Clinical Pharmacokinetic Service Policy & Procedure

The emphasis of pharmacy practice in this hospital is evolving away from managing the distribution of drug products toward providing patient-focused services. Clinical pharmacists in this hospital are interacting with the health care team, interviewing and assessing patients, making patient-specific recommendations, monitoring patient response to drug therapy, and providing drug information. The American Society of Health System Pharmacists (ASHP) believes that clinical pharmacokinetic monitoring is a fundamental responsibility of all pharmacists providing pharmaceutical care[1].
Pharmacokinetics is interrelated with many disciplines, particularly, biopharmaceutics, therapeutics, and pharmacology[2]. There is a strong correlation between drug concentration and pharmacologic response which enables pharmacists to apply the principles of pharmacokinetics to actual patient situations[2],

- Estimate rate of absorption, distribution, metabolism, and elimination of drugs in the body
- Predict the concentration of drug in the various body tissues, organs, and body fluids at any given time
- Determine the effect of plasma protein binding of the drug on the distribution of a drug in the body
- Determine the effect of concomitant administration of other drugs and nutrition on the absorption and elimination of drugs
- Design optimal dosage regimens to achieve optimum concentration of the drug at a specific site to produce an optimal therapeutic response in an individual patient
- Estimate renal impairment's impact on accumulation and elimination of drug
- Estimate fraction of the administered dose absorbed by extravascular routes of administration
- Calculate various pharmacokinetic parameters of the drug in order to describe the time course of drug in the body.

The success of drug therapy is highly dependent on the dosage regimen design, however, due to the variation in pharmacokinetics and pharmacodynamics, proper clinical evaluation and careful monitoring is required[2]. Not all drugs need rigid individualization of the dosage regimen, but for drugs with a narrow therapeutic window, such as digoxin, phenytoin, vancomycin, and aminoglycosides, antiarrhythmics, and theophylline, individualization of the dosage regimen is very important. Therefore, the objective is to produce a safe plasma concentration that does not exceed the toxic concentration or fall below a critical drug concentration for which the drug will be ineffective.

The pharmacokinetic team can be contacted by paging the pharmacotherapist on-call beeper number (3509). Physicians can page and make a request for a consult with the following information: patient name, medical record number, location, drug, and a reason for consult.

Pharmacokinetic Consultation can be initiated in one of the following ways:

1. A physician can request for a drug to be dosed "per pharmacokinetic consultation". The pharmacokinetic team will review all the necessary information (patient chart, laboratory values, time when blood sample was drawn) and provide a recommendation to the physician. The pharmacokinetic team will provide an initial dosing strategy, based on approved calculations (as per the TBHC PK Manual). The pharmacokinetic team will implement the initial dosing plan and continue to monitor the patient. Evaluation of levels and other pharmacodynamic parameters will be included into regular progress notes. A progress note shall be written whenever a level is resulted, and/or a dosing parameter (renal function, weight, etc) has changed until the therapy has completed, the patient is deemed to be at steady state on a maintenance dose, or the patient has been discharged. Steady state will be defined as a period individually calculated at least 4-5 half-lives of the medication elimination with no dosing changes, parameter changes, or changes in serum/plasma drug levels. Recommendations will be communicated verbally and in a written document in the electronic medical record.
2. During physician regulated therapy when serum drug concentrations require pharmacokinetic calculation for proper interpretation (e.g., non-steady state concentrations), a physician can request for a pharmacokinetic consultation. The pharmacokinetic team will review all the necessary data and provide a recommendation to the physician. The pharmacokinetic team will continue to monitor the patient and make recommendations to the physician as appropriate until the therapy has completed, or the patient has been discharged. Recommendations will be communicated verbally and in a written document in the electronic medical record.

Responsibilities of the pharmacokinetic team before making a recommendation include evaluating patient parameters such as height, age, sex, weight, pertinent laboratory parameters, renal function, indication of therapy, culture and sensitivity reports, the dates and times when blood samples were obtained, the dose of the drug at that time, and the reported concentration. The pharmacokinetic team will provide a dose and interval based on patient variables, desired peak and trough, average serum level at steady state, and maintenance dose if appropriate. First, the pharmacokinetic team will discuss the specific recommendation for dosing and monitoring the patient's drug therapy with the physician. For permanent documentation, a written consult will be provided in the patient's electronic medical record and will include a summary of the patient's pharmacokinetic parameters, dosing recommendations, and recommendations for therapeutic drug monitoring. Additional comments may be noted to explain unexpected serum concentrations such as,

- *Reflects steady-state, peak or trough on dosage regimen as charted…*
- *Reflects loading dose, and does not reflect steady state concentration…*
- *Level drawn too soon after the dose was administered and therefore not a true level…*

The turn around time for all pharmacokinetic consults will be approximately 2 hours and no later than 24 hours. If the consultation is provided after hours or during weekends, and the

recommendation is accepted by the physician, then it will be reviewed by the clinical pharmacist within 24 hours or on the next business day to be co-signed for appropriateness. Daily follow-up and monitoring will be documented in the document section of the electronic medical record.

Pharmacokinetics is a further step toward rational and optimal therapy. The goal is to maintain therapeutic drug concentration while preventing life threatening toxicity.

References

1. P.L. Madan. Principles of Pharmacokinetics. College of Pharmacy and Allied Health Professions St.John's University New York. 2001; p.5-8.