

Prescribing Guidelines For Special Populations

General Prescribing Guidelines for Paediatric Patients

Introduction

- Paediatric pharmacotherapy is a specialized branch of medicine focusing on the rational and safe use of medications in neonates, infants, children, and adolescents.
- Children are not miniature adults — their body composition, organ function, drug metabolism, and responses to medications differ significantly according to developmental stage.
- Therefore, drug therapy in children demands precise calculation, vigilant monitoring, and individualized decision-making.

Age Classification and Physiological Differences

Age Group	Age Range	Key Physiological Characteristics
Neonate	0–28 days	Immature liver and kidneys, high body water, poor fat stores
Infant	1 month–1 year	Developing enzyme systems, improving renal function
Toddler	1–3 years	Increased metabolic rate, growing organs
Child	4–12 years	Enhanced hepatic metabolism, improving clearance
Adolescent	13–18 years	Hormonal changes influence drug distribution and metabolism

- These age-dependent physiological variations influence **absorption, distribution, metabolism, and excretion (ADME)** of drugs.

Pharmacokinetic and Pharmacodynamic Considerations

Absorption

- **Gastrointestinal pH:** Neonates have a higher (more alkaline) gastric pH, reducing absorption of weak acids (e.g., phenytoin).
- **Gastric emptying:** Delayed in neonates → slower drug absorption and delayed onset.
- **Enzyme activity:** Immature gut enzymes (CYP450, esterases) alter drug bioavailability.
- **Bile salts and pancreatic enzymes:** Low levels reduce absorption of lipophilic drugs and fat-soluble vitamins.
- **Topical absorption:** Enhanced in infants due to thin stratum corneum and higher surface area-to-weight ratio.

Distribution

- **Total body water:** Neonates ≈ 75–80% vs. adults ≈ 60%; increases the volume of distribution (Vd) for hydrophilic drugs (e.g., aminoglycosides).
- **Fat content:** Lower in neonates, decreasing Vd for lipophilic drugs.

- **Protein binding:** Plasma albumin and α_1 -acid glycoprotein levels are lower, increasing free drug concentration and potential toxicity.
- **Blood-brain barrier:** More permeable in infants → higher CNS exposure to drugs.

Metabolism

- **Immature hepatic enzyme systems:** Especially cytochrome P450 enzymes, leading to reduced metabolism.
- **Enzyme maturation:** Progresses over months to years; some drugs (e.g., theophylline) metabolized faster in children aged 1–9 years due to enzyme hyperactivity.
- **Phase I and II reactions:** Glucuronidation and sulfation pathways mature gradually.

Excretion

- **Renal function:** GFR, tubular secretion, and reabsorption are immature in neonates, causing prolonged drug half-lives.
- **Dose adjustment:** Essential for renally excreted drugs like aminoglycosides, digoxin, and vancomycin.
- **By 1 year of age:** Renal clearance typically approaches adult levels.

Dosing Principles

- **Weight-based dosing:** Most paediatric doses are expressed as mg/kg or mg/m².
- **Accurate weight measurement:** Must be current and in kilograms.
- **Avoid scaling down adult doses:** Paediatric pharmacokinetics differ significantly.
- **Use of standard references:** e.g., BNF for Children, Lexicomp, WHO guidelines.
- **Narrow therapeutic index drugs:** Require special caution and monitoring (e.g., digoxin, phenytoin).

Age Stratification for Dosing

- Neonate: Birth–28 days
- Infant: 1 month–1 year
- Child: 1–12 years
- Adolescent: 12–18 years

Rational Drug Selection

- **Formulation preference:** Use age-appropriate dosage forms — syrups, suspensions, chewable tablets, mini-tablets, or dispersible forms.
- **Avoid toxic excipients:**
 - Benzyl alcohol → “Gasping syndrome” in neonates
 - Propylene glycol → CNS depression
 - Ethanol → CNS toxicity

- **Taste masking:** Improves adherence (especially for bitter antibiotics).
- **Simplify regimens:** Minimize polypharmacy to reduce errors and interactions.

Common Drug Restrictions in Paediatrics

Drug/Class	Reason for Avoidance
Tetracyclines	Tooth discoloration, bone growth suppression
Fluoroquinolones	Cartilage toxicity
Aspirin	Risk of Reye's syndrome during viral illness
Promethazine (<2 years)	Respiratory depression
Codeine (<12 years)	Ultra-rapid metabolism → toxicity
Chloramphenicol (neonates)	Gray baby syndrome

Monitoring and Safety

1. Clinical monitoring:

- Vital signs (age-specific norms)
- Growth and development charts

2. Laboratory monitoring:

- Liver function tests (for hepatotoxic drugs)
- Renal function (BUN, serum creatinine)
- Serum drug levels (for drugs like vancomycin, phenytoin, digoxin)

3. Watch for ADRs:

- Children may not verbalize symptoms → look for irritability, poor feeding, vomiting, rash, or drowsiness.
- **Document:** Allergies, immunization status, past adverse reactions.

Parental Counseling and Education

- **Dosing devices:** Use calibrated oral syringes or droppers — avoid household spoons.
- **Administration schedule:** Explain timing, especially for night or missed doses.
- **Adherence:** Emphasize full course completion (especially antibiotics).
- **Storage:** Maintain appropriate temperature and avoid contamination.
- **Recognizing adverse effects:** Teach parents when to seek medical help.

Legal and Ethical Considerations

- **Consent:** Obtain informed consent from parents or guardians before initiating therapy.
- **Off-label use:** Common due to lack of paediatric trials; ensure benefit-risk justification and thorough documentation.
- **Emergency care:** In life-threatening conditions, treatment takes precedence over consent.
- **Documentation:** Record rationale for off-label use, dose calculations, and monitoring plans.

Preventing Medication Errors

- Paediatric patients are highly susceptible to **dose calculation errors** and **formulation confusion**.
- **Strategies to reduce errors:**
 - Always double-check weight-based calculations.
 - Use standardized dosing charts or electronic calculators.
 - Avoid trailing zeros and use leading zeros for decimals (e.g., 0.5 mg, not .5 mg).
 - Implement checklists and clinical decision support systems where available.

Utilization of Clinical Resources

- **Reference materials:**
 - British National Formulary (BNF) for Children
 - WHO Model Formulary for Children
 - NICE Guidelines
 - Standard pediatric pharmacotherapy texts
- Regularly consult **updated clinical guidelines** and participate in continuing education for safe Paediatric prescribing.

General Prescribing Guidelines for Geriatric Patients

Introduction

- Geriatric pharmacotherapy refers to the appropriate and rational use of medications in elderly patients, typically defined as individuals aged 65 years and older.
- With advancing age, physiological functions decline, resulting in altered pharmacokinetics and pharmacodynamics, increased susceptibility to adverse drug reactions (ADRs), and the frequent presence of multiple comorbidities and polypharmacy.
- Therefore, prescribing for older adults requires balancing efficacy with safety, avoiding unnecessary medications, and tailoring therapy to individual functional status and comorbid conditions.

Age-Related Physiological Changes Affecting Pharmacokinetics

Aging causes predictable alterations in all four phases of pharmacokinetics — **absorption, distribution, metabolism, and excretion (ADME)** — influencing drug response.

Absorption

- **Gastric acid production:** Decreased (hypochlorhydria) → reduced solubility and absorption of certain drugs (e.g., calcium carbonate, iron).
- **Gastrointestinal motility:** Slightly delayed → slower absorption rate but minimal effect on overall extent.
- **Splanchnic blood flow:** Reduced, affecting onset of drug action.
- **Drug formulations:** Enteric-coated or sustained-release preparations may behave differently due to slower transit.

Distribution

- **Increased body fat:** Leads to higher volume of distribution (Vd) for lipophilic drugs (e.g., diazepam, amiodarone) → prolonged half-life and accumulation risk.
- **Decreased lean body mass and total body water:** Increases plasma concentration of hydrophilic drugs (e.g., aminoglycosides, lithium).
- **Reduced plasma albumin:** Increases the free fraction of highly protein-bound drugs (e.g., warfarin, phenytoin) → enhanced pharmacological and toxic effects.
- **Possible increased α_1 -acid glycoprotein:** May alter binding of basic drugs.

Metabolism

- **Liver mass and blood flow:** Decline by 20–40%, reducing hepatic clearance of many drugs.
- **Phase I (oxidation, reduction, hydrolysis):** Reduced activity of cytochrome P450 enzymes → slower metabolism of drugs such as theophylline, diazepam, and propranolol.
- **Phase II (conjugation — glucuronidation, sulfation):** Usually preserved in aging → safer to prefer drugs metabolized mainly by conjugation (e.g., lorazepam, oxazepam).
- **Bioavailability:** May increase for drugs with extensive first-pass metabolism (e.g., morphine, propranolol).

Excretion

- **Renal function:** Declines with age — GFR decreases ~1% per year after age 40.
- **Serum creatinine may appear normal** due to reduced muscle mass, masking renal impairment.
- **Accurate assessment:** Calculate creatinine clearance (CrCl) using the Cockcroft-Gault equation for dose adjustments:

$$CrCl = \frac{(140 - \text{age}) \times \text{weight (kg)}}{72 \times \text{serum creatinine (mg/dL)}} (\times 0.85 \text{ for females})$$

- **Drugs requiring dose adjustment:** Digoxin, aminoglycosides, lithium, certain antibiotics (e.g., vancomycin).



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