

UNIVERSITY OF KENTUCKY HOSPITAL
CHANDLER MEDICAL CENTER

POLICY NUMBER: PH-02-05
FIRST ISSUED: 1/88

Department of Pharmacy Policy

CURRENT AS OF: 6/09

SUBJECT: Clinical Pharmacokinetics Service Policy/Procedures

PURPOSE: To establish a standardized pharmacokinetic monitoring approach for patients receiving drugs that are routinely monitored utilizing serum drug concentrations at the University of Kentucky Hospital.

FUNCTIONS

AFFECTED: Clinical Pharmacist Specialists, Clinical Staff Pharmacists, Pharmacy Residents, and Pharmacy Students

GENERAL: The Clinical Pharmacokinetics Service (CPS) Guidelines were developed to ensure safe and efficacious dosage regimens through the application of pharmacokinetic/pharmacodynamic principles and the determination of drug serum concentrations. The policy/procedure manual outlines standard guidelines which should be followed when providing clinical pharmacokinetic monitoring of the following drugs: aminoglycosides, carbamazepine, digoxin, fosphenytoin, lidocaine, lithium, phenobarbital, phenytoin (free and total), procainamide, quinidine, theophylline, valproic acid, and vancomycin. In addition to the above list, the CPS will also provide monitoring for warfarin for patients without assigned pharmacists.

Monitoring Responsibility

Within the pharmaceutical care process, the primary pharmacist/resident who attends rounds or precepts pharmacy students on the primary medical team is responsible for providing appropriate and cost-conscious therapeutic drug monitoring and provision of clinical pharmacokinetic evaluations. The CPS is responsible for overseeing the kinetic monitoring process for all patients and providing pharmacokinetic assessments for any patient that does not have an assigned primary pharmacist/resident. This responsibility is met through a team approach including a faculty member who serves as the Manager of Clinical Pharmacokinetics Service along with Pharmacy Practice Residents, PY4 pharmacy students, and clinical staff pharmacists.

Patients with serum drug concentrations are identified on a daily basis utilizing Sunrise Clinical Manager (SCM). Also, the Therapeutic Drug Monitoring (TDM) Laboratory provides an electronic report of all completed serum drug concentrations of patients admitted to the hospital twice daily. This allows for

identification of any non-covered patients who are prescribed monitorable drugs which have not obtained serum concentrations. Physicians may also initiate a request for pharmacy to provide a clinical pharmacokinetic evaluation by verbal communication or through a pharmacy to dose requisition in (SCM).

TDM Notification of Supratherapeutic Concentrations

The Therapeutic Drug Monitoring Laboratory is responsible for the analysis of all "routine" serum drug assays evaluated by pharmacy during a pharmacokinetic evaluation. The TDM Lab notifies the primary pharmacist of any supra-therapeutic concentrations between 8AM-4PM during the week; after 4PM and on weekends and holidays the Pharm D. resident on-call (beeper #330-3883) is notified. The TDM Lab notifies the clinical pharmacokinetic service of any supra-therapeutic levels for any uncovered service. All other TDM issues should be directed to either Daniel Lewis (pager #330-4325) or George Davis (pager #330-4215).

Documentation in the Patient Medical Record

When a patient has a serum drug concentration drawn, the primary pharmacist should write a "Clinical Pharmacokinetics" note in the patient's chart within 24 hours for normal or subtherapeutic concentrations. For concentrations that are supratherapeutic, the medical team should be notified immediately if clinically warranted and a chart note should be written as soon as possible, but no more than 12 hours after the concentration is reported. The chart note should contain all relevant patient information and pharmacokinetic parameters necessary to produce the dosing and monitoring recommendations. Please refer to the CPS Policy/Procedure Manual (<http://www.hosp.uky.edu/pharmacy/cps/default.html>) for guidelines for documentation of pharmacokinetic evaluations for specific monitorable drugs. Notes written by students and non-licensed pharmacists/residents must be co-signed by a Kentucky-licensed pharmacist within 24 hours.

Pharmacy to Dose Orders

Purpose:

To provide a policy/procedure for provision of pharmacy-directed monitoring in patients on medication regimens that lend themselves to therapeutic monitoring. Therapeutic drug monitoring is the utilization of pharmacokinetic and pharmacodynamic principles (often through drug concentrations) to optimize the safety and efficacy of a medication regimen.

Information:

All new orders for monitorable drugs will be assessed by a clinically trained pharmacist within 48 hours of initiation. If further monitoring is determined to be necessary by the pharmacist, the primary service will be contacted with the initial recommendation. At that time, the consulting pharmacist may request a verbal order for a pharmacy to dose order for that patient's medication regimen in order

to continue to follow the medication regimen. Alternatively, at any time, a physician may choose to order a pharmacy to dose consult.

Pharmacy to Dose:

1. Any physician may request a pharmacist to provide therapeutic dosing and/or monitoring services for any specified pharmacologic agent. Such a request may be made by submitting a pharmacy to dose order in Sunrise Clinical Manager (SCM) or by giving a verbal order entered on his/her behalf.
 - a. Such requests by the physician will result in the pharmacist being authorized to write orders for the initial drug dose, laboratory tests relevant to monitoring the drug, and/or subsequent orders for dosing adjustments as deemed appropriate by the pharmacist. Examples of these include ordering drug concentrations and/or assessments of renal/hepatic function relative to the dosing of an agent.
 - b. At any time, the physician may alter the dosing and/or monitoring orders that have been initiated by the pharmacist.
 - c. At any time, the physician may request the pharmacist discontinue the dosing/monitoring consult services being provided to a particular patient.
 2. Upon receiving an order for pharmacy to dose a specific medication, a pharmacist will assess the patient and collect relevant information necessary to appropriately dose/monitor the specified drug so as to achieve therapeutic drug levels and minimize any potential risks of toxicity. Such items of information may include, but are not limited to:
 - a. Indication for therapy (i.e. type and site of infection for antibiotic dosing/monitoring consults)
 - b. Age
 - c. Sex
 - d. Height/Weight
 - e. Renal/Hepatic function
 - f. Estimated pharmacokinetic parameters
 - g. Medication history and/or time of last dose (if applicable)
 - h. Current/last known serum drug concentration (if applicable)
 3. Upon selecting a dosing and/or monitoring plan, the pharmacist will enter applicable orders into SCM. Any orders written by the pharmacist in response to a pharmacy to dose order will be entered under the requesting physician with the specified source of "Per Protocol".
 4. The pharmacist will provide a progress note in the chart to provide information regarding the course of the dosing and/or monitoring services in accordance with department of pharmacy policies PH-02-04 and PH-02-05.
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- 5. The pharmacist will be responsible for follow-up monitoring and/or dose adjustments if the pharmacist deems such actions necessary as documented in the progress notes.

Pharmacokinetic Guidelines

Refer to Clinical Pharmacokinetics Service and Anticoagulation Guidelines (updated annually)

Approved: _____ Authorized: _____

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