

# CONCEPTS IN **CLINICAL PHARMACOKINETICS**



WEB-BASED CONTINUING EDUCATION COURSE FROM THE UNIVERSITY OF GEORGIA

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## Learning Objectives

### Lesson 1 — Introduction to Pharmacokinetics

- Define pharmacokinetics and clinical pharmacokinetics and differentiate between them.
- Explain the property of kinetic homogeneity.
- Define pharmacodynamics and relate it to pharmacokinetics.
- Define tolerance and relate it to pharmacokinetics.
- Describe the concept of the therapeutic concentration range.
- Define narrow therapeutic index.
- Identify factors that cause interpatient variability in drug disposition and drug response.
- Describe situations in which routine clinical pharmacokinetic monitoring would be advantageous.
- Define both one- and two-compartment models and list the assumptions made about drug distribution patterns in each.
- List the assumptions made when using a one-compartment model to describe the pharmacokinetics of a single intravenous dose.
- Represent graphically the typical natural log of plasma drug concentration versus time curve for a one-compartment model after an intravenous dose.

### Lesson 2 — Basic Pharmacokinetics

- Identify the components of body fluids that make up extracellular and intracellular fluids and know the percentage of each.
- Describe the difference between whole blood, plasma, and serum. Define drug clearance and show how it is related to organ blood flow.
- Describe the difference between first- and zero-order elimination and how each appears graphically.

### Lesson 3 — Half-Life, Elimination Rate Constant and AUC

- Calculate the elimination rate constant given a natural log of plasma drug concentration versus time curve.
- Define half-life and calculate a drug's half-life given a natural log of plasma drug concentration versus time curve.
- Define the relationship between half-life and elimination rate constant
- Define drug clearance and relate it to the area under the plasma drug concentration curve and drug dose.
- Calculate a drug's volume of distribution, concentration at time zero, and area under the plasma concentration versus time curve, given plasma concentration data after an intravenous drug dose.



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## **Lesson 4 — Intravenous Bolus Administration, Multiple Drug Administration, and Steady-State Average Concentrations**

- Describe the principle of superposition and how it applies to multiple drug dosing.
- Define steady state and describe how it relates to a drug's half-life.
- Provide the equation that estimates peak plasma concentration after multiple drug dosing and the equation that estimates trough concentration after multiple drug dosing (both at steady state).
- Understand the equation for accumulation factor at steady state.

## **Lesson 5 — Relationships of Pharmacokinetic Parameters and Intravenous Intermittent and Continuous Infusions**

- Describe how changes in dose or dosing interval affect plasma concentrations after multiple dosing.
- Describe the relationship between the rate of continuous intravenous drug infusion, drug clearance, and steady-state plasma concentration.
- Calculate plasma drug concentrations during and after continuous IV infusion.
- Calculate an appropriate loading dose to achieve therapeutic range at onset of infusion.
- Calculate peak and trough concentrations at steady state after intermittent IV infusions.

## **Lesson 6 — Two-Compartment Models**

- Describe when to use back-extrapolation versus method of residuals.
- Calculate a residual line.
- Calculate alpha ( $\alpha$ ), beta ( $\beta$ ), and intercepts A and B for a drug conforming to a two-compartment model
- Describe when to use a monoexponential versus a biexponential equation.
- Calculate  $V_c$ ,  $V_{area}$  (also known as  $V\beta$ ), and  $V_{ss}$  (using both methods) for a two-compartment model.

## **Lesson 7 — Biopharmaceutics: Absorption**

- Define and understand the factors that comprise the term biopharmaceutics.
- Understand the effects of the extent and rate of absorption of a drug on plasma concentrations and area under the curve (AUC).
- Name the factors that can affect a drug's oral bioavailability.
- Define and understand the relationship of bioavailability to drug absorption and AUC.
- Define and be able to calculate an F factor for a drug given its intravenous (IV) and oral absorption time vs. concentration AUCs.
- Define and understand the factors involved in the oral absorption model.
- Understand the pharmacokinetic differences and clinical utility of controlled-release products.
- Name several techniques used in formulating controlled-release drugs.

## **Lesson 8 — Drug Distribution and Protein Binding**

- Understand the major factors that affect drug distribution.
- Know the relative perfusion (i.e., high or low) characteristics of various body compartments (e.g., kidneys, fat tissue, lungs).
- Understand the physiochemical properties that affect drug distribution.
- Know the three main proteins that bind various drugs and their characteristics.
- Know the major factors that affect drug protein binding.
- Understand the dynamic processes involved in drug protein binding.
- Understand the difference between perfusion-limited distribution and permeability-limited distribution.

## Lesson 9 — Drug Elimination Processes

- Understand the impact of disease and altered physiologic states on the clearance and dosing of drugs.
- Know the various routes of drug metabolism and excretion.
- Understand the two general types (phase I and II) of drug metabolism.
- Understand the methods of hepatic drug metabolism and the approaches used to quantitate and characterize this metabolism.
- Understand the effects of a drug's hepatic extraction ratio on that drug's removal via the liver's first-pass metabolism.
- Understand the various processes involved in renal elimination (i.e., filtration, secretion, and reabsorption).
- Understand both the physiologic and mathematical relationship of drug clearance to glomerular filtration.

## Lesson 10 — Nonlinear Processes

- Describe the relationship of both drug concentration and the plasma drug concentration versus time curve (AUC) to the dose for a nonlinear, zero-order process.
- Explain the various biopharmaceutic processes that can result in nonlinear pharmacokinetics.
- Describe how hepatic enzyme saturation can result in nonlinear pharmacokinetics.
- Use the Michaelis-Menten model for describing nonlinear pharmacokinetics.
- Describe  $V_{max}$  and  $K_m$ .
- Use the Michaelis-Menten model to predict plasma drug concentrations.
- Use the 90% equation to estimate the time required for 90% of the steady-state concentration to be reached.

## Lesson 11 — Pharmacokinetic Variation and Model Independent Relationships

- Identify the various sources of pharmacokinetic variation.
- Explain how the various sources of pharmacokinetic variation affect pharmacokinetic parameters.
- Describe how to apply pharmacokinetic variation in a clinical setting.
- Name the potential sources of error in the collection and assay of drugs samples.
- Explain the clinical importance of correct sample collection, storage and assay.
- Describe ways to avoid or minimize errors in the collection and assay of drug samples.
- Explain the basic concepts and calculations of the model independent pharmacokinetic parameters of total body clearance, mean residence time (MRT), volume of distribution at steady-state, and formation clearance.

## Lessons 12-15 — Cases

### ***(Only Available for Participants Enrolled in Option #2 and Option #3)***

The goal of this Case Study is to allow pharmacy practitioners with significant pharmacokinetic dosing experience the opportunity to demonstrate their proficiency to college of pharmacy faculty. Competence will be assessed by instructional support through a series of assessment techniques that include discussion, case presentation and direct patient application. The following Cases will be explored:

- Aminoglycosides
- Vancomycin
- Theophylline
- Phenytoin and Digoxin

**OPTION #1: APPLICATION-BASED**

**Concepts in Clinical Pharmacokinetics Web-Based Continuing Education Course**

UAN 0014-9999-10-156-H01-P

Release date 8-1-2010; expiration date 8-1-2013

**OPTION #2: PRACTICE-BASED**

**Concepts in Clinical Pharmacokinetics Online Certificate Program**

Comprised of UAN 0014-9999-10-156-H01-P and UAN 0014-9999-10-157-H-01-P

Release date 8-1-2010; expiration date 8-1-2013

**OPTION #3: PRACTICE-BASED**

**Clinical Pharmacokinetics Online Certificate Program for Advanced Practitioners**

# 0014-0016 and UAN 0014-9999-10-157-H-01-P

Release date 8-1-2010; expiration date 8-1-2013



*The University of Georgia College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.*



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