

ASHP Statement on the Pharmacist's Role in Clinical Pharmacokinetic Monitoring

The American Society of Health-System Pharmacists (ASHP) believes that clinical pharmacokinetic monitoring is a fundamental responsibility of all pharmacists providing pharmaceutical care. Clinical pharmacokinetic monitoring is an integral component of pharmaceutical care for selected patients based on their specific pharmacotherapy, disease states and related factors, and treatment goals. ASHP believes that clinical pharmacokinetic monitoring is essential to achieving positive outcomes for these patients across the continuum of care and in all practice settings of health systems. Examples of such outcomes include decreased mortality, decreased length of treatment, decreased length of hospital stay, decreased morbidity (either improved symptoms of disease or improved recuperation), and decreased adverse effects from drug therapy.

Background

Clinical pharmacokinetics is the process of applying pharmacokinetic principles to determine the dosage regimens of specific drug products for specific patients to maximize pharmacotherapeutic effects and minimize toxic effects. Application of these principles requires an understanding of the absorption, distribution, metabolism, and excretion characteristics of specific drug products in specific diseases and patient populations. The influence of factors such as age, sex, diet, pathophysiologic conditions, and concomitant use of other drug products must also be understood. The development of patients' individualized dosage regimens should be based on integrated findings from monitoring both the drug concentration-versus-time profiles in biological fluids and the pharmacologic responses to these drug products.

Within the pharmaceutical care process, pharmacists' clinical functions include appropriate and cost-conscious therapeutic drug monitoring and provision of clinical pharmacokinetic assessments. Clinical pharmacokinetic monitoring is necessary when the range between minimal effectiveness and toxicity is narrow and the results of the drug assay provide significant information for clinical decision-making. In the absence of drug concentration measurements, patient-specific characteristics and physiological markers should be used to provide clinical pharmacokinetic assessments and make dosage-regimen recommendations.

Responsibilities

The following responsibilities should be part of clinical pharmacokinetic services or monitoring conducted by pharmacists:

1. Designing patient-specific drug dosage regimens based on the pharmacokinetic and pharmacologic characteristics of the drug products used, the objectives

of drug therapy, concurrent diseases and drug therapy, and other pertinent patient factors (e.g., demographics, laboratory data) that improve the safety and effectiveness of drug therapy and promote positive patient outcomes.

2. Recommending or scheduling measurements of drug concentrations in biological fluids (e.g., plasma, serum, blood, cerebrospinal fluid) or tissues in order to facilitate the evaluation of dosage regimens.
3. Monitoring and adjusting dosage regimens on the basis of pharmacologic responses and biological fluid and tissue drug concentrations in conjunction with clinical signs and symptoms or other biochemical variables.
4. Evaluating unusual patient responses to drug therapy for possible pharmacokinetic and pharmacologic explanations.
5. Communicating patient-specific drug therapy information to physicians, nurses, and other clinical practitioners and to patients orally and in writing, and including documentation of this in the patient's health record.
6. Educating pharmacists, physicians, nurses, and other clinical practitioners about pharmacokinetic principles and appropriate indications for clinical pharmacokinetic monitoring, including the cost-effective use of drug concentration measurements.
7. Developing quality assurance programs for documenting improved patient outcomes and economic benefits resulting from clinical pharmacokinetic monitoring.
8. Promoting collaborative relationships with other individuals and departments involved in drug therapy monitoring to encourage the development and appropriate use of pharmacokinetic principles in pharmaceutical care.

Pharmacists with specialized education, training, or experience may have the opportunity to assume the following additional responsibilities:

1. Designing and conducting research to expand clinical pharmacokinetic knowledge and its relationship to pharmacologic responses, exploring concentration-response relationships for specific drugs, and contributing to the evaluation and expansion of clinical pharmacokinetic monitoring as an integral part of pharmaceutical care.
2. Developing and applying computer programs and point-of-care information systems to enhance the accuracy and sophistication of pharmacokinetic modeling and applications to pharmaceutical care.
3. Serving as an expert consultant to pharmacists with a general background in clinical pharmacokinetic monitoring.

Readers are referred to ASHP's more thorough publications on the subject of clinical pharmacokinetic monitoring,

including *Clinical Pharmacokinetics Pocket Reference* and *Concepts in Clinical Pharmacokinetics: A Self-Instructional Course*.

This statement was reviewed in 2013 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

Approved by the ASHP Board of Directors, November 15, 1997, and by the ASHP House of Delegates, June 3, 1998. Revised

by the ASHP Council on Professional Affairs. Supersedes a previous version approved by the House of Delegates on June 5, 1989.

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