

PSAP-VII • PEDIATRICS

MODULE II LEARNING OBJECTIVES

LEGISLATION, REGULATIONS, AND GUIDANCES AFFECTING PEDIATRIC PHARMACOTHERAPY

1. Distinguish between the major regulations and guidances affecting off-label drug use in pediatric patients.
2. Apply the concepts of extrapolation and interpolation to the issue of pediatric drug development.
3. Given the context related to the development of a new drug, distinguish whether a waiver of pediatric studies for a new drug is appropriate.
4. Distinguish between the pediatric drug development processes of the U.S. Food and Drug Administration (FDA) and that of the European Medicines Agency.
5. Apply guidances on pediatric drug development from the FDA or the International Conference on Harmonization when considering pediatric studies with a new drug or biological agent.
6. Assess the involvement of the National Institutes of Health in the Best Pharmaceuticals for Children Act.
7. Given a particular research study design, distinguish the appropriate category of risk and the special protections required for children by the National Research Act.

EXTEMPORANEOUS FORMULATIONS

1. Justify the need for extemporaneous formulations in children.
2. Evaluate options for compounding extemporaneous formulations for use in children.
3. Develop a plan for preparing extemporaneous formulations.
4. Demonstrate knowledge of the key requirements of stability and sterility studies.
5. Assess the efficacy and safety of drugs and excipients in formulations.

GASTROESOPHAGEAL REFLUX DISEASE

1. Analyze the differences in the clinical presentation and management of gastroesophageal reflux and gastroesophageal reflux disease (GERD) in infants and children.
2. Assess the benefits of nonpharmacologic treatments in children with GERD.
3. Demonstrate an understanding of the relationship between GERD and asthma.
4. Evaluate the safety and efficacy of the available treatments for GERD in children.
5. Develop a pharmacotherapy plan for a child with a diagnosis of GERD.
6. Based on patient-specific factors, justify modifications to a treatment plan for a child with GERD.

PARENTERAL NUTRITION IN THE NEONATE

1. Distinguish the nutrient environment of the neonate before and after birth and the consequences for parenteral nutrition (PN) composition in the neonate.
2. Assess the growth of a neonate using appropriate reference standards.
3. Distinguish valid indications for neonatal PN.
4. Justify the use of a pediatric-specific amino acid formulation in PN solutions administered to neonates.
5. Analyze the consequences of inadequate or excessive intakes of various nutrients in the neonate.
6. Assess the complications associated with PN in the neonate.
7. Evaluate system processes to enhance the safety of providing neonatal PN.
8. Design a basic PN formulation for a preterm or term infant.
9. Recommend a monitoring plan for the neonate receiving PN.