Medication Safety in Pediatric Patients

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Disclosure to Learners

Karla A. Rivera, faculty for this CE activity, has no relevant financial relationship(s) with ineligible companies to disclose.

“The Colegio de Farmacéuticos de Puerto Rico is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.”

Provider Number: 0151

Objectives

- Explain why pediatric patients are at increased risk for medication errors compared with adults.
- Describe key pharmacokinetic and physiologic differences in pediatric patients that influence medication dosing and safety.
- Calculate weight-based pediatric medication doses and evaluate dose appropriateness.
- Identify common medication error types encountered in pediatric pharmacotherapy in both community and inpatient settings.
- Recognize strategies and system safeguards that reduce pediatric medication errors in pharmacy practice.

Pre-Test

1. Which of the following factors contributes most to the increased risk of medication errors in pediatric patients?
   a. Pediatric medications are usually standardized across all patients
   b. Pediatric dosing often requires individualized weight-based calculations
   c. Pediatric patients typically receive fewer medications than adults
   d. Pediatric patients rarely require preparation or manipulation

Pre-Test

2. Which of the following represents a common type of medication error in pediatric pharmacotherapy?
    a. Misinterpreting dosing instructions written as mg/kg/day versus mg/kg/dose
    b. Selecting medications that include FDA-approved pediatric labeling
    c. Recording the patient’s weight in kilograms before calculating doses
    d. Using calibrated oral syringes to measure pediatric liquid medications

Pre-Test

3. Which of the following is a physiologic difference in pediatric patients that can affect how medications are distributed in the body compared to adults?
    a. Higher amount of body water relative to body weight
    b. More consistent medication absorption across all ages
    c. Fully developed organ function at birth
    d. Lower variability in how medications are processed

Pre-Test

4. A 4-year-old child weighs 40 lbs and is prescribed amoxicillin for acute otitis media. The recommended dosing range is 80–90mg/kg/day divided every 12 hours.

   Which of the following total daily doses would be appropriate for this patient?

   a. 3,400 mg/day
   b. 1,500 mg/day
   c. 1,500 mg/dose every 12 hours
   d. 1,800 mg/dose every 12 hours

Pre-Test

5. Which practice is most effective in reducing medication dosing errors in pediatric patients?
    a. Documenting patient weight in pounds and converting during dispensing
    b. Estimating medication doses using standard adult dosing guidelines
    c. Measuring pediatric liquid medications using household teaspoons
    d. Documenting patient weight in kilograms and verifying dose calculations independently

Why does Pediatric Medication Safety Matter?

- Children are not small adults
  - Organ system maturation drives disposition
  - Adverse drug reactions differ in nature and frequency from adults
- The error burden is real and disproportionate
  - Medication error rates in pediatrics are roughly 3 times higher than in adults
- Most pediatric care is outpatient, and that is where the gap is widest
  - Root causes are squarely within pharmacy's control or influence
    - Prescribing practices
    - Dispensing practices
    - Confusing measurement units and dosing tools for liquid medications
    - Multiple caregivers
    - Health literacy and language barriers

Cochrane Database Syst Rev. 2015;2015(3):CD006208
Pediatrics. 2016;138(6):e20163215

Why does Pediatric Medication Safety Matter?

- Pediatric medication errors are a **leading cause of preventable harm**
- Reported inpatient and primary care prevalence rates ranging widely from roughly 15% to over 65%
  - **Dosing Errors**: most prevalent error type
    - Often driven by weight-based calculation mistakes and decimal misplacements
  - **Administration Errors**
  - **Prescribing and Frequency Errors**

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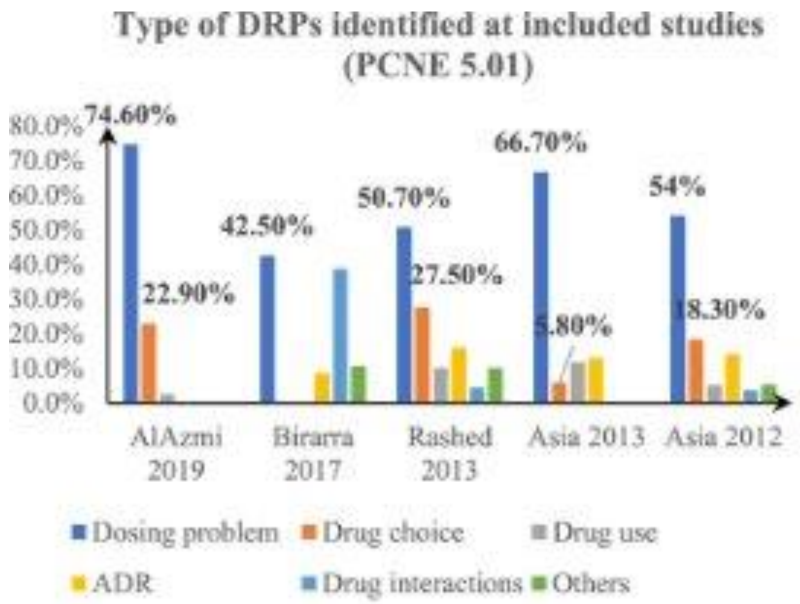
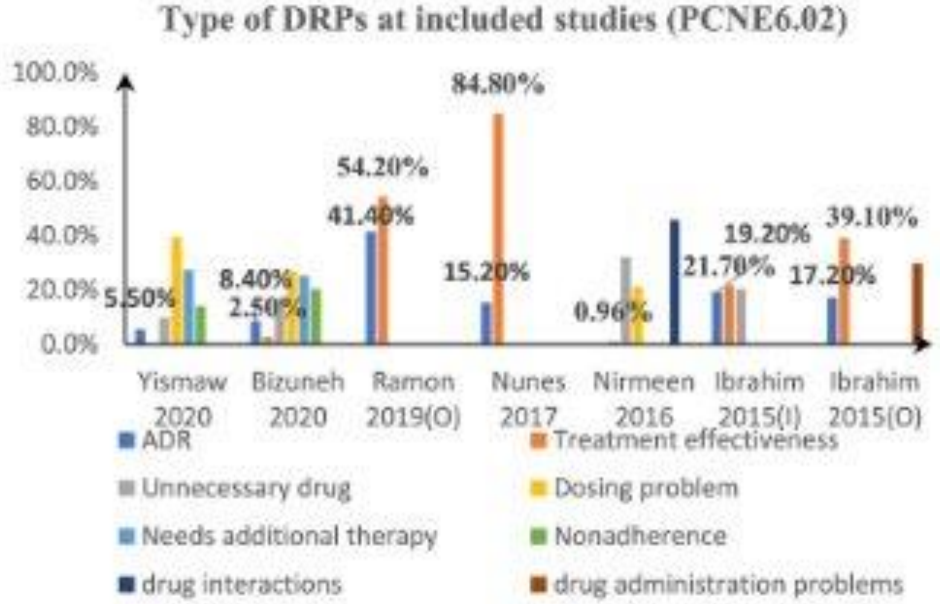
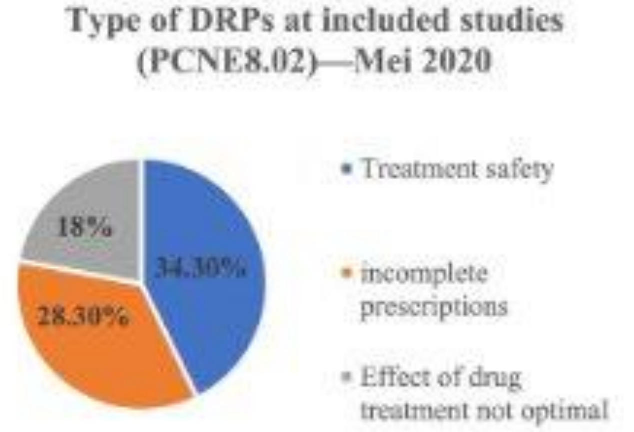
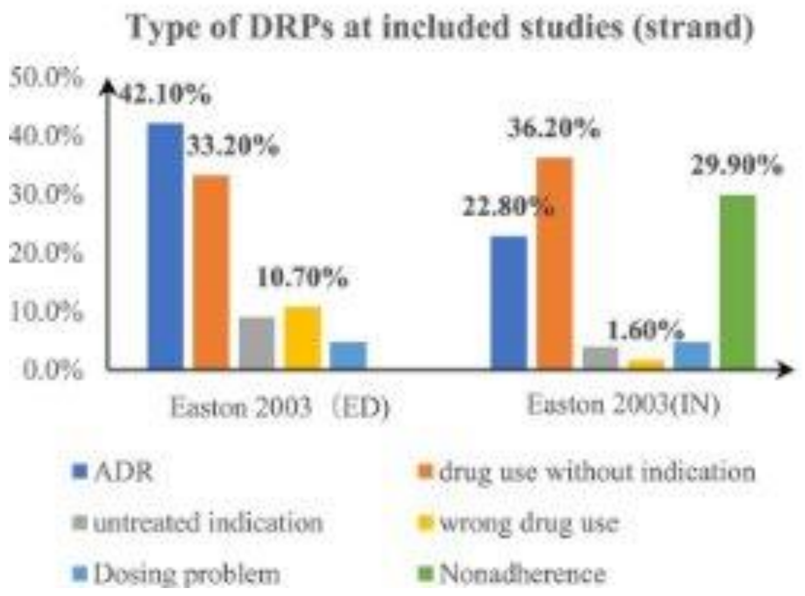
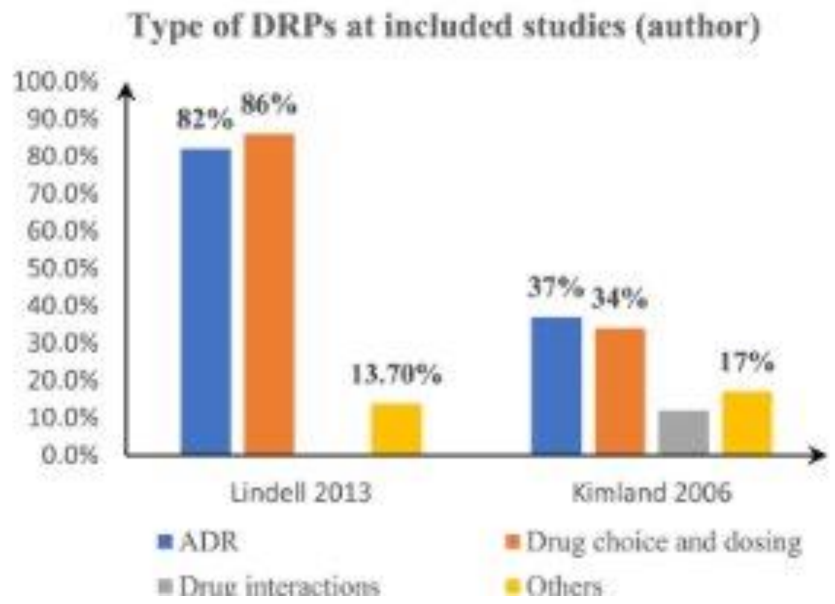
Why does Pediatric Medication Safety Matter?

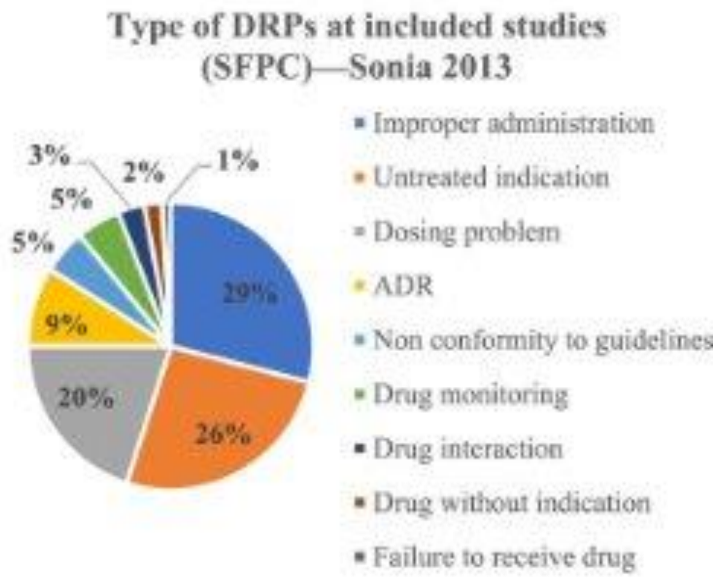












Ann Pharmacother. 2002;36(12):1833-1839

Classification of pediatric patients

- Classification of pediatric patients is of utmost importance when selecting pharmacotherapy
- Some medications are contraindicated for patients of certain ages
- Ages may be expressed in days, weeks, months, or years

Classification	Age range
Neonate	Birth (day 0) to 28 days PNA
Infant	1 month (>28 days) to 12 months of age
Child	1 to 12 years of age
Adolescent	13 to 18 years of age

Kraus DM. Interpreting pediatric laboratory data. In: Lee M, ed. *Basic skills in interpreting laboratory data*. 6th ed. 2017:547-70

Pharmacokinetics in pediatrics

Pharmacokinetic alterations occur with growth

- Changes in physiological functions
- Organ maturation

Pharmacokinetic differences are seen in:

- Absorption
- Distribution
- Metabolism
- Excretion

Pettit RS, et al. *Am J Health-Syst Pharm*. 2019; 76:1472-80

Absorption Changes

Practice Pearl:
Be cautious with oral, IM, and topical drug exposure in infants and neonates.

Higher gastric pH in neonates

- ↑ absorption of acid-labile drugs (e.g., ampicillin)
- ↓ absorption of weak acids (e.g., phenytoin)

Delayed gastric emptying and GI motility

- Slower time to peak concentration

Increased skin permeability

- Greater toxicity risk from topical medications

IM absorption is erratic and difficult to predict in neonates

Pettit RS, et al. *Am J Health-Syst Pharm*. 2019; 76:1472-80

Distribution Changes

Neonates have **~20% more total body water**

- ↑ volume of distribution for hydrophilic drugs

Lower body fat

- ↓ volume of distribution of lipophilic drugs

Reduced protein binding

- Higher free drug concentrations

Examples:

- Aminoglycosides: larger volume of distribution
- Phenytoin: higher free fraction
- Ceftriaxone/SMX: bilirubin displacement concern

Pettit RS, et al. *Am J Health-Syst Pharm*. 2019; 76:1472-80

Metabolism Changes

Practice Pearl:
Neonates often require lower doses, longer intervals, or both.

Hepatic enzymes are immature at birth

CYP3A4 activity <10% of adult levels in newborns

Reduced Phase I and Phase II metabolism

Many drugs have:

- ↓ clearance
- ↑ half-life
- Higher toxicity risk

Pettit RS, et al. *Am J Health-Syst Pharm*. 2019; 76:1472-80

Renal Elimination Changes

Practice Pearl:
Neonates often require lower doses, longer intervals, or both.

Neonatal renal function is markedly reduced

GFR reaches adult levels around 1 year of age

Renally eliminated drugs clear more slowly in neonates

Result:

- Neonates: longer dosing intervals
- Older infants/children: may require higher mg/kg doses or more frequent dosing than adults

Pettit RS, et al. *Am J Health-Syst Pharm*. 2019; 76:1472-80

Age- and population-specific vulnerabilities

Neonates/infants:	dependence on dilution and infusion pumps, narrow margins for IV antibiotic rates
Young children	liquid formulations, need for special preparations, multiple available concentrations, tablet splitting
School-age/older children	rising prescribing and administration error frequency, more complex clinical profiles, less vigilance around medication practices

J Pediatr. 2024;272:114087.

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Off-label use with doses extrapolated from adult literature

J Pediatr. 2024;272:114087.

Off-label Use of Medications

- More than 1400 medications available in the US
  - Many approvals without pediatric exposure or evidence of safety and/or efficacy
- Legislative efforts have provided incentives **for new drugs** to study use in pediatrics
- Off-label medication use in pediatrics is widespread and necessary
  - Often must rely on low level evidence and anecdotal observational studies

Meyers RS et al. J Pediatr Pharmacol Ther. 2020; 25(3):175-91.
Sachs AN et al. JAMA. 2012; 307(18):1914-15.

Age- and population-specific vulnerabilities

Adolescents	less caregiver supervision increases home errors, particularly for confidentially treated conditions such as STIs where the caregiver is unaware of the prescription
Children with medical complexity or chronic disease	polypharmacy, complex instructions, multiple caregivers, and heightened vulnerability at care transitions

What do Medication Errors Look Like?

- Dosing Errors:
  - Incorrect weight-based dose **calculation** (mg/kg)
  - **Decimal point errors** resulting in **10-fold overdoses**
  - Confusion between **mg and mL**
  - Selection of the **wrong concentration** (e.g., digoxin formulations)
  - Failure to update doses as the child grows

Arch Dis Child. 2005;90(7):698-702

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Nearly every dose requires calculation, and multiple formulations/concentrations are often available

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Tenfold Dosing Errors

- **Tenfold errors** are the archetypal high-consequence pediatric dosing error
- Morphine and opioids were the single most frequently involved drug/class
- The three **recurring mechanisms** were:
  - Errors of dose calculation
  - Misdocumentation of decimal points
  - Confusion with zeroes
- Example:
  - Morphine 0.1 mg/kg/dose IV for an infant weighing 5 kg
  - Correct dose: 0.1 mg/kg/dose x 5 kg = 0.5 mg
  - Tenfold error: 1 mg/kg/dose x 5 kg = 5 mg
  - Implication: tenfold overdosing of morphine → increased risk of **respiratory depression**, profound **sedation**, need for **naloxone**, **respiratory arrest**

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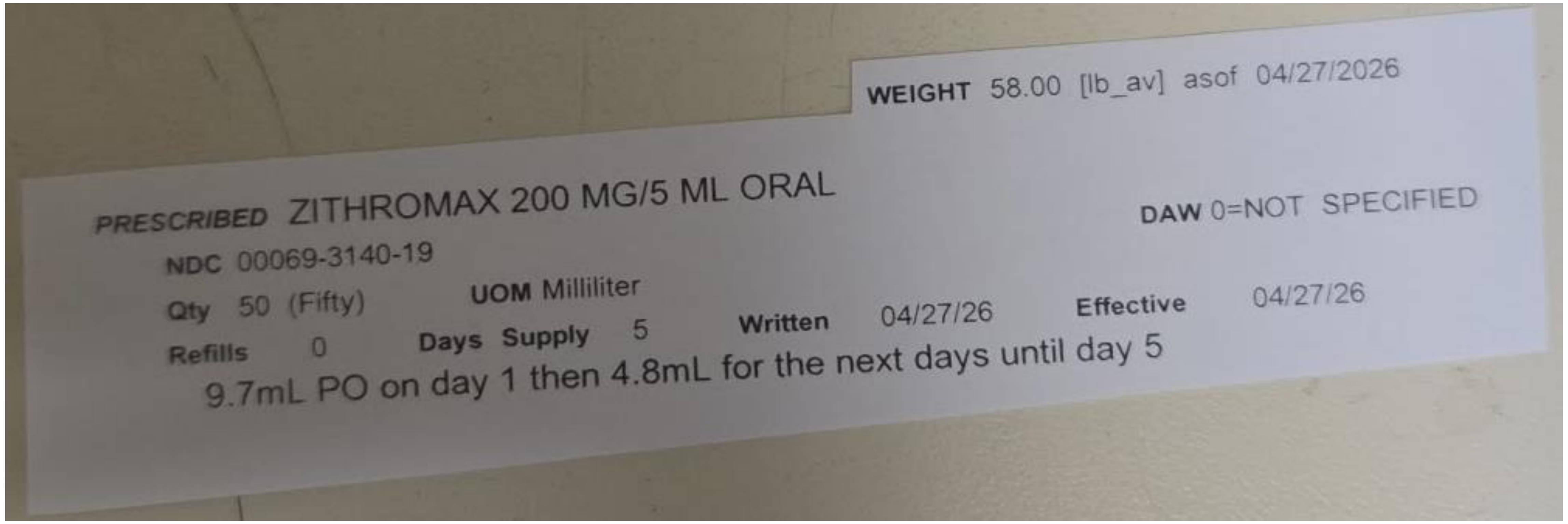
Decimal Point Dosing Errors

- In a study of 200 consecutive tenfold prescribing errors (~20% pediatric), the errors were produced by:
  - Misplaced decimal point in 43.5%
  - Extra zero in 31.5%
  - Omitted zero in 25%
- Contributing features were:
  - Multiple zeroes in the dose (45%)
  - Use of calculations/equations (92% of pediatric cases)
  - Dose amounts less than 1 (25%)
- Never use **trailing zeros** (5 mg, NOT 5.0 mg)
- Always use a **leading zero** (0.5 mg, NOT .5 mg)

Ann Pharmacother. 2002;36(12):1833-1839

Dosing Error Example



- According to prescription:
  - **Patient weight**: 58 lbs.
  - **DOB or Age**: not included
  - **Directions**: 9.7 mL PO on day 1 then 4.8 mL PO daily x 4 days
  - **Medication presentation**: 200 mg / 5 mL oral suspension

What Does the Literature Say?

UpToDate® Lexidrug™ Standard

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Trissel's IV Compatibility | Interactions | Drug I.D. | Patient Education | Calculators | More Clinical Tools

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Azithromycin (Systemic) (Lexi-Drugs)

Outline | Alphabetical | Expand All

- Drug Shortages
- Pronunciation
- Brand Names
  - Brand Names: US
  - Brand Names: Canada
- Pharmacologic Category
- Dosages
  - Dosing: Adult
  - Dosing: Older Adult
  - Dosing: Altered Kidney Function: Adult

Monograph | Images | Adult Patient Education | Pediatric Patient Education | Pediatric and Neonatal Lexi-Drugs

Dosing: Pediatric

Dosage guidance:

Safety: Dosing presented as weight-directed (mg/kg) and fixed dosing (mg); use caution. Dosing interval varies by indication (eg, single dose, once daily, 1 to 3 times weekly); ensure accurate interval.

Dosage form information: Zithromax (brand and generic) oral packets for suspension have been discontinued >1 year.

General dosing:

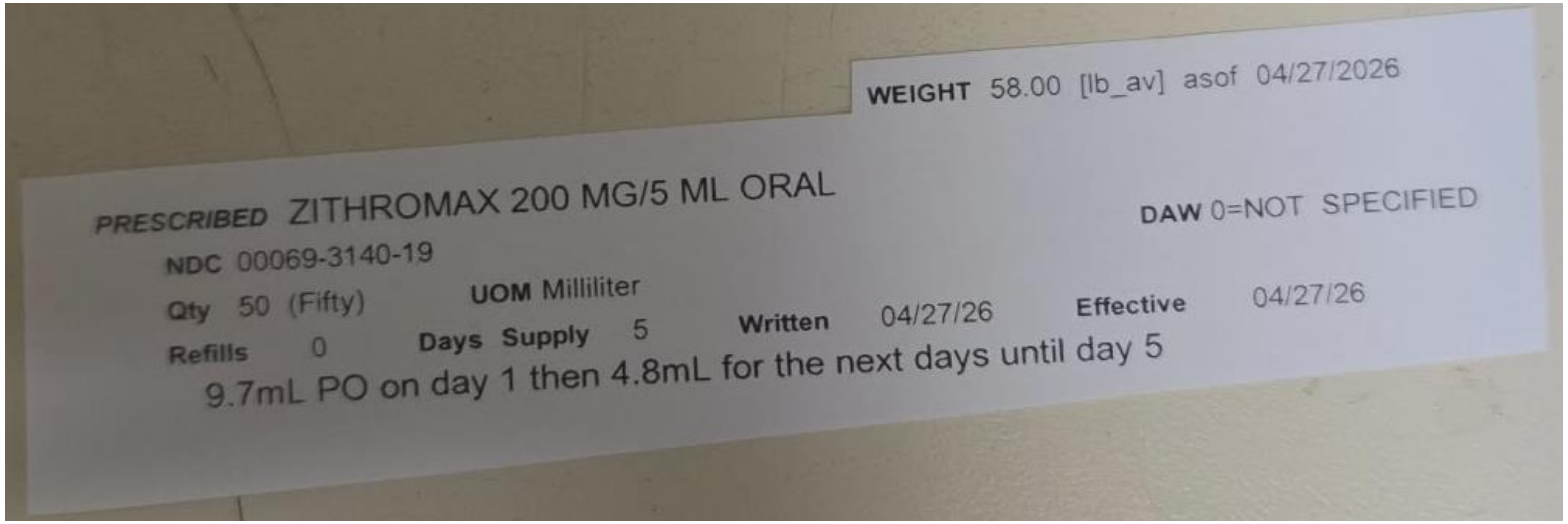
Infants, Children, and Adolescents:

Oral: 5 to 12 mg/kg/dose; typically administered as 10 to 12 mg/kg/dose on day 1 (usual maximum dose: 500 mg/dose) followed by 5 to 6 mg/kg once daily (usual maximum dose: 250 mg/dose) for remainder of treatment duration ([Ref]).

IV: 10 mg/kg once daily; maximum dose: 500 mg/dose ([Ref]).

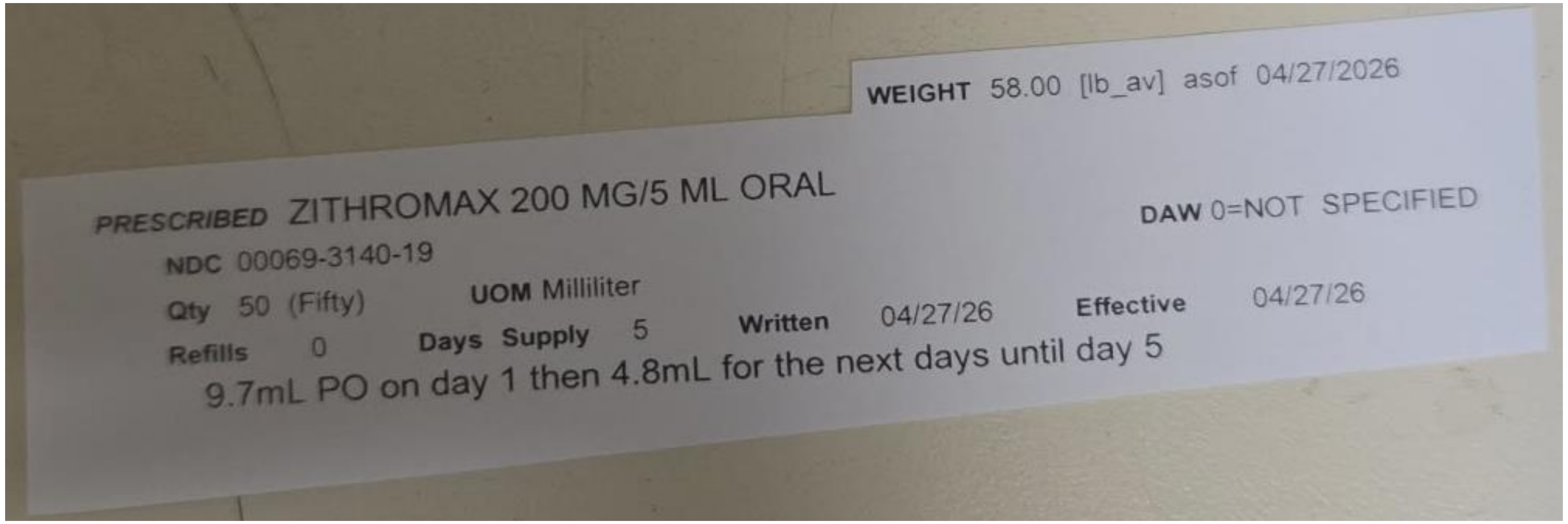
- Indicated for use in infants, children, and adolescents
  - Some indications exclude certain pediatric populations, like infants – making the **DOB/age and diagnosis** a critical component of the prescription
- Oral dosing varies, but maximum is typically 12 mg/kg/dose on day 1 and 6 mg/kg/dose or 250 mg /dose after day 1

Dosing Error Example



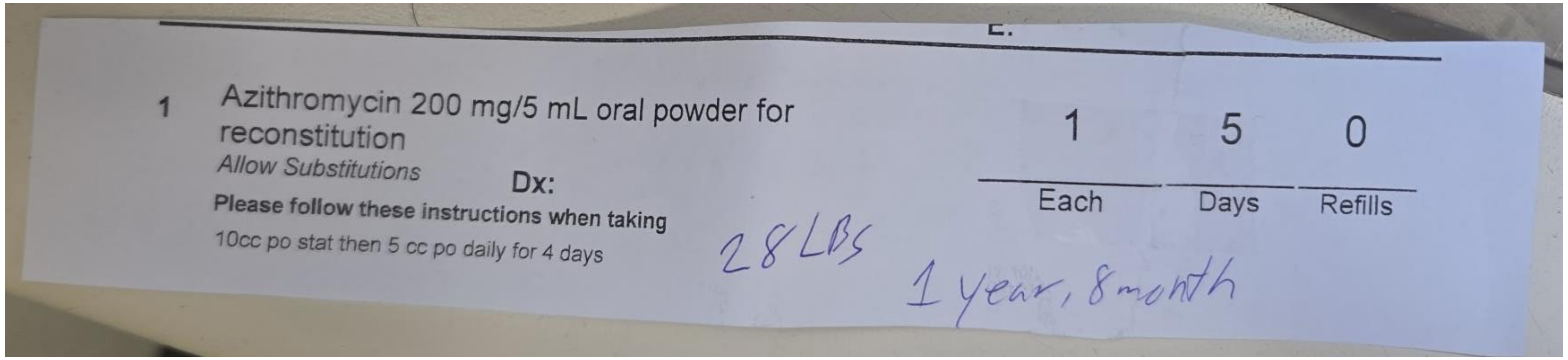
- According to prescription:
  - **Patient weight**: 58 lbs. → ~26 kgs.
  - **DOB or Age**: not included
  - **Directions**: 9.7 mL PO on day 1 then 4.8 mL PO daily x 4 days
  - **Medication presentation**: 200 mg / 5 mL oral suspension
- 9.7 mL of a 200 mg / 5 mL suspension = 388 mg / dose
- 160 mg / 26 kgs = ~15 mg/kg/dose on day 1
- 4.8 mL = ~7.4 mg/kg/dose on days 2 through 5

Dosing Error Example



1. 26 **kg** x 12 mg/**kg**/dose on day 1 = 312 mg/dose
2. 5 mL / 200 **mg** x 312 **mg** = **7.8 mL PO on day 1**
3. you can half the dose for day 1 to get the dose for days 2 through 5 or…
4. 26 **kg** x 6 mg/kg/dose = 156 mg
5. 5 mL / 200 **mg** x 156 **mg** = **3.9 mL PO on days 2 – 5**

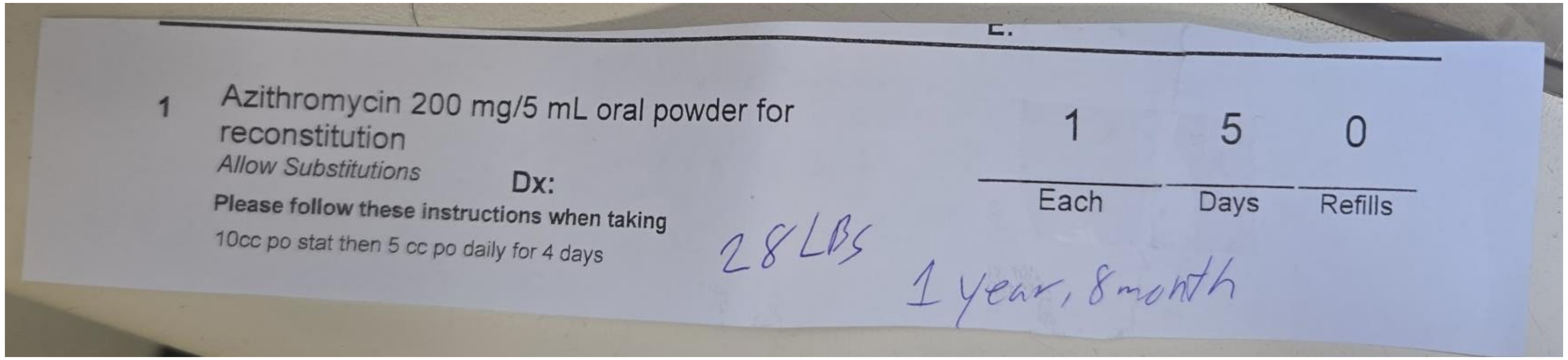
Dosing Error Example


1 Azithromycin 200 mg/5 mL oral powder for reconstitution
Allow Substitutions Dx:
Please follow these instructions when taking
10cc po stat then 5 cc po daily for 4 days
28 LBs
1 year, 8 month

1	5	0
Each	Days	Refills

- According to prescription:
  - **Patient weight**: 28 lbs.
  - **DOB or Age**: 1 year and 8 months
  - **Directions**: 10 cc PO STAT then 5 cc PO daily x 4 days
  - **Medication presentation**: 200 mg / 5 mL oral suspension

Dosing Error Example



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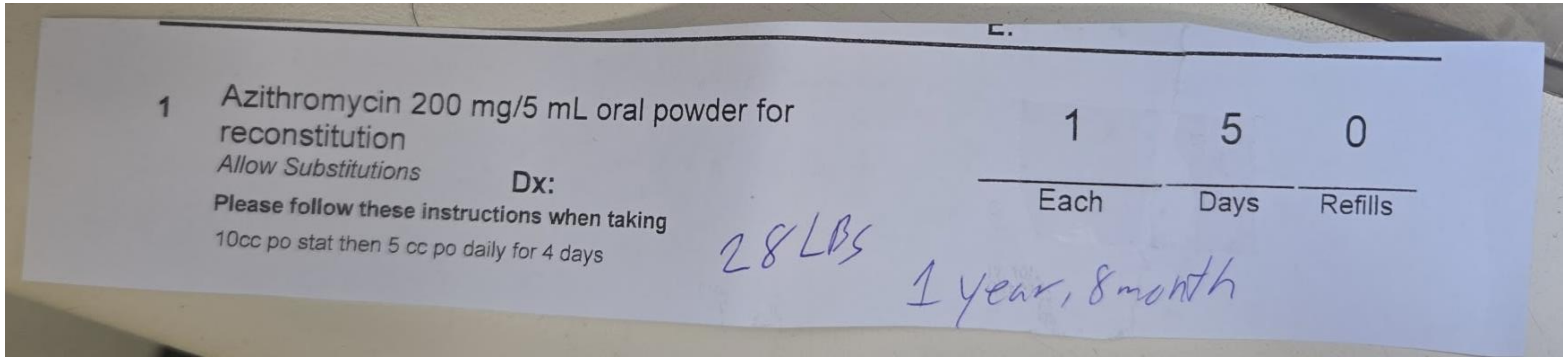
Based on what we've discussed so far, **what's wrong with this prescription?**

Dosing Error Example



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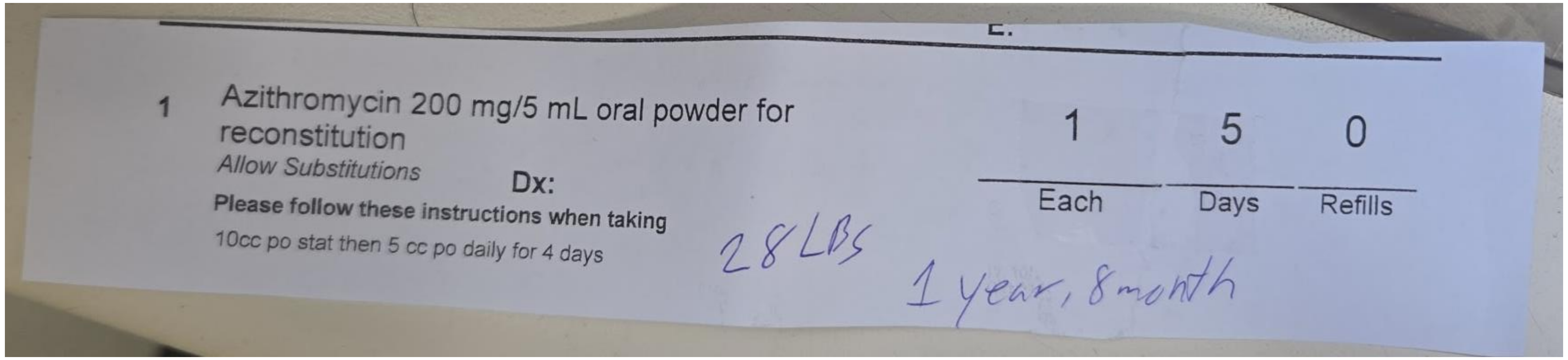
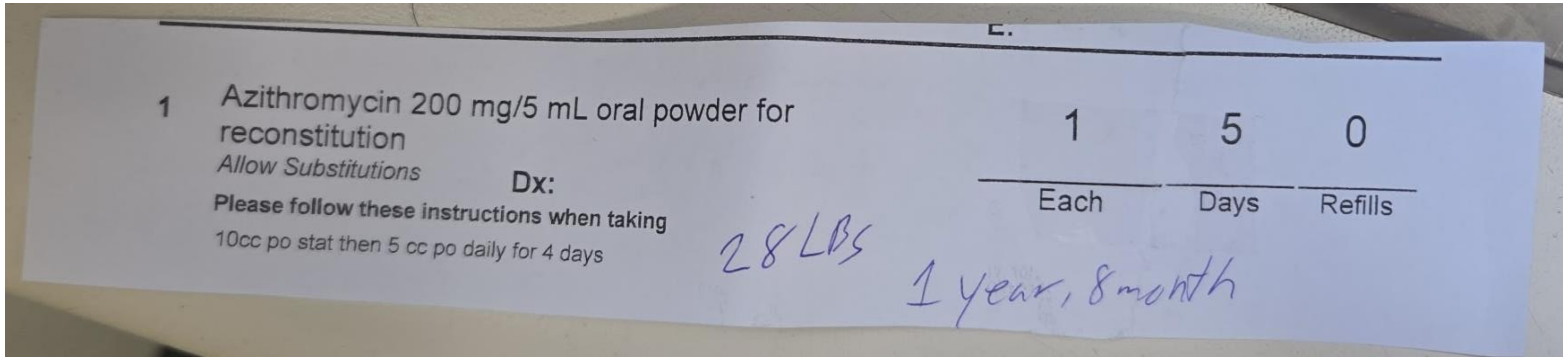


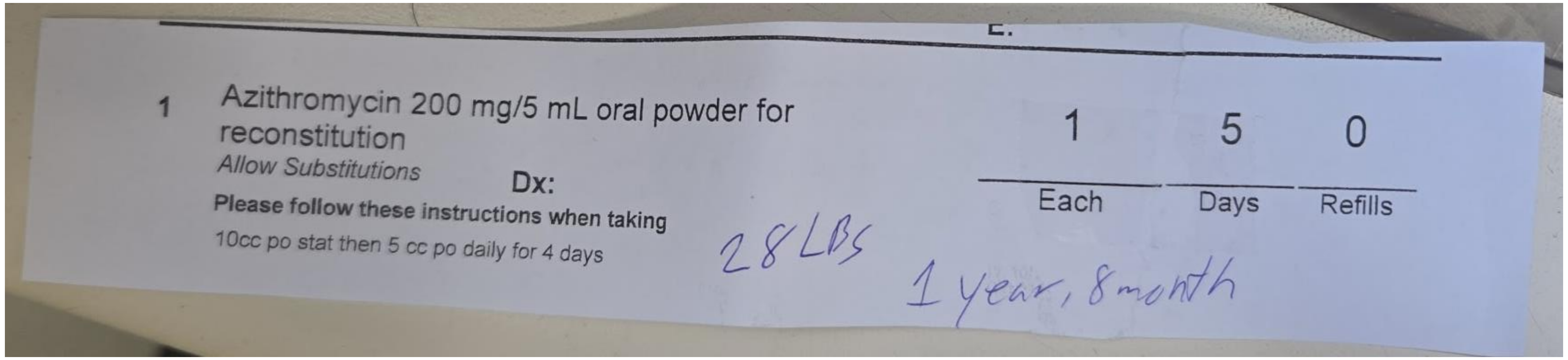
- According to prescription:
  - **Patient weight**: 28 lbs.
  - **DOB or Age**: 1 year and 8 months
  - **Directions**: 10 cc PO STAT then 5 cc PO daily x 4 days → **mL only dosing**
  - **Medication presentation**: 200 mg / 5 mL oral suspension

Dosing Error Example



- According to prescription:
  - **Patient weight**: 28 lbs. → ~12.7 kgs
  - **DOB or Age**: 1 year and 8 months
  - **Directions**: 10 mL PO STAT then 5 mL PO daily x 4 days
  - **Medication presentation**: 200 mg / 5 mL oral suspension
- 10 mL of a 200 mg / 5 mL suspension = 400 mg / dose
- 400 mg / 12.7 kgs = ~31.5 mg/kg/dose on day 1 → ~ 15.7 mg/kg/dose on days 2 – 5

Dosing Error Example



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What do Medication Errors Look Like?

- Prescribing/Ordering Errors
  - Wrong dose or frequency
  - Missing **patient weight** on orders
  - Illegible or incomplete prescriptions
  - Use of **unsafe abbreviations**
  - Failure to account for **age-specific PK differences**
- Dispensing Errors
  - Wrong medication selected
  - Wrong **concentration** dispensed
  - Improper antibiotic **reconstitution**
  - Incorrect **labeling** instructions

Arch Dis Child. 2005;90(7):698-702

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  - Incorrect **labeling** instructions

In the outpatient setting, this is where **the pharmacist's role** is most impactful

Arch Dis Child. 2005;90(7):698-702

What do Medication Errors Look Like?

- Administration Errors
  - Wrong dose administered
  - Wrong administration rate
  - Wrong time
  - Missed doses
- Caregiver Administration Errors
  - Household teaspoons used instead of dosing devices
  - Misunderstanding label instructions
  - Measurement errors with liquid medications
  - Health literacy barriers

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  - Measurement errors with liquid medications
  - Health literacy barriers

Pharmacists also play a key role in medication administration through **education and counseling**

Arch Dis Child. 2005;90(7):698-702

Standardizing dosing of oral liquid medications

- The National Council for Prescription Drug Programs (**NCPDP**) provides guidance on standardization of dosing designation on oral liquid medication labels dispensed from **community pharmacies**
  - Reduce variation in dosing designations
  - Facilitate proper administration by patients / caregivers
- Aligns with the recommendations from regulatory bodies (e.g., TJC) for **inpatient settings**

Am J Health Syst Pharm. 2021;78(7):578-605

NCPDP Standardization Recommendations

Dosing Designations on Prescription Container Labels for Oral **Liquid** Medications

- **Milliliter** (mL) should be the standard unit of measure
- Dosing directions in terms of teaspoon (tsp) and tablespoon (tbsp) should be **avoided**
- **Concentration** should always appear on the label
- Doses should **always include leading zeros** in front of the decimal point (e.g., 0.5 mL)
- Doses should **never use trailing zeros** after decimal points (e.g., 5 mL)
- Dosing devices with numeric graduations and units that correspond to the dose prescribed should be **dispensed with every oral liquid** prescription medication
- **Education** should be provided to parents and caregivers on the appropriate administration and instruction on the **proper use of dosing devices**

Am J Health Syst Pharm. 2021;78(7):578-605

Measuring Oral Liquid Medications: **Appropriate vs. Inappropriate Devices**

Appropriate:

- Oral syringes
- Calibrated dosing cups
- Calibrated medication spoons
- Calibrated medicine droppers

Inappropriate:

- Baking spoons
- Kitchen spoons
- Household measuring cups
- Dosing cups for small volumes
- Parenteral syringes
- Mismatched tool sizes

Mini Case

TM is a 2-year-old (8 kg) female patient with a history of epilepsy and developmental delay. She presents to the clinic with fever, decreased appetite, vomiting, diarrhea, and abdominal pain. Her current medications according to her mother are (the mother does not know the concentrations):

- levetiracetam 5 mL twice daily
- phenobarbital 5 mL twice daily

Which of the following best exemplifies ***safe pediatric oral liquid dosing instructions*** for phenobarbital?

a. Phenobarbital 20 mg (5.0 mL) orally twice daily

b. Phenobarbital 20 mg (1 tsp) orally twice daily

c. Phenobarbital 20 mg (5 mL) orally twice daily

d. Phenobarbital 5 cc orally twice daily

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Which of the following best exemplifies ***safe pediatric oral liquid dosing instructions*** for phenobarbital?

a. Phenobarbital 20 mg (5.0 mL) orally twice daily → trailing zero

b. Phenobarbital 20 mg (1 tsp) orally twice daily

c. Phenobarbital 20 mg (5 mL) orally twice daily

d. Phenobarbital 5 cc orally twice daily

Medication Dosing in Pediatrics

- Pediatric patients are classified into different age groups and **dosing often depends upon their age group**
- Different approaches to dosing
  - Weight-based
    - mg/kg/**day** → divided doses or daily dose
    - mg/kg/**dose**
  - Body surface area (BSA)-based
    - mg/**m**^{2}/dose
- Calculation errors mixing up the two are common
  - Dose checking software built into EMRs can help prevent these errors

Am J Health Syst Pharm. 2019;76(19):1463-1471

Calculating Weight-based Doses

- Take the dose in mg (or g) and divide it by the patient's weight (in kgs) to get mg/kg or g/kg
  - Compare to a dosing reference
- Example: Amoxicillin 400 mg PO BID for a 9 kg patient

Amoxicillin is dosed mg/kg/**DAY**

400 mg PO BID = 800 mg / day

800 mg / 9kg = 88.9 mg/kg/day

Dosing ranges from **20 to 100 mg/kg/day** depending on indication

Calculating Weight-based Doses

- Take the dose in mg (or g) and divide it by the patient's weight (in kgs) to get mg/kg or g/kg
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- Example: Amoxicillin 400 mg PO BID for a 9 kg patient

Dose is within range!

Amoxicillin is dosed mg/kg/**DAY**

400 mg PO BID = 800 mg / day

800 mg / 9kg = 88.9 mg/kg/day

Dosing ranges from **20 to 100 mg/kg/day** depending on indication

Weight-based Dosing – Practice

A 3-year-old boy weighing 15 kg has been admitted and diagnosed with meningitis. The physician would like to start empiric vancomycin at 60 mg/kg/day, divided either every 8 or every 6 hours.

Which of the following would be an appropriate dose?

a. 225 mg IV Q 6 hours
b. 300 mg IV Q 6 hours
c. 450 mg IV Q 8 hours
d. 900 mg IV Q 8 hours

Weight-based Dosing – Practice

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c. 450 mg IV Q 8 hours
d. 900 mg IV Q 8 hours

60 mg/**kg**/day x 15 **kg**
900 mg/**day**
Divided in 3 doses/**day** = 300 mg per dose or Q8HR
Divided in 4 doses/**day** = 225 mg per dose or Q6HR

Calculating Body Surface Area-based Doses

- Mosteller method of calculating Body Surface Area (BSA)

$$BSA\ (\mathbf{m^2}) = \sqrt{\frac{Height\ (cm) x\ Weight\ (kg)}{3600}}$$

- Example: Acyclovir for a patient that weighs 5 kg and is 58 cm tall; dose needed is 300 mg/**$\mathbf{m^2}$/DOSE** every 8 hours

√ [(58 cm x 5 kg)/3600]

BSA = 0.28 m^2

300 mg/m^2 x 0.28 m^2 = 85 mg/DOSE

Suspension is 200 mg / 5 mL

Dose rounding recommended; round down to 80 mg or 2 mL Q8H

Am J Health Syst Pharm. 2019;76(19):1463-1471

Key Potentially Inappropriate Drugs In Pediatrics: The KIDs List

- Extensive literature review to identify medications with heightened risk of adverse drug events or reactions in pediatric patients
- Likened to “Beers criteria” list created in 1990s for potentially inappropriate medication use in older adults
- Goal to enhance medication safety and quality of patient care in pediatric population
- Identified 67 drugs and/or drug classes and 10 excipients considered “potentially inappropriate”
  - Classified as “avoid use” or “caution” based on strength of evidence and severity of ADE and/or ADR

J Pediatr Pharmacol Ther. 2020;25(3):175-191

KIDs List

Drug	Risk/Rationale	Recommendation	Strength of Recommendation	Quality of Evidence
Atazanavir[51]	Kernicterus	Caution in neonates unless pharmacogenetic testing is used	Weak	Very low
Benzocaine[52–57]	Methemoglobinemia	Avoid in infants for teething or pharyngitis	Strong	High
Camphor[58–60]	Seizures	Caution in children	Weak	Low
Carbinoxamine[61]	Death	Avoid in <1 year	Strong	Low
Ceftriaxone[62,63]	Kernicterus	Caution in neonates	Weak	Very low
Chloramphenicol[64]	Gray baby syndrome	Avoid in neonates unless serum concentration monitoring is used	Strong	High
Chlorhexidine[65]	Chemical burn	Caution in very low birth weight neonates	Strong	Low
Codeine[66–69]	Respiratory depression, death	Avoid in children unless pharmacogenetic testing is used	Strong	High
Darunavir[70]	Seizures, death	Avoid in <3 years or <10 kg	Strong	Very low
Daptomycin[71]	Neuromuscular and skeletal adverse events	Caution in <1 year	Weak	Very low
Dicloxacillin[72]	Kernicterus	Caution in neonates	Weak	Very low
Dicyclomine[73]	Apnea	Avoid in <6 months	Strong	Low
Difluprednate[74,75]	Increased intraocular pressure	Caution in children	Weak	Low
Diphenoxylate and atropine[76]	Respiratory depression, death	Avoid in <6 years	Strong	Moderate
Dopamine antagonists Chlorpromazine[77] Fluphenazine[77] Haloperidol[77,78] Metoclopramide[77,81–88] Perphenazine[77] Pimozide[77,78,87] Prochlorperazine[77,79,83,88–90] Promethazine[91–93] Trifluoperazine[77] Trimethobenzamide[94]	Acute dystonia (dyskinesia); increased risk of respiratory depression, extravasation, and death with intravenous use	Avoid in infants Caution in children	Strong: Chlorpromazine Fluphenazine Haloperidol Perphenazine Pimozide Prochlorperazine Promethazine Trifluoperazine Weak: Metoclopramide Trimethobenzamide	Moderate
Gentamicin ophthalmic ointment[95–97]	Severe ocular reactions	Avoid in neonates	Strong	High

J Pediatr Pharmacol Ther. 2020;25(3):175-191

KIDs List

Drug	Risk/Rationale	Recommendation	Strength of Recommendation	Quality of Evidence
Hexachlorophene[98]	Neurotoxicity	Avoid in neonates	Strong	High
Indinavir[99]	Nephrolithiasis Hyperbilirubinemia	Avoid in children Avoid in neonates	Strong Strong	High Low
Ivermectin (oral)[100,101]	Encephalopathy	Avoid in <1 year	Weak	Low
Lamotrigine[102]	Serious skin rashes	Caution in children; titration needed	Strong	High
Lidocaine 2% viscous[103,104]	Seizures, arrhythmia, death (due to CNS depression, seizures, or dysrhythmias)	Avoid in infants for teething	Strong	High
Linaclotide[105]	Death from dehydration	Avoid in <6 years	Weak	Very low
Lindane[106,107]	Seizure, spasm	Avoid in <10 years or <50 kg	Moderate	Low
Loperamide[108]	Ileus, lethargy	Avoid in infants for acute infectious diarrhea	Strong	High
Macrolides[109–112] Azithromycin Erythromycin (oral and intravenous)	Hypertrophic pyloric stenosis	Avoid in neonates, unless treating *Bordetella pertussis* (azithromycin), or *Chlamydia trachomatis* pneumonia (azithromycin and erythromycin) Consider risk/benefit ratio when using for ureaplasma (azithromycin)	Strong	High
Malathion[113]	Increased absorption (organophosphate poisoning)	Avoid in <1 year	Weak	Very low
Meperidine[114,115]	Respiratory depression	Avoid in neonates Caution in children	Strong	High
Midazolam[116]	Severe intraventricular hemorrhage, periventricular leukomalacia, or death	Avoid in very low birth weight neonates	Strong	High
Mineral oil, oral[117]	Lipid pneumonitis	Avoid in <1 year	Strong	Low
Naloxone[118,119]	Seizure	Avoid in neonates for postpartum resuscitation	Strong	High
Nitrofurantoin[120,121]	Hemolytic anemia	Avoid in neonates	Weak	Very low
Olanzapine[122]	Metabolic syndrome (weight gain, hyperlipidemia, hyperglycemia)	Caution long-term use (>24 weeks) in children	Strong	High
Opium tincture[123]	Respiratory depression	Avoid in neonates Caution in children	Strong	High

J Pediatr Pharmacol Ther. 2020;25(3):175-191

KIDs List

Drug	Risk/Rationale	Recommendation	Strength of Recommendation	Quality of Evidence
Paregoric[123]	Gasping syndrome, seizures, CNS depression, hypoglycemia	Avoid in children	Strong	High
Plecanatide[124]	Death from dehydration	Avoid in <6 years	Weak	Very low
Propofol[125–130]	Propofol-related infusion syndrome; higher rate in children than adults because higher relative doses of propofol are needed, especially in status epilepticus	Avoid doses >4 mg/kg/hr for greater than 48 hours	Strong	Moderate
Salicylates[42,131–134] ★ Aspirin Bismuth subsalicylate Choline magnesium trisalicylate Magnesium salicylate Methenamine, sodium phosphate monobasic, phenyl salicylate, methylene blue, and hyoscyamine Methyl salicylate (topical) Salicylic acid Salsalate	Reye's syndrome	Caution in children with suspicion of viral illness (influenza and varicella)	Weak	Very low
Sodium phosphate solution, rectal (enema)[135,136]	Electrolyte abnormalities, acute kidney injury, arrhythmia, death	Avoid in infants	Strong	High
Sodium polystyrene sulfonate[137,138]	Colonic perforation	Avoid in very low birth weight neonates	Weak	Low
Sulfonamides ★ Silver sulfadiazine[139] Sulfadiazine[139] Sulfamethoxazole[72,140]	Kernicterus	Avoid in neonates except as adjunctive therapy with pyrimethamine as a treatment of congenital toxoplasmosis (sulfadiazine)	Weak	Very low
Tetracyclines[141–147] ★ Demeclocycline Tetracycline	Tooth discoloration (demeclocycline and tetracycline)	Caution in <8 years	Strong	High
	Enamel hypoplasia (tetracycline)	Caution in <8 years	Strong	High
	Retardation of skeletal development and bone growth in premature neonates (tetracycline)	Caution in neonates	Strong	Moderate

J Pediatr Pharmacol Ther. 2020;25(3):175-191

KIDs List

Drug	Risk/Rationale	Recommendation	Strength of Recommendation	Quality of Evidence
Topical corticosteroids (medium, high and very high potency)[148,149] ☆	Adrenal suppression; higher rate of systemic absorption in children than adults	Avoid in <1 year for diaper dermatitis	Strong	Low
Tramadol[66,150]	Respiratory depression	Caution in children unless pharmacogenomic testing is used	Weak	Low
Tricyclic antidepressants[151–153] Desipramine Imipramine	Sudden cardiac death	Avoid in children (desipramine) Caution in children (imipramine)	Strong	High (desipramine) Moderate (imipramine)
Valproic acid and derivatives[154–156]	Pancreatitis, fatal hepatotoxicity	Avoid in infants Caution in <6 years	Strong	High
Verapamil[157–159]	Asystole	Avoid in <1 year	Weak	Low

J Pediatr Pharmacol Ther. 2020;25(3):175-191

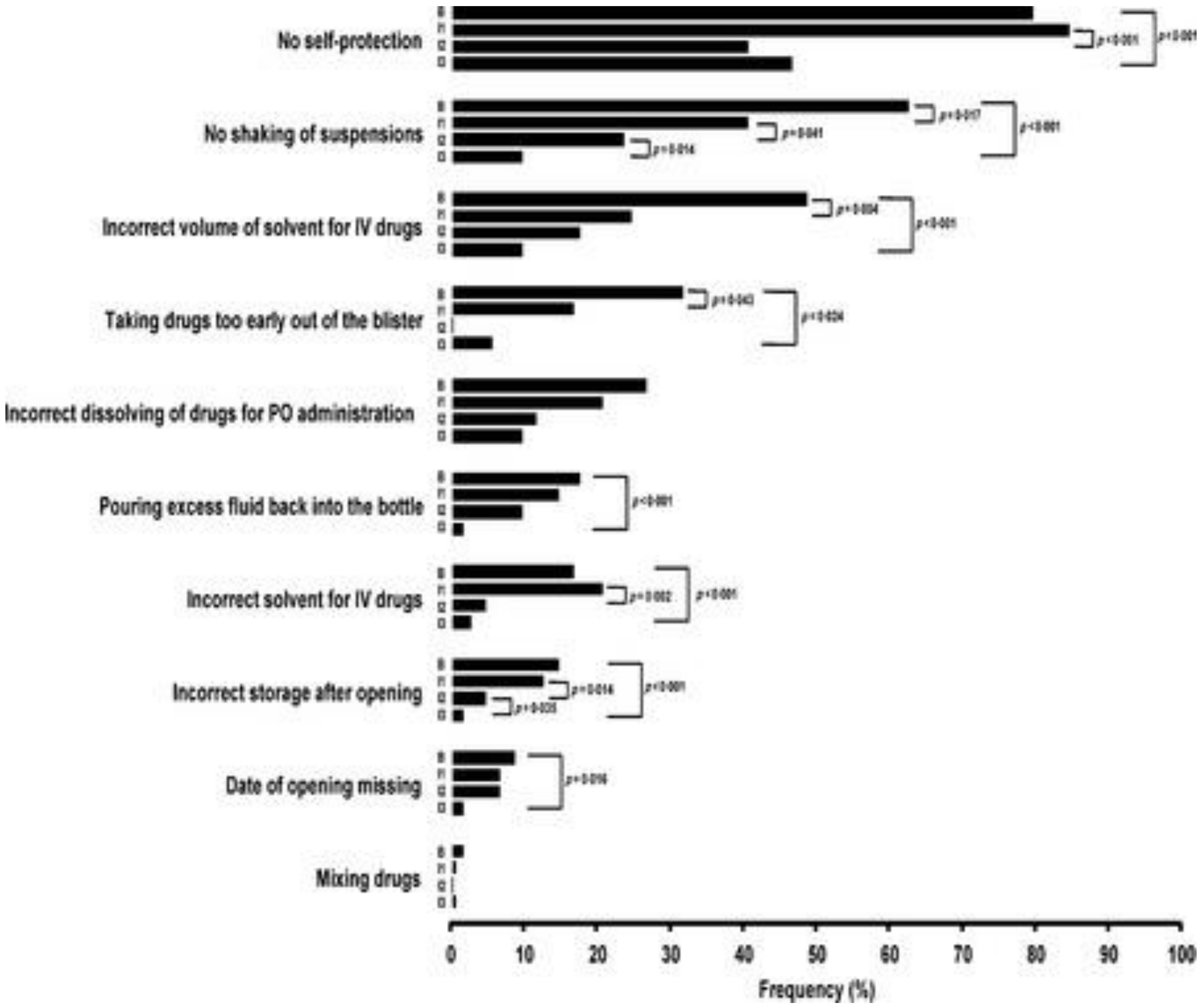
Compounding and Preparation Errors

- Wrong dilution/solvent and suspension handling
  - Incorrect volume or type of solvent for IV drugs
  - Failing to shake suspensions before administration
- Unit/measurement confusion
  - Teaspoon-milliliter confusion can cause a **fivefold over- or underdose**
  - Milligram-milliliter confusion also occurs
- Push for **milliliter-only dosing**

Pediatrics (2021) 148 (6): e2021054666

Compounding and Preparation Errors

- The following figure from the pediatric drug-handling intervention study shows the **ten most common drug-handling/preparation errors**



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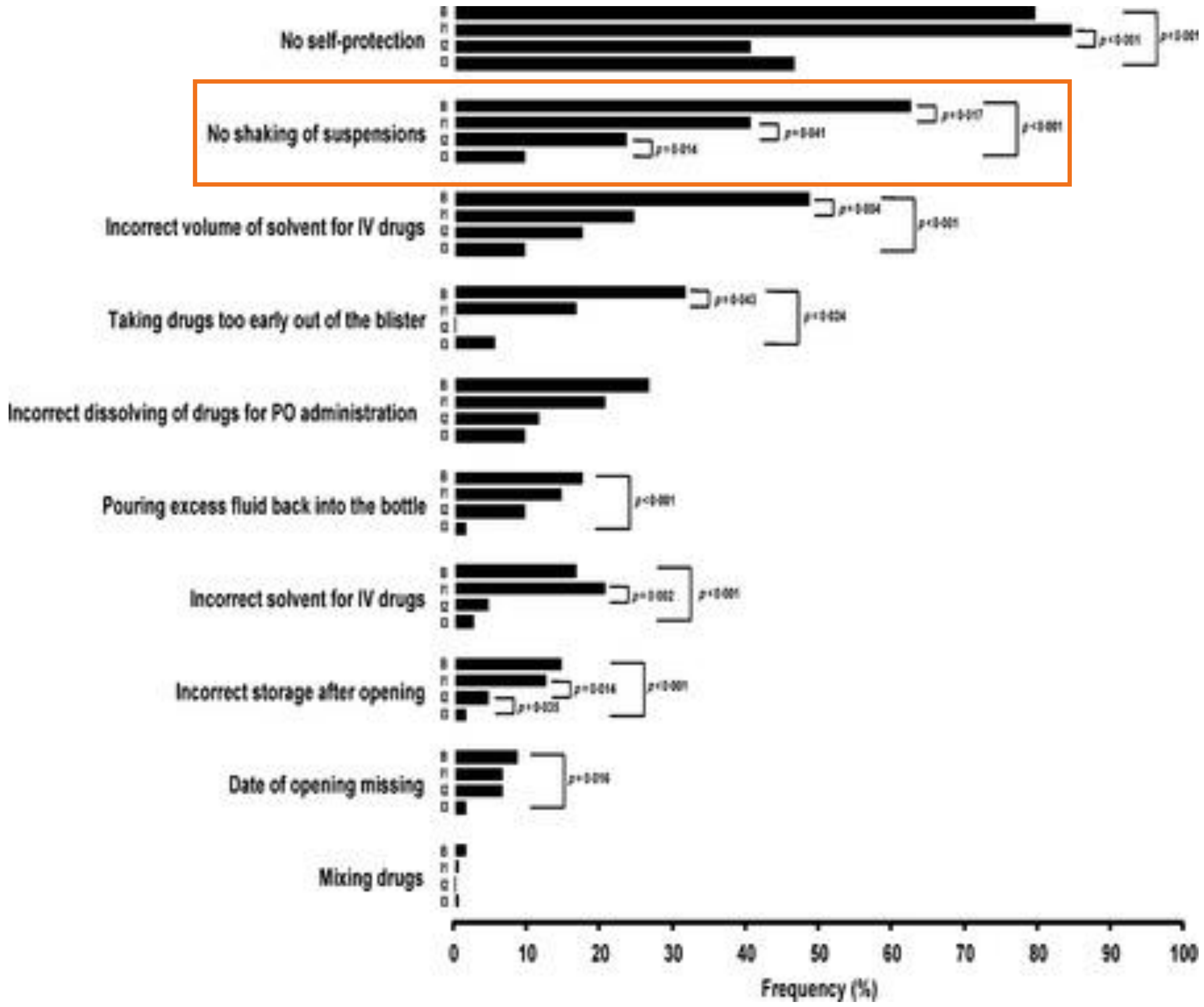

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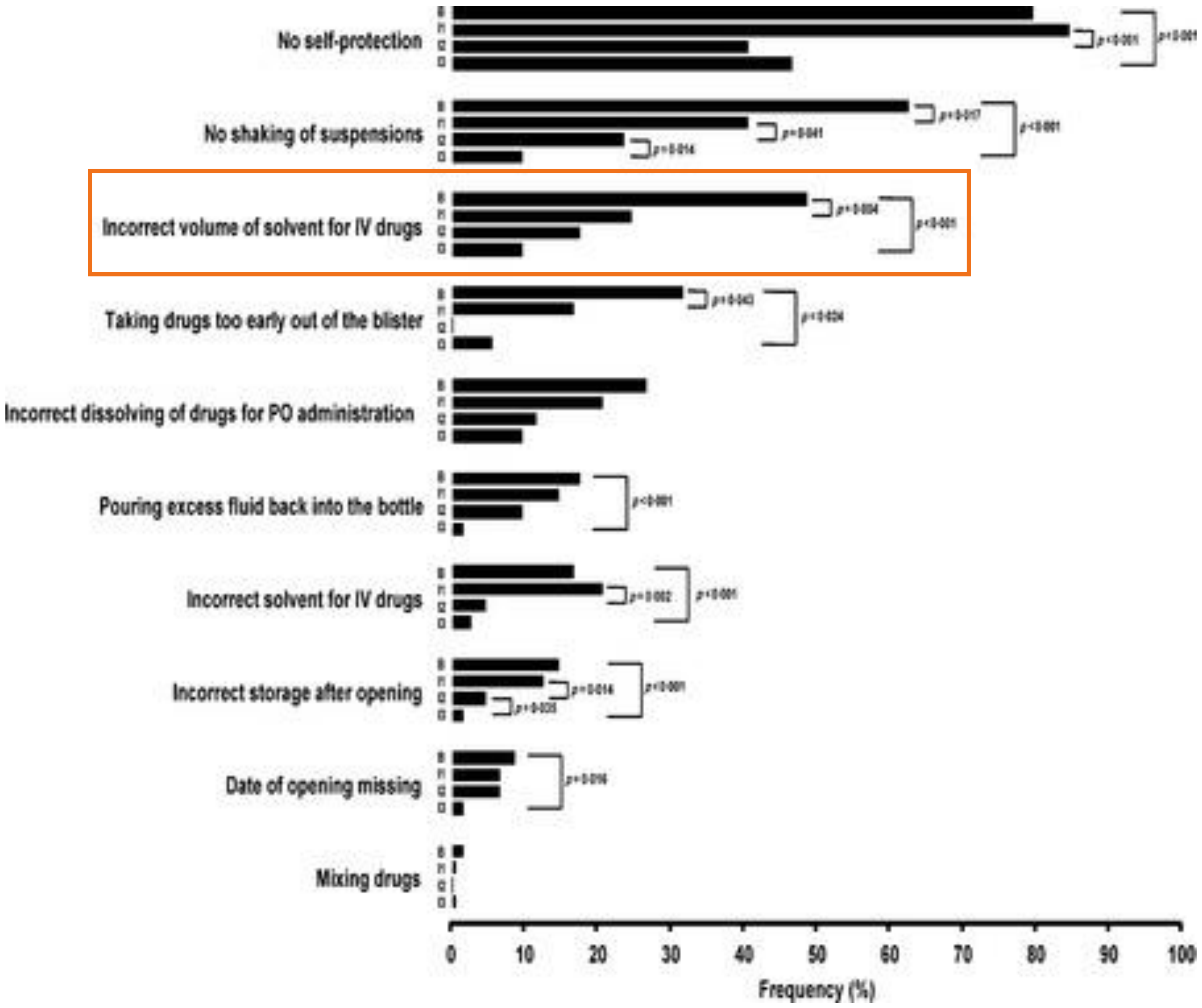

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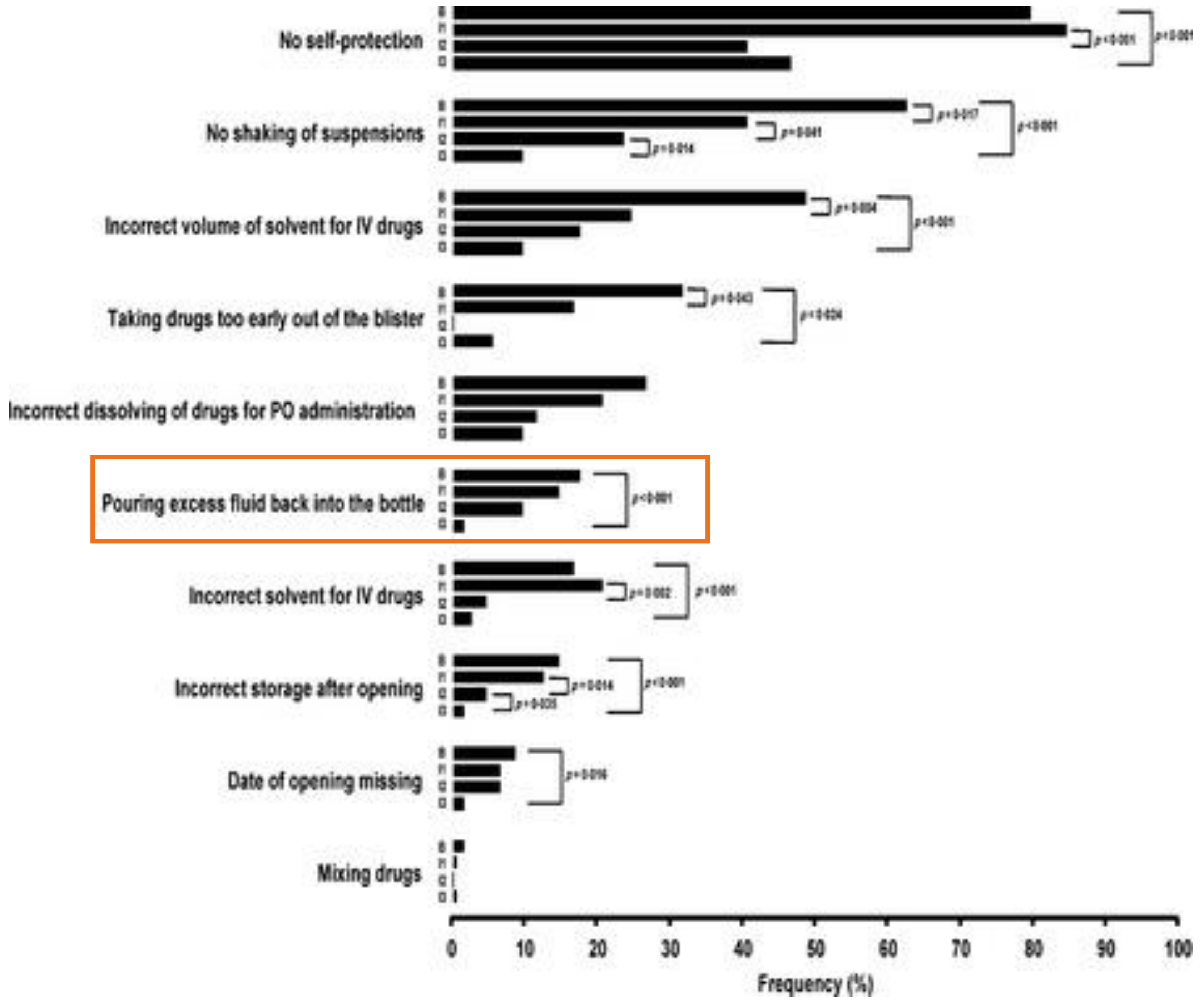

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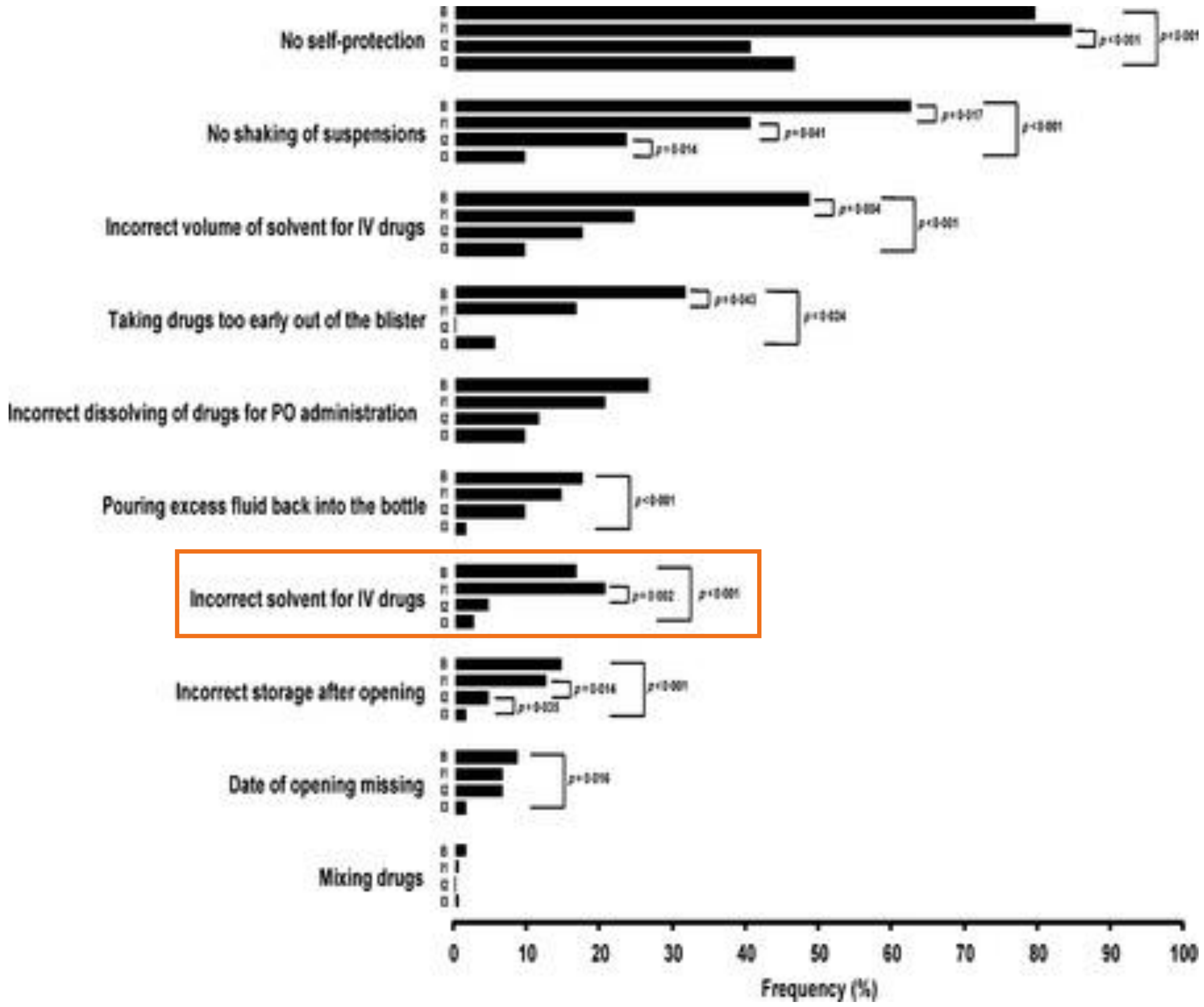
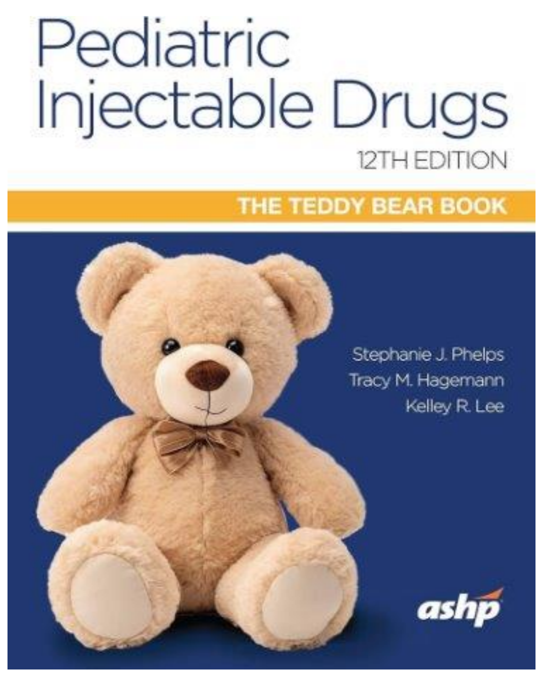
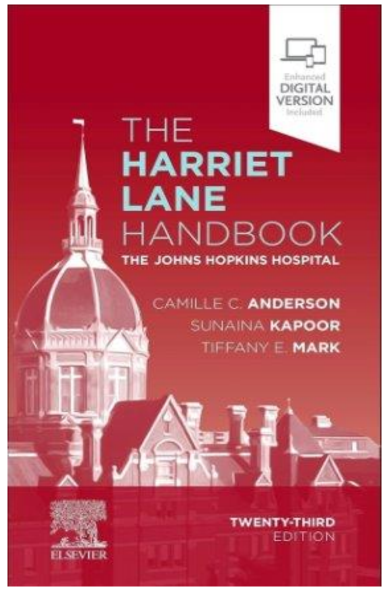


J Clin Nurs, 24: 101-114

Drug Information Resources for Pediatrics

- **General Resources:**
  - FDA Approved Labeling (Package Insert)
  - Micromedex | Neofax®
  - Pediatric and Neonatal Dosage Handbook (Lexicomp®)
  - The Harriet Lane Handbook
- **Parenteral Therapy Resources:**
  - Pediatric Injectable Drugs (The Teddy Bear Book)
  - Handbook of Injectable Drugs (Trissel's)
- **Websites:**
  - American Academy of Pediatrics (AAP) – www.aap.org
  - Pediatric Pharmacy Advocacy Group (PPAG) – www.ppag.org





Pediatric Risk Factors

Different and **changing** PK parameters	Need for **calculation** of individualized doses; unique risk for 10-fold errors	Lack of available **dosage forms and concentrations** appropriate for administration	Need for **precise dose measurement** and appropriate **drug delivery systems**
Limited reserve to withstand errors	Limited ability to **communicate** to prevent an error or signal that an error has occurred	Wide range of correct drug doses depending on **indication**	Lack of published information or FDA-approved labeling

Levine SR et al. J Pediatr Pharmacol Ther. 2001; 6:427-43.
Abramson EL. Pediatr Clin North Am. 2012; 59:1247-55.

Patient Safety Strategies

Metric units of measure should be the standard nomenclature for pediatric weight documentation	The volume of liquid pediatric medication doses should be expressed using **metric units** only	Concentrations / strengths of high-alert drugs are **standardized** and limited	Prescribers include **both** the mg/kg or mg/m^2 dose AND the calculated amount per dose
Use **weight-based dosing** for pediatrics	PN / complex electrolyte solutions are made with **automated** compounding devices	Dispense patient-specific doses of liquid oral / enteral / parenteral as **unit doses**	Pharmacists verify components of pediatric sterile preparations prior to adding to the solution

Kennedy AR et al. Am J Health SystPharm. 2019; 76(19):1481-91.
Institute for Safe Medication Practices (ISMP).

Medication Use Process Vulnerabilities

- Medication errors occur at all stages of the medication use process
  - Unique risks at every step
- Surveys have indicated increased compliance with error prevention strategies in pediatric hospitals versus adult hospitals that care for pediatric patients
- Risk mitigation is critical to prevention of errors
- Technology should be leveraged to help drive best practices
  - Make it easy to do the right thing

Procurement and Formulary Management → Medication Reconciliation → Ordering → Preparation and Dispensing → Administration → Monitoring

Kennedy AR, et al. *Am J Health Syst Pharm*. 2019;76(19):1481-91.

Pediatric Risk Considerations in the Medication-Use Process

Procurement

- **Adult-focused** medications in formulary
- Lack of stocked pediatric-friendly/appropriate dosage forms and/or concentrations
- Medications frequently require **off-label use**

Medication Reconciliation

- Need for **familiarity** with medications used in this population
- Extemporaneously **compounded medications** are common

Ordering

- Lack of **pediatric-specific** order sets and protocols
- Paucity of pediatric-specific dosing literature
- Dosing is **weight-based** and requires calculation

Kennedy AR, et al. *Am J Health Syst Pharm*. 2019;76(19):1481-91.

Pediatric Risk Considerations in the Medication-Use Process

Preparation and Dispensing

- Requires multistep processes and manipulations to provide appropriate dosage forms and concentrations
- Standard or **commercially available concentrations used in adults may not be suitable** for pediatric patients

Administration

- Need for **unique medication delivery devices** (e.g., syringe pumps, IV and PO dosing syringes)
- Infusion rates may need to be calculated and programmed into delivery device

Monitoring

- **Unique monitoring** may be required due to differences in medication metabolism or excretion
- Pediatric-specific **target reference ranges may not be stated** in literature or easily accessible within the laboratory or system's library

Kennedy AR, et al. *Am J Health Syst Pharm*. 2019;76(19):1481-91.

Risk Mitigation Strategies

- Procurement and formulary management
  - Stock pediatric formulations whenever possible
  - Consider pediatric formulations in drug shortage management
  - Assess historical data related to past pediatric patients
- Medication Reconciliation
  - Utilize pharmacy personnel to conduct medication history taking
  - Provide training
- Ordering
  - Use rule-based contexts in EMR
  - Implement published best practices in medication safety (e.g., eliminate use of trailing zeros, record measurements in metric units)
  - Continue to use weight-based dosing unless the dose or daily total exceeds the recommended adult dose for the same indication

Kennedy AR, et al. *Am J Health Syst Pharm*. 2019;76(19):1481-91.

Risk Mitigation Strategies

- Preparation, Dispensing, and Administration
  - Utilize compounding records in EMR
  - Provide standardized preparation instructions in EMR
  - Dispense doses in most ready-to-administer form
  - Utilize smart infusion pumps, syringe pumps or modules, pediatric and/or neonatal drug libraries, and infusion pump integration technology
- Miscellaneous
  - Provide pharmacy students and residents with exposure to pediatric populations
  - Require basic pediatric competencies for pharmacy personnel
  - Provide access to pediatrics references
  - Facilitate pharmacist involvement in pediatric services and drug policy

Kennedy AR, et al. *Am J Health Syst Pharm*. 2019;76(19):1481-91.

Computerized Physician Order Entry (CPOE) in Pediatrics

- Tremendous potential for improving patient safety
- Research has focused on reduction in prescribing errors
- Implementation phase critical to success
- Reports of unintended consequences

Potential benefits of CPOEs
• **Eliminate illegibility** of prescribing • **Ensure completeness** of prescribing fields • Reduce **transcription** errors • Provide **clinical decision support** (CDS) to aid in preventing prescribing errors (i.e., order sets, alerts, reminders, and screening guidelines) • Improve **tracking** of orders

Abramson EL. *PediatrClin North Am*. 2012;59:1247-55
Kennedy AR, et al. *Am J Health Syst Pharm*. 2019;76(19):1481-91.

Important Considerations with CPOEs

- Significant variation exists in functionality available for pediatrics
  - Use of EHR that allow for configuration of default medication doses or frequencies based on patient's age, weight, or location is an important risk mitigation strategy
  - Leverage EHR compounding records and labels to provide explicit guidance
- Conflicting mortality outcomes with pediatric studies to date

Unintended Consequences of CPOEs

- Fostering of new types of errors (i.e., wrong patient selection, wrong drug selection)
- Alert fatigue resulting in overriding of appropriate alerts
- Inappropriate alerts resulting in delay in appropriate therapy
- Changes in communication patterns (i.e., illusion of communication electronically)
- Workflow alteration that may impact delivery of patient care

Abramson EL. *PediatrClin North Am*. 2012;59:1247-55
Kennedy AR, et al. *Am J Health Syst Pharm*. 2019;76(19):1481-91.

Self-assessment

As a pharmacist serving on the medication safety committee, you are asked by a physician what type of medication errors may be **increased** after the implementation of a CPOE system at your facility based on published literature?

Which of the following is the most appropriate response?

a. Incomplete medication orders leading to errors
b. Prescriber dosing errors
c. Wrong patient selection errors
d. Transcription errors

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Employing Barcode Medication Administration

- Barcode medication administration (BCMA) systems reduce medication administration errors
  - Wrong-patient
  - Wrong-medication
- BCMA is specifically designed to verify a patient's identity and the medication at the bedside
- Typically paired with an electronic medication administration record (eMAR) that imports orders electronically
  - **41.4% relative reduction** in non-timing administration errors (11.5% → 6.8%)
  - **50.8% relative reduction** in potential adverse drug events (3.1% → 1.6%)

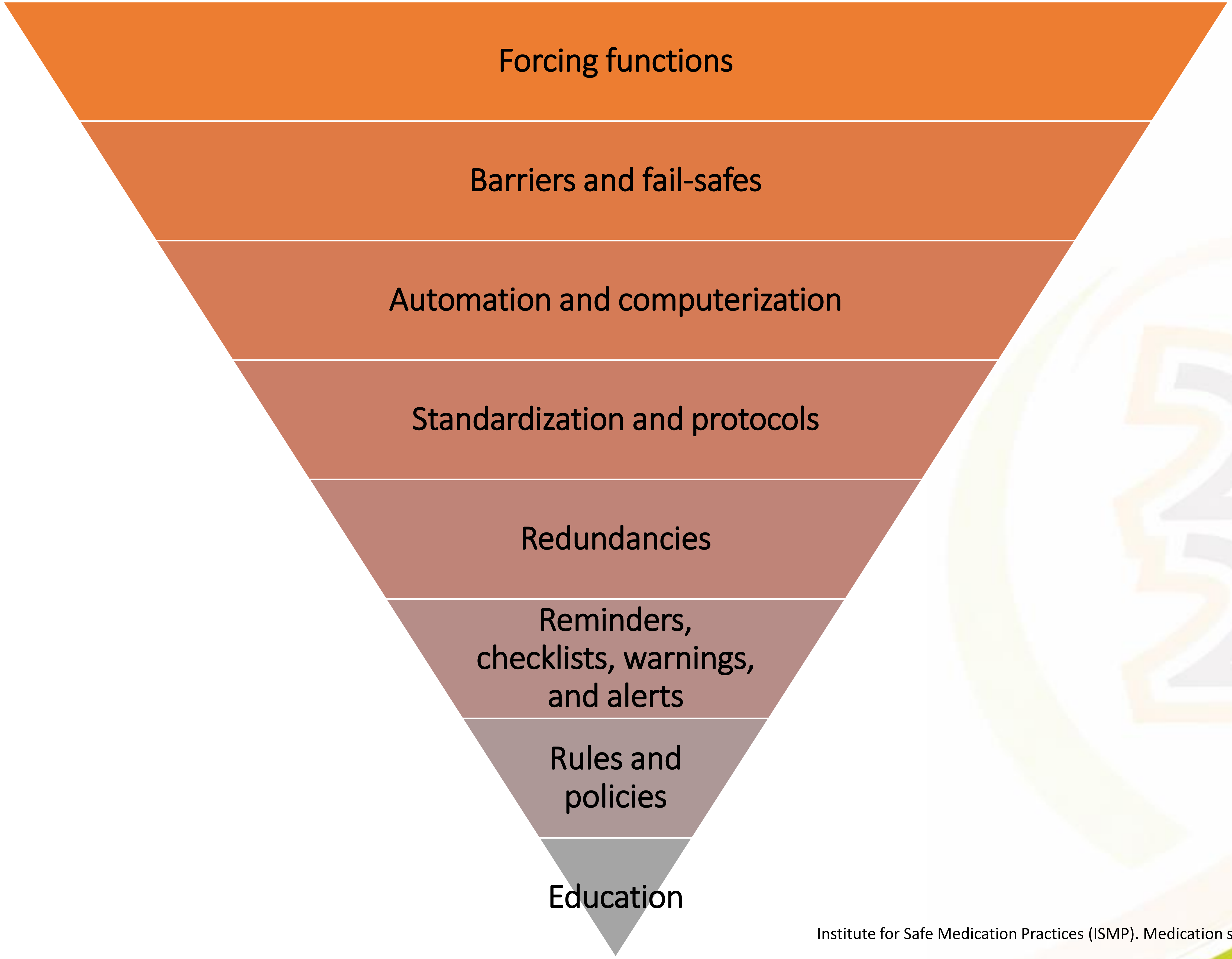
Cochrane Database Syst Rev. 2015;2015(3):CD00620
N Engl J Med. 2010;362(18):1698-1707

Employing Barcode Medication Administration

- BCMA is most effective as part of a bundled strategy combined with CPOE
- Prerequisites to capturing the wrong-drug/wrong-patient benefit include:
  - Pediatric-tailored barcoding (many liquid/compounded preparations lack usable barcodes)
  - EHR customization

Cochrane Database Syst Rev. 2015;2015(3):CD00620
N Engl J Med. 2010;362(18):1698-1707

Error Reduction Strategies



Institute for Safe Medication Practices (ISMP). Medication safety alert! Acute care. Volume 25 Issue 11 June 4, 2020.

Key Takeaways

- Children are **not** small adults
- Dosing errors are the most common pediatric medication error
- Always verify the fundamentals:
  - Correct patient
  - Weight in kilograms
  - Appropriate **dose** → mg/kg/**day**, mg/kg/**dose**, mg/**m^2**
  - Correct **concentration**
  - Final volume and directions in **milliliters** (mL)
- Oral liquid medications require special attention
  - Use mL only → avoid tsp, tbsp, and cc
  - Provide calibrated dosing devices AND caregiver education
- Independent verification prevents serious harm
- Technology helps, but does not replace clinical judgement
  - CPOE, BCMA, smart pumps, and decision support reduce errors but create new risks

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The safest pediatric medication process combines **age-appropriate dosing knowledge**, **independent verification**, **standardized practices**, and **caregiver education**.

Post-Test

1. Which of the following factors contributes most to the increased risk of medication errors in pediatric patients?
   a. Pediatric medications are usually standardized across all patients
   b. Pediatric dosing often requires individualized weight-based calculations
   c. Pediatric patients typically receive fewer medications than adults
   d. Pediatric patients rarely require preparation or manipulation

Post-Test

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    a. Pediatric medications are usually standardized across all patients
    b. Pediatric dosing often requires individualized weight-based calculations
    c. Pediatric patients typically receive fewer medications than adults
    d. Pediatric patients rarely require preparation or manipulation

Many pediatric medications are dosed using weight-based calculations (mg/kg), which increases the complexity of prescribing, dispensing, and administration compared with standardized adult doses. These **calculations introduce additional opportunities for errors** such as incorrect weight entry or mathematical mistakes.

Post-Test

2. Which of the following represents a common type of medication error in pediatric pharmacotherapy?
    a. Misinterpreting dosing instructions written as mg/kg/day versus mg/kg/dose
    b. Selecting medications that include FDA-approved pediatric labeling
    c. Recording the patient's weight in kilograms before calculating doses
    d. Using calibrated oral syringes to measure pediatric liquid medications

Post-Test

2. Which of the following represents a common type of medication error in pediatric pharmacotherapy?
   a. Misinterpreting dosing instructions written as mg/kg/day versus mg/kg/dose
   b. Selecting medications that include FDA-approved pediatric labeling
   c. Recording the patient's weight in kilograms before calculating doses
   d. Using calibrated oral syringes to measure pediatric liquid medications

Confusion between mg/kg/**day** and mg/kg/**dose** dosing instructions can significantly **alter the total amount of medication administered** to pediatric patients. If dosing frequency is misunderstood, the patient may receive several times the intended daily dose.

Post-Test

3. Which of the following is a physiologic difference in pediatric patients that can affect how medications are distributed in the body compared to adults?
   a. Higher amount of body water relative to body weight
   c. More consistent medication absorption across all ages
   d. Fully developed organ function at birth
   e. Lower variability in how medications are processed

Post-Test

3. Which of the following is a physiologic difference in pediatric patients that can affect how medications are distributed in the body compared to adults?
   a. Higher amount of body water relative to body weight
   c. More consistent medication absorption across all ages
   d. Fully developed organ function at birth
   e. Lower variability in how medications are processed

Pediatric patients, especially neonates, have a **higher proportion of total body water** compared to adults. This affects how medications are distributed in the body, particularly water-soluble drugs.

Post-Test

4. A 4-year-old child weighs 40 lbs and is prescribed amoxicillin for acute otitis media. The recommended dosing range is 80–90mg/kg/day divided every 12 hours.

   Which of the following total daily doses would be appropriate for this patient?

   a. 3,400 mg/day
   b. 1,500 mg/day
   c. 1,500 mg/dose every 12 hours
   d. 1,800 mg/dose every 12 hours

Post-Test

4. A 4-year-old child weighs 40 lbs and is prescribed amoxicillin for acute otitis media. The recommended dosing range is 80–90mg/kg/**day** divided every 12 hours.

   Which of the following total daily doses would be appropriate for this patient?

   a. 3,400 mg/day
   b. 1,500 mg/day
   c. 1,500 mg/dose every 12 hours
   d. 1,800 mg/dose every 12 hours

The child's weight is **40 lb ÷ 2.2 = 18.2 kg**. The appropriate total daily dose is **80–90 mg/kg/day** × 18.2 kg = **1456–1638 mg/day**. A total daily dose of 1500 mg/day falls within this range. 1,500 mg/dose and 1,800 mg/dose Q12HR would result in 3,000+ mg/day, which exceeds the recommended range. 3,400 mg/day is calculated using lbs instead of kgs.

Post-Test

5. Which practice is most effective in reducing medication dosing errors in pediatric patients?
    a. Documenting patient weight in pounds and converting during dispensing
    b. Estimating medication doses using standard adult dosing guidelines
    c. Measuring pediatric liquid medications using household teaspoons
    d. Documenting patient weight in kilograms and verifying dose calculations independently

Post-Test

5. Which practice is most effective in reducing medication dosing errors in pediatric patients?
    a. Documenting patient weight in pounds and converting during dispensing
    b. Estimating medication doses using standard adult dosing guidelines
    c. Measuring pediatric liquid medications using household teaspoons
    d. Documenting patient weight in kilograms and verifying dose calculations independently

Recording pediatric patient weights in kilograms **reduces the risk of conversion errors during dose calculations**. Independent verification of weight-based dosing calculations provides an additional safeguard against dosing errors.

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Thank you!

Questions?

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