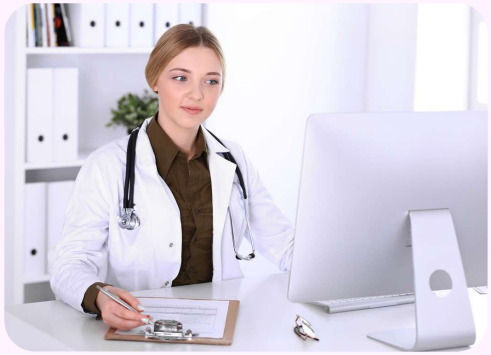
Potential Medication Process Pediatric Risks



Kennedy
2019



Prescribing Errors and Prevention Strategies

- Use of neonatal or pediatric drug references
- Limited pediatric-specific order sets/protocols -> Pharmacist involvement in development
- Weight-Based dosing and calculations
  - Manual dose calculations -> automated in EHR
  - Decimal point errors result in ten-fold dosing errors -> clinical decision support
- Variable concentrations
- Caution with transitions of care and medication reconciliation

Off-label Use of Medications

- Limited pediatric clinical trials
  - Extrapolation of adult data
- Limited suitable manufactured dosage formulations
  - Excipients may be harmful
  - Taste masking
- Risk for inadvertent poisonings

McPherson 2025
Petkova 2023
Jaworski 2022

High-Risk Medications in Pediatrics

Table 2. Common Medications Harmful to Children in One or Two Dosage Forms[a]

Medication Class	Select Examples
Antiarrhythmic Agents	
Class IA	Quinidine, procainamide
Class IC	Flecainide, propafenone
Class III	Amiodarone
Other	Digoxin
Antihypertensive Agents	
α2-Agonists	Clonidine
β-Blockers	Atenolol, metoprolol, propranolol
Calcium channel blockers	Amlodipine, diltiazem, nifedipine, verapamil
Antidepressant Agents	
Tricyclic antidepressants	Amitriptyline, desipramine, imipramine
Oral Antidiabetic Agents	
Sulfonylureas	Glipizide, glyburide
GI Agents	
Antidiarrheals	Lomotil
Analgesics and Opioids	
Opioids	Buprenorphine, fentanyl, hydrocodone, oxycodone, methadone
Salicylates	Aspirin, oil of wintergreen (methyl salicylate)

[a]Please note: This list highlights some of the most commonly prescribed medications and does not include all medications and substances that can be harmful to children in small amounts.

Jaworski 2022

PROTECT Initiative

PRevention of Overdoses and Treatment Errors in Children Taskforce (PROTECT) Initiative focuses:

1. Improved safety packaging
2. Improved labeling to reduce errors
3. Safe use and storage education

Put your medicines up AND away and out of sight

POISON HELP! 1-800-222-1222

PROTECT Initiative 2024
Up and Away 2026
UPMC Mr Yuk 2026

Dispensing Errors and Prevention Strategies

- Variable medication concentrations increase risk -> **S4S initiative**
  - Amoxicillin 125 mg/5 mL; 200 mg/5 mL; 250 mg/5 mL; 400 mg/5 mL
- Potential compounding errors with dilutions and manipulations
  - Multistep processes
  - Changes to expiration dating
- Confusion with adult and pediatric concentrations
  - Store pediatric medications in separate area of pharmacy
  - Inappropriate medications for pediatrics, excipients -> **KIDs List**

Standardize 4 Safety Initiative

Standardize 4 Safety is the first national, interprofessional effort to standardize medication concentrations in order to reduce errors and improve transitions of care.

Standardize 4 Safety

National Standards Lists

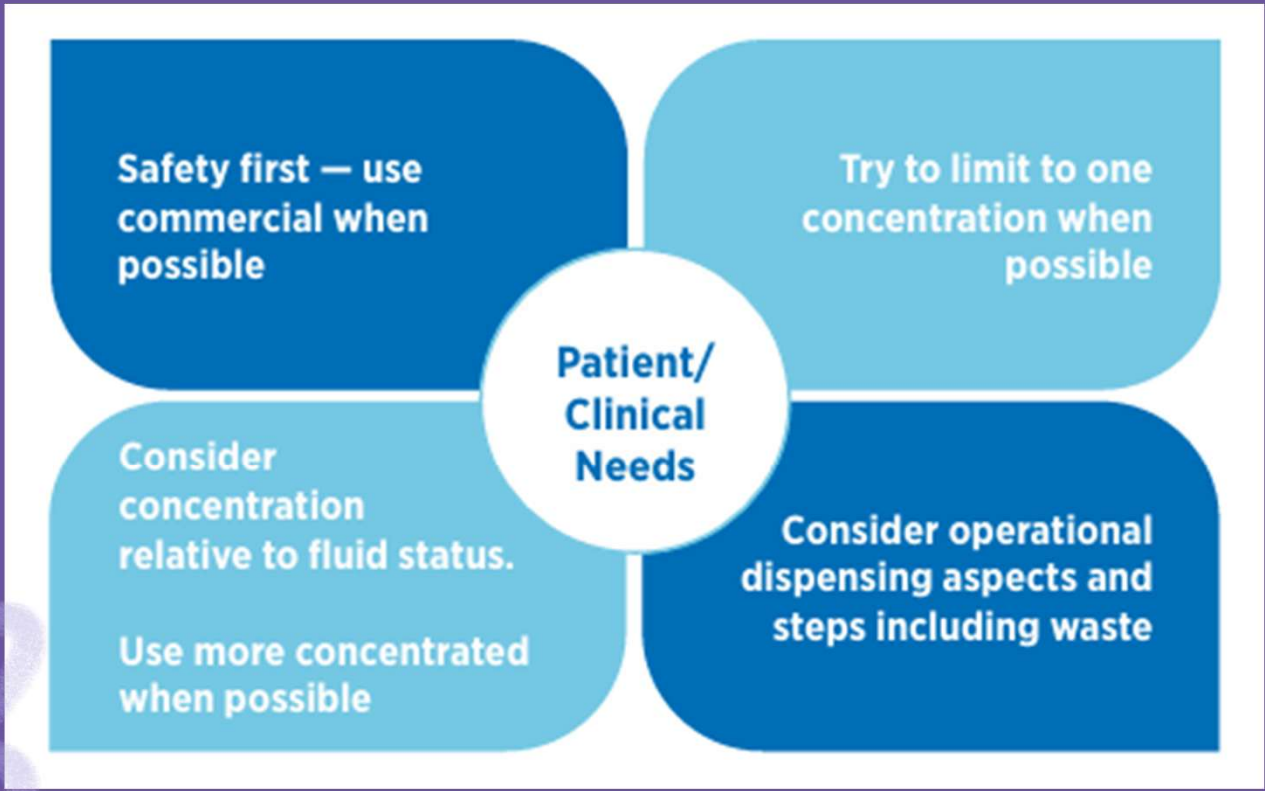
Adult Continuous Infusion Standard

Compounded Oral Liquid Standard

Pediatric Continuous Infusion Standard

PCA and Epidural Standards

S4S Initiative



Drug	Concentration Standards	Dosing units	Commercially available	Concentration vs. unit mismatch	References
Morphine	1. 0.2 mg/mL 2. 0.5 mg/mL 3. 1 mg/mL	mg/kg/hour	Yes, undiluted drug from the vial of 1 mg/mL vial or ready-to-use products or premix products available	Possibly depending on pharmacy label or oursourcing facility label	1. Veechio M, Walker SE, Iazzetta J et al. The stability of morphine intravenous infusion solutions. *Can J Hosp Pharm*. 1988; 41:5–9. 2a. McMullin ST, Schaiff RA, and Dietzen DJ, "Stability of Midazolam Hydrochloride in Polyvinyl Chloride Bags Under Fluorescent Light," *Am J Hosp Pharm*, 1995, 52(18), 2018-20. 2b. Altman L, Hopkins RJ, Ahmed S, et al: Stability of morphine sulfate in Cormed III (Kalex) intravenous bags. *Am J Hosp Pharm* 1990; 47:2040-2042 3. Stiles ML, Tu YH, & Allen LV Jr: Stability of morphine sulfate in portable pump reservoirs
Vasopressin	1. 0.05 units/mL 2. 0.2 units/mL 3. 1 units/mL	VASOCONSTRICTION/ GI BLEED: **milliunits/kg/ min*** DIABETES INSIPIDUS: **milliunits/kg/hr***	No	Yes	1. Wise-Faberowski L, Soriano SG, Ferrari L, et al. Perioperative management of diabetes insipidus in children. J Neurosurg Anesthesiol. 2004;16(3):220-225. 2. ASHP Interactive Handbook on Injectable Drugs Accessed July 13, 2020 3. Par Pharmaceutical Companies, Inc. Vasostrict® (vasopressin) injection prescribing information. Spring Valley, NY; 2015 Mar.

JPPT | 2025 KIDs List

Pediatric Pharmacy Association 2025 KIDs List of Key Potentially Inappropriate Drugs in Pediatrics

Christopher McPherson, PharmD; Rachel S. Meyers, PharmD; Jennifer Thackray, PharmD; Danielle L. Stutzman, PharmD; Kimberly P. Mills, PharmD; Sana J. Said, PharmD; Karisma Patel, PharmD; Robert C. Hellinga, PharmD; Amy L. Potts, PharmD, MMHC; Lisa Lubsch, PharmD; Kelly L. Matson, PharmD; and David S. Hoff, PharmD

Table 1. Key Potentially Inappropriate Drugs in Pediatrics (KIDs) List: Second Edition

Drug (Systemic Administration Unless Otherwise Noted)	Risk/Rationale	Recommendation	Strength of Recommendation	Quality of Evidence
Benzocaine, topical[102]	Methemoglobinemia	Avoid oral application in younger than 2 yr	Strong	High
Codeine[126–130]	Respiratory failure, death	Avoid in younger than 12 yr Avoid in 12–18 yr of age after surgery to remove tonsils and/or adenoids Caution in 12–18 yr of age Recommend pharmacogenetic testing	Strong	High

McPherson 2025

Table 1. Key Potentially Inappropriate Drugs in Pediatrics (KIDs) List: Second Edition *(cont.)*

Drug (Systemic Administration Unless Otherwise Noted)	Risk/Rationale	Recommendation	Strength of Recommendation	Quality of Evidence
Tetracyclines[33,146–150] Demeclocycline Eravacycline Minocycline Omadacycline Sarecycline Tetracycline Tigecycline	Tooth discoloration	Caution in younger than 8 yr	Strong	High (demeclocycline, tetracycline) Low (minocycline, sarecycline, tigecycline) Very low (eravacycline, omadacycline)
	Enamel hypoplasia (tetracycline)	Caution in younger than 8 yr	Strong	High
	Retardation of skeletal development and bone growth (tetracycline)	Caution in younger than 1 mo	Strong	Moderate

Administration Errors and Prevention Strategies

- Barcode medication administration
- Availability and use of appropriate administration devices
  - Enteral administration
    - Oral syringe
    - EnFIT syringe
  - Intravenous administration -> smart infusion pumps
    - Syringe pump
    - Large volume pump
      - Low-rate infusions: min = 0.1 mL/hr

Kennedy
2019

Self-Assessment Question #2

Which combination of strategies is most effective in reducing the risk of serious medication errors in pediatric patients?

a. Increasing reliance on individual clinician vigilance and double-checking calculations manually
b. Using age-specific references while allowing multiple concentrations to remain available
c. Restricting pharmacist involvement to dispensing verification only
d. Implementing standardized concentrations, dose-range checking, and smart infusion pump technology

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Role of the Pharmacist

- Verify patient weight, age, and indication
  - Neonatal and pediatric specific dosing references
- Utilize and optimize EHR automation and smart technologies
  - Limit concentrations available (S4S)
  - Consider formulary medications (KIDs List)
  - Pediatric order sets/protocols
  - Standardize medication reconciliation
- Educate healthcare staff and caregivers
- Participate in medication safety

Self-Assessment Question #3

Which pharmacist activity has the greatest impact on preventing serious medication errors in pediatric patients?

a. Verifying medication orders only after administration
b. Identifying doses outside expected pediatric ranges and clarifying unclear or unsafe orders
c. Relying on prescriber documentation to confirm appropriate dosing
d. Limiting involvement to product preparation and dispensing accuracy

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Second Victim Syndrome

- Second Victim Syndrome occurs when a **health care provider** is traumatized by an adverse patient care event.
  This can include:
  - Near-misses
  - Deaths
  - Medical errors
  - Any event causing emotional or psychological distress

- Common symptoms may include:
  - Troubling memories (81%)
  - Anxiety
  - Anger
  - Regret or remorse
  - Physical or psychological distress
  - Feat of future errors, embarrassment, and guilt
  - Loss of confidence
  - Difficulty sleeping

Busch 2020

Second Victim Support

1.Local unit support
2.Peer support from trained staff
3.Professional counseling services

- APhA Connect & Care
- R.I.S.E. (Resilience in Stressful Events)/ Second Victim Program
- Employee Assistance Programs

APhA 2026
R.I.S.E 2026

Changes from Errors

- 2007: Three infants received heparin for an intravenous line flush that was 1000-fold higher than what was intended. Heparin vial labeling changes occurred.
- Broselow Tape 2025 recall
- BD Alaris™ Pump Infusion Sets – LVP module recall

Conclusions

- **Recognize the risk**
  - Pediatric patients are uniquely vulnerable to medication errors.
- **Build safer systems**
  - Most pediatric medication errors occur during the prescribing and administration phases with dosing and concentration errors being the most common and most harmful.
- **Act as safety leaders**
  - Pharmacists play a critical role in pediatric medication safety through proactive order review, optimization of technology, standardization efforts, education, and participation in safety initiatives.

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