CHAPTER 10

SPECIAL POPULATIONS

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Abstract

Special populations require modified pharmaceutical care approaches due to physiological differences affecting drug response, disposition, and safety profiles. Pediatric pharmacy addresses age-dependent variations across neonatal, infant, child, and adolescent groups, with developmental pharmacokinetic changes affecting absorption, distribution, metabolism, and excretion requiring weight-based or body surface area calculations, specialized formulations addressing swallowing difficulties, and particular vigilance for medications lacking pediatric labeling or safety data. Geriatric pharmacy focuses on multimorbidity, polypharmacy, and age-related physiological changes including reduced renal function, altered body composition, and diminished homeostatic mechanisms, necessitating deprescribing approaches, fall risk assessment, anticholinergic burden evaluation, and medication regimen simplification to enhance adherence and minimize adverse effects. Pregnancy and lactation considerations balance maternal benefit against fetal or infant risk using classification systems that evaluate reproductive toxicity and transplacental or breast milk transfer, with recommendations varying by trimester, condition severity, and alternative therapy availability. Renal and hepatic impairment significantly alter drug clearance pathways, requiring systematic dosage adjustments based on quantitative organ function assessment, with kidney dysfunction necessitating modifications for renally eliminated medications based on creatinine clearance calculations, and liver impairment affecting highly extracted drugs through altered metabolism and protein binding, requiring Child-Pugh classification-guided interventions. Therapeutic approaches across these populations emphasize individualized therapy, heightened monitoring, and interdisciplinary collaboration to optimize medication effectiveness while minimizing iatrogenic harm.

Keywords: *Pharmacokinetics; Physiological alterations; Dose individualization; Organ dysfunction; Vulnerability*

Learning Objectives

After completion of the chapter, the learners should be able to:

- Calculate pediatric medication doses using weight-based, body surface area, and age-based methods with appropriate safety checks.
- Apply geriatric-specific prescribing principles including Beers Criteria and STOPP/START criteria to optimize medication therapy in older adults.
- Evaluate medication risks during pregnancy and lactation using FDA pregnancy categories and lactation safety data.
- Recommend appropriate dosage adjustments for patients with varying degrees of renal impairment based on drug properties and kidney function.
- Modify medication regimens for patients with hepatic impairment based on Child-Pugh classification and drug metabolism pathways.
- Develop monitoring plans addressing population-specific medication risks including growth effects in pediatrics, fall risk in geriatrics, fetal effects in pregnancy, and organ function in impaired patients.

PEDIATRIC PHARMACY

Pediatric pharmacy encompasses the art and science of providing pharmaceutical care to infants, children, and adolescents. This specialized practice recognizes that children are not simply "small adults" but rather individuals with distinct physiological, pharmacokinetic, and pharmacodynamic characteristics that evolve throughout development. Medication therapy in pediatric patients requires careful consideration of age-appropriate dosing, suitable formulations, developmental pharmacology, and unique monitoring parameters to ensure both safety and efficacy.

Developmental Pharmacokinetics

Developmental changes in absorption, distribution, metabolism, and excretion significantly influence drug disposition throughout childhood. Gastric pH progresses from relative neutrality in neonates toward adult acidity by approximately two years of age, affecting ionization and subsequent absorption of pH-dependent medications. Gastric emptying time and intestinal transit demonstrate reduced efficiency and predictability in neonates and young infants, introducing variability in oral drug absorption rates. Skin permeability remains increased in premature and term neonates, potentially enhancing

absorption of topically applied substances with systemic toxicity risk. Body composition varies markedly with age, with neonates demonstrating higher total body water percentage and lower adipose tissue proportion compared to older children and adults. These differences alter the volume of distribution for water-soluble and lipophilic medications, necessitating weight-based dosing adjustments. Plasma protein binding capacity is reduced in neonates due to lower albumin concentrations and reduced protein binding affinity, potentially increasing the free fraction of highly protein-bound drugs with subsequent enhanced pharmacological effects or toxicity. Hepatic drug metabolism undergoes significant maturation throughout development, with phase I oxidative pathways mediated by cytochrome P450 enzymes displaying variable ontogeny patterns. CYP3A7 predominates in fetal life but diminishes postnatally, while CYP3A4, CYP2D6, and CYP1A2 demonstrate delayed maturation, reaching adult capacity at different developmental stages. Phase II conjugation pathways, particularly glucuronidation, show significant immaturity in neonates, affecting medications requiring this metabolic pathway. Renal function matures progressively, with glomerular filtration rate approaching adult values by 6-12 months of age when normalized to body surface area, though absolute capacity remains lower throughout childhood.

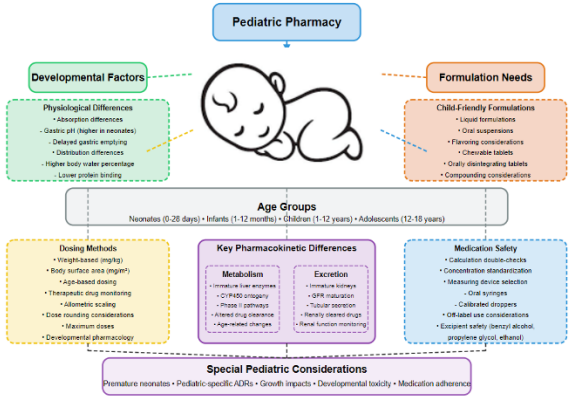

Figure 10.1: Pediatric Pharmacy

Medication Formulations and Administration Techniques

Age-appropriate formulation selection remains fundamental to pediatric medication safety and adherence. Liquid formulations including solutions and suspensions accommodate flexible dosing requirements while eliminating swallowing difficulties common in

younger patients. However, these preparations often contain potentially problematic excipients including preservatives, sweeteners, and alcohol that require careful evaluation, particularly in neonates and infants. Measuring devices including oral syringes and calibrated cups should accompany liquid medications to prevent dosing errors associated with household spoons. Solid dosage forms present swallowing challenges for younger children, with tablets generally considered appropriate after age 6-7 years, though individual development determines actual capability. Dispersible tablets and orally disintegrating formulations offer alternatives for children transitioning from liquids to conventional solid forms. Extemporaneous compounding addresses the frequent absence of commercially available pediatric formulations, though stability, bioavailability, and excipient safety require thorough consideration. Beyond formulation selection, administration techniques significantly influence therapeutic outcomes.

Table 10.1: Pediatric Pharmacokinetic Considerations

Parameter	Neonates (0-28 days)	Infants (1-12 months)	Children (1-12 years)	Adolescents (12-18 years)
Gastric pH	Increased (>4)	Gradually decreases	Adult values by age 2	Adult values
Gastric Emptying	Delayed, irregular	Approaches adult values	Similar to adults	Adult values
GI Transit Time	Prolonged	Variable	Similar to adults	Adult values
Gastric Enzymes	Reduced activity	Developing	Near adult levels	Adult values
Body Water %	75-80%	60-65%	60-65%	55-60%
Body Fat %	10-15%	20-25%	20-30%	10-25%
Plasma Proteins	Decreased albumin, binding affinity	Gradually increasing	Near adult levels	Adult values
Blood-Brain Barrier	More permeable	Developing	Near adult function	Adult function
Phase I Metabolism	Reduced (30-50% of adult)	Developing (50-70% of adult)	May exceed adult values	Adult values or higher

Parameter	Neonates (0-28 days)	Infants (1-12 months)	Children (1-12 years)	Adolescents (12-18 years)
Phase II Metabolism	Significantly reduced	Gradually developing	Variable by pathway	Adult values
CYP Enzyme Development	CYP3A7 predominant Limited CYP3A4, 2D6, 1A2	CYP3A4 developing Limited 2D6, 1A2	Variable enzyme maturation	Adult values
Glomerular Filtration	30-40% of adult values	50-80% of adult values	Reaches adult values by 1 year (per BSA)	Adult values
Tubular Secretion	Reduced	Gradually developing	Near adult function	Adult function
Renal Blood Flow	Reduced	Increasing	Proportional to kidney size	Adult values
Half-life	Often prolonged	Variable, approaching adult values	May be shorter than adults	Adult values

Nasogastric and gastrostomy tube administration necessitates assessment of medication compatibility with enteral feeding formulas, adequate tube flushing protocols, and consideration of potential adsorption to tubing materials. Intravenous administration in pediatric patients requires precise calculation of appropriate concentrations and infusion rates based on fluid restrictions and vascular access limitations. Small-volume parenteral medications often necessitate dilution for accurate administration, introducing potential for calculation and preparation errors. Inhalation delivery techniques must accommodate developmental capabilities, with transition from nebulizers to metered-dose inhalers with valved holding chambers and eventually dry powder inhalers as coordination and inspiratory capacity develop.

Medication Safety Considerations

Pediatric patients face disproportionate medication safety challenges due to weight-based dosing requirements, developmental variability, and communication limitations. Dosing errors represent the most common medication error type in pediatric settings, with ten-fold miscalculations particularly problematic due to decimal point placement errors and confusion between milligram and microgram units. Standardized medication ordering processes, including mandatory weight documentation, dose calculation verification, and maximum dose alerts, provide essential safeguards.

Table 10.2: Pediatric Medication Administration Considerations

Age Group	Preferred Dosage Forms	Administration Challenges
Premature Neonates	IV solutions Oral liquids	Limited IV access Small fluid volumes Immature organs
Full-term Neonates	IV solutions Oral liquids	Bitter taste rejection Need for precision Limited blood volume
Infants (1-12 months)	Oral liquids Oral drops Rectal formulations	Spitting out medication Taste preferences Positioning challenges
Toddlers (1-3 years)	Oral liquids Chewable tablets ODTs	Refusal behavior Limited cooperation Taste sensitivity
Preschool (3-5 years)	Oral liquids Chewable tablets ODTs Oral sprays	Fear of medication Autonomy issues Swallowing difficulties
School-age (6-11 years)	Chewable tablets Tablets Liquids Inhalers	Pill swallowing School administration Independence vs. supervision
Adolescents (12-18 years)	Adult formulations Tablets/capsules Inhalers Transdermal	Adherence issues Privacy concerns Risk-taking behavior

Age Group	Preferred Dosage Forms	Administration Challenges
Special Needs	Formulation based on capabilities	Cognitive limitations Physical disabilities Sensory issues
NICU Patients	IV infusions Micro-drop oral	Limited access sites Fluid restrictions Drug compatibility
PICU Patients	IV infusions Specialized formulations	Multiple medications Sedation issues Organ dysfunction
Oncology Patients	Various routes	Immunocompromised status Taste changes Multiple medications

Dose range checking incorporating both minimum and maximum parameters helps identify potential underdosing and overdosing situations before administration. Therapeutic duplication monitoring holds particular importance in pediatric practice where multiple formulations or concentrations of the same medication may be prescribed simultaneously. Electronic health record systems with pediatric-specific functionality, including weight-based dose calculators and pediatric-specific clinical decision support, significantly enhance medication safety. Medication reconciliation processes must incorporate age-appropriate interview techniques and multiple information sources, recognizing that children often receive medications across various settings including school, childcare facilities, and multiple caregivers' homes. Adverse drug reaction identification presents unique challenges in non-verbal or pre-verbal children who cannot report subjective symptoms, necessitating careful observation for behavioral changes, feeding pattern alterations, or developmental regression that might indicate medication-related problems. Pharmacists must consider developmental stages when providing medication education, adapting communication strategies to the cognitive capabilities of both pediatric patients and their caregivers while emphasizing proper administration techniques, expected effects, and concerning symptoms requiring healthcare provider notification.

Common Pediatric Therapeutic Challenges

Certain therapeutic areas present recurring challenges in pediatric pharmacy practice, requiring specialized knowledge and approaches.