

The University of Jordan
Faculty of Pharmacy
Department of Biopharmaceutics and Clinical Pharmacy

Clinical Pharmacokinetics Clerkship

Course No.: (1203607)

Level: Sixth year PharmD

2014/2015

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| <u>Title:</u> | Clinical Pharmacokinetics Clerkship (1203607) |
| <u>Credit Hours:</u> | 2 hours |
| <u>Pre or Co-requisite:</u> | Pharmacotherapy IV (1203506) (note: Clinical Pharmacokinetics (1203577) should be a pre-requisite) |
| <u>Course Instructor:</u> | Dr. Maysa Suyagh Faculty of Pharmacy / Dept of Biopharmaceutics and Clinical Pharmacy Office No.: 106 / Phone No.: 5355000 ext. 23337 / Email: m.suyagh@ju.edu.jo Office hours: to be arranged |
| <u>Other Course Instructors:</u> | Dr. Sameh Al-Zubiedi Dr. Muhammed Issa Dr. Amal Akour Dr. Mariam Hantash |
| <u>Course Website:</u> | http://elearning.ju.edu.jo All course related materials and announcements will be posted on the course page at the JU e-learning website. |
| <u>Course Material:</u> | Course material can be found on the following site: http://eacademic.ju.edu.jo/m.suyagh/Material/ClinPK%20Clerkship |

Course Description

The clerkship in clinical pharmacokinetics is intended to allow PharmD students an opportunity to acquire the practical experience in the application of clinical pharmacokinetic principles to various drug therapies with emphasis on the selection and design of antimicrobial therapies. Students will learn how to apply these principles by gathering pertinent clinical information, development of pharmaceutical care and monitoring plans, thorough literature evaluation, and case discussions.

Course Aims:

This course aims to:

- Allow students to apply knowledge of pharmacokinetic principles to design optimal drug dosage regimens for individual patients taking into account their clinical and demographic characteristics.

- Establish a standardized pharmacokinetic monitoring approach for patients receiving drugs that are routinely monitored utilizing serum drug concentrations.

Intended Learning Outcomes:

A- Knowledge and Understanding:

Student is expected to

- A1. Discuss and understand the basic pharmacokinetic principles and key pharmacokinetic parameters.
- A2. Discuss and understand various aspects of a drug’s pharmacokinetic properties and factors affecting them.
- A3. Discuss the effect of different disease states on the pharmacokinetics and pharmacodynamics of drugs
- A4. Understand the theoretical basis of therapeutic drug monitoring.

B- Intellectual, Analytical and Cognitive Skills:

Student is expected to

- B1. Perform calculations to predict drug concentration after drug administration.
- B2. Given a pharmacokinetic data set, determine the value of pharmacokinetic parameters after different modes of drug administration.
- B3. Be able to develop a strategy for therapeutic drug monitoring for a range of narrow therapeutic window drugs.
- B4. Identify the problems associated with dosage regimens through analyzing patient data.
- B5. Gain therapeutic problem-solving skills.

C- Subject-Specific Skills:

Student should be able to

- C1. Recommend initial dosage regimen, or adjust dosage and recommend monitoring strategy to ensure safe and effective drug therapy.
- C2. Identify clinical manifestations of potential toxicities associated with patient’s medication and recommend the appropriate course of action.
- C3. Apply the pharmacokinetic principles to specific problems commonly encountered in practice setting.
- C4. Identify patients who are likely to get maximal benefit from clinical pharmacokinetic monitoring.

D- Transferable Key Skills:

Students is expected to

- D1. Use different information sources to solve pharmacokinetics problems.
- D2. Develop the ability to communicate scientific principles and dosage recommendations to other healthcare professionals.

ILOs: Learning and Evaluation Methods

| ILOs | Learning Methods | Evaluation Methods |
|--------------------------------------|---------------------------------------|------------------------------------|
| A1, A2, A3, A4 | Student led learning and case studies | Quizzes, Exams and Case Discussion |
| B1, B2, B3, B4, B5 C1, C2, C3, C4 | Student led learning and case studies | Quizzes, Exams and Case Discussion |
| D1, D2 | Case studies and journal club | Case discussion and Journal Club |

Learning Methodology

- Student led learning
- Case Studies
- Journal Clubs

Course content:

Students are expected to read course related material to cover the following objectives:

1. Review the basic principles of clinical pharmacokinetics

Students should review and familiarize themselves with the basic concepts of pharmacokinetics before the beginning of the course. They should be able to:

- Define zero and first order processes and distinguish between them
- Identify the difference between linear and non-linear pharmacokinetics
- Identify the differences between one, two and multi compartment models
- Explain the concept of volume of distribution
- Calculate clearance and half-life for patients given steady state serum concentrations (assuming one compartment model)
- Calculate loading dose and maintenance dose (assuming a one compartment model)
- Explain the term population data and describe its limitations
- Estimate the serum level at given time following single and multiple oral dosing
- Estimate the serum level at given time following single and multiple intravenous dosing (bolus and infusion)
- Calculate minimum, maximum and average serum concentrations
- Calculate the time taken for a toxic level to decay to within the therapeutic range.
- Review the general equations for BSA, IBW, and Clcr...
- Understand the relationship between drug concentration, effect and side effects

2. Apply the basic principles of clinical pharmacokinetics to patients in various clinical settings.

- Students should review and familiarize themselves with principles of therapeutic drug monitoring and the design of optimized and individualized dosage regimens. The focus here is given to drugs with narrow therapeutic window that are routinely monitored including:

Aminoglycosides

Vancomycin,

Digoxin,

Carbamazepine,

Phenobarbital,

Phenytoin,

Valproic Acid,

Cyclosporine,

Tacrolimus.

Theophylline

Methotrexate

3. **Know how to collect relevant patient information and pharmacokinetic parameters necessary to produce the dosing and monitoring recommendations for specific drugs.** Such items of information may include, but are not limited to:
- Indication for therapy (i.e. Type and site of infection for antibiotic dosing/monitoring consults)
 - Patient demographics: age, gender, height/weight
 - Renal/hepatic function
 - Estimated pharmacokinetic parameters
 - Accurate medication history and/or time of last dose (if applicable)
 - Current/last known serum drug concentration (if applicable)
 - Other disease states and medication history.

Course References:

1. **Basic clinical pharmacokinetics**, By Michael E. Winter. Edition: 5 – 2009 (ISBN-13: 978-0781779036)
2. **Applied clinical pharmacokinetics**, By Larry Bauer. Edition: 2 – 2008 (ISBN-13: 978-0071476287)
3. **Applied pharmacokinetics & pharmacodynamics: principles of therapeutic drug monitoring**, By Michael E. Burton. Edition: 4 – 2006 (ISBN-13: 978-0071603935)
4. **Pharmacotherapy: A Pathophysiological Approach**, ed. DiPiro *et al*, 9th edition, 2014. (ISBN-13: 978-0071800532)

Other Useful References:

1. **Clinical pharmacokinetics: concepts and applications**, By Malcolm Rowland, Thomas N. Tozer. Edition: 4 – 2010
2. **Handbook of drug monitoring methods: Therapeutics and Drugs of Abuse**, By Amitava Dasgupta. Edition: 1 – 2008
3. **Concepts in Clinical Pharmacokinetics**, By Joseph T. DiPiro. Edition:5 – 2010
4. **Applied Biopharmaceutics & Pharmacokinetics**, By Leon Shargel *et al*. Edition:6 – 2012
5. **Introduction to pharmacokinetics and pharmacodynamics: the quantitative basis of drug therapy**, By Thomas N. Tozer, Malcolm Rowland. Edition 1: 2006
6. **Relevant original and review articles from scientific journals**

Course Assessment:

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| Case Study Each student will present an interesting pharmacokinetic case based on their experience during their clerkship. | 25% |
| Term Paper (Journal Club) Each student has to prepare a term paper on a PK/PD topic. The paper will be presented in class (15 min). Both oral and written performance will be graded. | 15% |
| Quiz | 10% |
| Final Exam | 50% |

Note:

With each case students need to submit the following:

- Printed and electronic copy of the presentation
- Completed data collection sheet
- Full calculations
- Detailed pharmacokinetic assessment
 - o For example, students should aim to:
 - o Document pertinent clinical monitoring parameters, dose recommendations and estimated and/or calculated pharmacokinetic parameters
 - o Briefly describe the rationale of the drug and determine if warranted based on clinical and patient information.
 - o Document the current day of therapy and goal length of therapy and any concomitant medications.
 - o Document the collect times of the reported concentrations and note if the samples were obtained appropriately.
 - o Write the new dose recommendations (if applicable)
 - o When changing a dosage, include the start time of new dosing regimen with the order
 - o Include a range for the predicted concentrations with the new dosage recommendation:
 - o Include pertinent information used to assess the patient.

IMPORTANT

Roles of the course coordinator

- Preparing the course outline and objectives
- Coordinating
 - Students' allocation to groups at the beginning of the course for:
 - o Case discussions
 - o Journal clubs
 - Examination process
 - o Assembling questions from different parties and reaching a consensus
 - o Students' allocation to examinations rooms
 - o Copying of the exam
 - Keeping graded exam papers
 - Reviewing grades of exam papers upon students requests
 - Grading process
 - o Assembling grades from all teams
 - o Reaching a consensus with grades to letters conversion
 - o uploading grades on the ACAD system

Role of the academic supervisor (PhD holder)

- Reviewing the course outline and objectives
- Controlling the case selection process by the preceptors
- Case discussion and case assessment
- Journal club discussion and assessment
- Assessment of the students (quiz, attendance, attitude, participation)
- Preparing the final exam
- Supervising the final exam

Role of the Preceptor (MSc holder)

- Allocating cases to the students through collaboration with the clinical laboratory at the hospital and the academic supervisors.
- Journal club discussion and assessment