PHA5132 Principles of Drug Therapy Individualization

Spring, 2021

4 Credit Hours – [A-E Grading]

Individualization of drug therapy, described as tailoring drug selection and drug dosing to a given patient, has been an objective of physicians and other health-care providers for centuries. An understanding of the disease, the mechanism of the drug's action, and dose-exposure-response relationships provides the framework for individualization. The goal of individualization is to optimize the efficacy of a drug, minimize toxicity, or both on a patient-by-patient basis. The objective of this course is to provide students with an introductory course in pharmacokinetics (PK), Pharmacodynamics (PD) and Pharmacogenomics (PGx) that, in conjunction with other coursework, equips them with the knowledge and skills to serve as the drug expert in an interdisciplinary team of health care professionals. The knowledge acquired in this course will provide students with the tools and principles to individualize a patient's treatment by selecting an optimal dose and dosing regimen.

Teaching Partnership Leaders

Stephan Schmidt, B.Pharm, Ph.D., F.C.P.

- Email: sschmidt@cop.ufl.edu
- Office: 467/ORL
- Phone: 407-313-7012
- Office Hours: Please see the Canvas course site for posted office hours.

See Appendix A. for Course Directory of Faculty and Staff Contact Information.

Entrustable Professional Activities

This course will prepare you to perform the following activities which the public entrusts a Pharmacist to perform:

1. Patient Care Provider Domain

2. Analyze information to determine the effects of medication therapy, identify medication-related problems, and prioritize health-related needs.

    ST2.1. Interpret laboratory test results

    ST 2.1b Interpret data related to personalized medicine.

    ST2.2. Evaluate an existing drug therapy regimen

3. Establish patient-centered goals and create a care plan for a patient in collaboration with the patient, caregiver(s), and other health professionals that is evidence-based and cost-effective

    ST3.1. Develop a treatment plan with a patient (including recommend therapeutic alternatives and generic substitution).

    ST3.2. Manage drug interactions.

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Course-Level Objectives

Upon completion of this course, the student will be able to:

1. Describe the influence of dosage forms, dosing regimens and dose on drug levels and to understand the relationship between drug concentration, effect and side effects.
2. Apply mathematical principles to calculate the change in a patient's drug concentration over time, the elimination rate constant, drug volume of distribution, and area under the curve (AUC).
3. Explain the following concepts: first-order elimination, zero-order elimination, half-life, volume of distribution, and clearance.
4. Predict the effects of blood flow, intrinsic clearance, and protein binding on drug clearance for high and low extraction drugs.
5. Determine whether a drug is predominately reabsorbed or secreted based on renal clearance and protein binding.
6. Predict the relationship between pH (and urine flow) and renal clearance.
7. Calculate a patient's peak and trough plasma drug concentrations after receiving single and multiple intravenous bolus doses/at steady-state.
8. Recommend dosing for a patient who is receiving a continuous IV drug infusion by considering the relationships of clearance, elimination rate constant, and volume of distribution.
9. Recommend dosing for a patient who is receiving an oral drug by considering the relationships of clearance, elimination rate constant, and volume of distribution.
10. Contrast two- and three-compartment body models with the one-compartment body model with respect to assumptions, drug distribution, and drug elimination.
11. Explain the nomenclature that is used to describe genotype and phenotype.
12. Demonstrate how to use available pharmacogenomics databases.
13. Describe the purpose of the CPIC guidelines and how to use them as a clinician.
14. Discuss how "OMICs" technologies can be used to stratify disease classification and personalize drug therapy.
15. Discuss how pharmacogenetics contributes to variability in drug metabolism and transport.
16. Discuss Food-Drug/Drug Interactions and their consequences as well as understand how to change or adjust treatment plans accordingly.
17. Understand the different and typical BA/BE study designs and discuss the criteria for acceptance of BE testing.
18. Describe the common special patient populations and the characteristics of each that must be considered during drug individualization.

Course Pre-requisites

1. Admission into the Doctor of Pharmacy program.
2. Satisfactory completion of Blocks 1 and 2.

Course Co-requisites

1. There are no co-requisites for this course.

Course Outline

See Appendix. Please routinely check your campus calendar and the Canvas course site for any messages about changes in the schedule including meeting dates/times, deadlines, and room changes.

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Required Textbooks/Readings

1. There are no required textbooks for this course.

Use UF VPN to access UF Libraries Resources when off-campus.
The UF HSC library staff can assist you with questions or issues related to accessing online library materials. For assistance contact your College of Pharmacy librarian or visit the HSC Library Website at this URL:http://www.library.health.ufl.edu/

Suggested Textbooks/Readings

Basic Pharmacokinetics by David Bourne: https://itunes.apple.com/us/book/basic-pharmacokinetics/id505553540?mt=11

Derendorf H and Schmidt S (ed.) *Rowland and Tozer's Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications*. Fifth Edition. Wolters Kluwer, Alphen aan den Rijn, Netherlands, 2019, 1-939. https://books.google.com/books/about/Rowland_and_Tozer_s_Clinical_Pharmacokin.html?id=4OuhDwAAQBAJ

Leon Shargel, Susanna WuPong, Andrew Yu, Applied Biopharmaceutics and Pharmacokinetics, 6th ed. McGraw Hill (This text is available via the UF library/Pharmacy Access)

Larry A. Bauer, Applied Clinical Pharmacokinetics, 2nd ed. (This text is available via the UF library/Pharmacy Access)

David Kisor, Michael Kane, Jon Sprague, Jeffery Talbot, Pharmacogenetics, Kinetics, and Dynamics for Personalized Medicine, Burlington, Jones & Bartlett Publishers, 2013. ISBN 978-1-44496-5273-9 https://books.google.com/books/about/Pharmacogenetics_Kinetics_and_Dynamics_f.html?id=DchzGBa3AoYC

Pharmacogenomics: An Introduction and Clinical Perspective. Bertino, Joseph S. New York: McGraw-Hill, 2013. ISBN 978-0-07-174169-9. Available through Access Pharmacy at: http://www.accesspharmacy.com/resourceToc.aspx?resourceID=783

Use UF VPN to access UF Libraries Resources when off-campus. The UF HSC library staff can assist you with questions or issues related to accessing online library materials. For assistance contact your College of Pharmacy librarian or visit the HSC Library Website at this URL: http://www.library.health.ufl.edu/

Other Required Learning Resources

N/A

Materials & Supplies Fees

None

Student Evaluation & Grading

Evaluation Methods and How Grades are calculated.

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[The Canvas© gradebook will be set-up using the percentages below to compute the grade.]

Table 1.1 Evaluation and Grading Below

Assessment Item	Grade Percentage
Quizzes	22%
Active Learning Sessions	11%
Exam 1 and Exam 2	40%
Exam 3	27%
Total	100%

Table 1.2 Grading Scale

Percentage	Letter Grade
92.50-100%	A
89.50-92.49%	A-
86.50-89.49%	B+
82.50-86.49%	B
79.50-82.49%	B-
76.50-79.49%	C+
72.50-76.49%	C
69.50-72.49%	C-
66.50-69.49%	D+
62.50-66.49%	D
59.50-62.49%	D-
< 59.50%	E

Rounding of grades:
Final grades in Canvas will be rounded to the 2nd decimal place. If the decimal is X.495 or higher, Canvas will round the grade to X.50. The above scale depicts this policy and grades are determined accordingly. Grade assignment is made using this policy and NO EXCEPTIONS will be made in situations where a student's grade is "close."

Educational Technology Use

The following technology below will be used during the course and the student must have the appropriate technology and software.

1. ExamSoft™ Testing Platform
2. Canvas™ Learning Management System

For technical support, navigate to Educational Technology and IT Support Contact Information at this URL: http://curriculum.pharmacy.ufl.edu/current-students/technical-help/

Pharm.D. Course Policies

The Policies in the following link apply to this course. Review the General Pharm.D. Course Policies carefully, at this URL: http://curriculum.pharmacy.ufl.edu/current-students/course-policies/

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Course Evaluation Process

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at https://gatorevals.aa.ufl.edu/students/. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via https://ufl.bluera.com/ufl/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/.

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Appendix A. Course Directory

Teaching Partnership Leader/Course Director:

Stephan Schmidt, B.Pharm, Ph.D., F.C.P.
Email: sschmidt@cop.ufl.edu
Office: 464/ORL
Phone: 407-313-7012
Office Hours: Please see the Canvas course site for posted office hours.

Questions to Ask:

- Concerns about performance
- Guidance when there are performance problems (failing grades)
- General questions about content

Other Teaching Partnership Faculty Members:

Emily J. Cicali, Pharm.D., BCPS
Email: emily.cicali@cop.ufl.edu
Office: DG-22R (Gainesville)
Phone: 352-273-7919

Guenther Hochhaus, Ph.D.
Email: hochhaus@cop.ufl.edu
Office: MSB P3-33
Phone: 352 273 7861

Valvanera Vozmediano, Ph.D.
Email: valva@cop.ufl.edu
Office: 465, 6550 Sanger Road, Orlando
Phone: 407 313 7052

Instructional Designer:

Name: Holly Fremen

- Email: holly.fremen@cop.ufl.edu
- Office: HPNP 4309
- Phone: 352-273-5558

Academic Coordinator Gainesville Campus:

Name: Misti Merril

- Email: mmerrill@cop.ufl.edu
- Office: HPNP 4312
- Phone: 352-273-5617

Absence/Tardy Email: absent1pd@cop.ufl.edu (Visit the course policy site for further instructions)

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Educational Coordinators

Name: McKenzie Wallen

- Email: mwallen@cop.ufl.edu
- Office: Jacksonville Campus

Name: Iverta Allen

- Email: iallen1@cop.ufl.edu
- Office: Orlando Campus

Questions to Ask:

- Issues related to course policies (absences, make up exams, missed attendance)
- Absence/tardy requests (Only the Academic Coordinator handles absence requests)
- Questions about dates, deadlines, meeting place
- Availability of handouts and other course materials
- Assignment directions
- Questions about grade entries in gradebook (missing grades, incorrect grade)
- Assistance with ExamSoft® (Distance campus students may contact the Educational
- Coordinator for use of Examplify and assistance during exams. The Academic Coordinator is the contact person for issues related to grading and posting of ExamSoft grades.

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Student Dates of Study	Mod#	Activity	Unit Topic	Contact Min	Learning Objectives	Responsible
01/06/2021	1	Module	Module 1: Introduction to Pharmacokinetics; Pharmacodynamics & Personalized Medicine	45	1	Stephan Schmidt
01/06/2021	1.1	Video Lecture	Watch: Introduction to Pharmacokinetics, Pharmacodynamics & Personalized Medicine	45	1	Stephan Schmidt
01/07/2021	2	Module	Module 2: Basic Pharmacokinetics	110	2-3	Guenther Hochhaus
01/07/2021	2.1	Video Lecture	Watch: Basic Pharmacokinetics, Part 1	90	2-3	Guenther Hochhaus
01/07/2021	2.2	Video Lecture	Watch: Basic Pharmacokinetics, Part 2	20	2-3	Guenther Hochhaus
01/12/2021 1:55pm - 3:50pm	1-2	Active Learning Session--VC	Active Learning Session 1: Module 2	120	2-3	Stephan Schmidt, Guenther Hochhaus
01/12/2021	1-2	Quiz In-class Graded	Quiz 1		2-3	Stephan Schmidt, Guenther Hochhaus
01/13/2021	3	Module	Module 3: Distribution	185	3	Guenther Hochhaus
01/13/2021	3.1	Video Lecture	Watch: Drug Distribution, Part 1	45	3	Guenther Hochhaus
01/13/2021	3.2	Video Lecture	Watch: Drug Distribution, Part 2	140	3	Guenther Hochhaus
01/14/2021 1:55pm - 3:50pm	3	Active Learning Session--VC	Active Learning Session 2: Module 3	120	3	Guenther Hochhaus
01/14/2021	3	Quiz In-class Graded	Quiz 2		3	Guenther Hochhaus
01/15/2021	4	Module	Module 4: Hepatic Clearance	150	3-4	Guenther Hochhaus

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01/15/2021	4.1	Video Lecture	Watch: Hepatic Clearance	30	3-4	Guenther Hochhaus
01/19/2021	4.2	Video Lecture	Watch: Hepatic Metabolism	120	3-4	Guenther Hochhaus
01/20/2021 8:30am - 10:25pm	4	Active Learning Session--VC	Active Learning Session 3: Module 4	120	3-4	Guenther Hochhaus
01/20/2021	4	Quiz In-class Graded	Quiz 3		3-4	Guenther Hochhaus
01/21/2021	5	Module	Module 5: Renal Clearance		3, 5-6	Guenther Hochhaus
01/21/2021	5.1	Video Lecture	Watch: Drug Elimination; Renal Clearance	132	3, 5-6	Guenther Hochhaus
01/26/2021 1:00pm - 3:00pm	5	Active Learning Session--VC	Active Learning Session 4: Module 5	120	3, 5-6	Guenther Hochhaus
01/26/2021	5	Quiz In-class Graded	Quiz 4		3, 5-6	Guenther Hochhaus
01/27/2021	6	Module	Module 6: Intravenous Bolus Administration		7	Stephan Schmidt
01/27/2021	6.1	Video Lecture	Watch: IV Bolus Administration, Part 1	45	7	Stephan Schmidt
01/28/2021	6.2	Video Lecture	Watch: IV Bolus Administration, Part 2	31	7	Stephan Schmidt
02/03/2021	6.3	Video Lecture	Watch: IV Bolus Administration, Part 3	51	7	Stephan Schmidt
02/04/2021 8:30am - 10:25am	6	Active Learning Session--VC	Active Learning Session 5:Module 6	120	7	Stephan Schmidt
02/04/2021	6	Quiz In-class Graded	Quiz 5		7	Stephan Schmidt
02/05/2020 TBD	1-6	Active Learning Session--Web	Exam 1 Review	60	1-7	Stephan Schmidt, Guenther Hochhaus

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02/09/2021 2:00 - 4:00pm	1-6	Exam	Exam 1, Modules 1-6	120	1-7	Stephan Schmidt, Guenther Hochhaus
02/10/2021	7	Module	Module 7: Intravenous Infusion		8	Stephan Schmidt
02/10/2021	7.1	Video Lecture	Watch: Continuous Intravenous Infusion	32	8	Stephan Schmidt
02/10/2021	7.2	Video Lecture	Watch: Intermittent Intravenous Infusion	22	8	Stephan Schmidt
02/10/2021	7.3	Video Lecture	Watch: IV Infusion Examples	24	8	Stephan Schmidt
02/12/2021 1:55pm - 3:50pm	7	Active Learning Session--VC	Active Learning Session 6: Module 7	120	8	Stephan Schmidt
02/12/2021	7	Quiz In-class Graded	Quiz 6		8	Stephan Schmidt
02/16/2021	8	Module	Module 8: Oral Administration		9	Stephan Schmidt
02/16/2021	8.1	Video Lecture	Watch: Oral Administration	46	9	Stephan Schmidt
02/16/2021	9	Module	Module 9: Compartmental Models		10	Stephan Schmidt
02/16/2021	9.1	Video Lecture	Watch: Compartmental Models	32	10	Stephan Schmidt
02/17/2021 8:30am-10:25am	8-9	Active Learning Session--VC	Active Learning Session 7: Module 8-9	120	9-10	Stephan Schmidt
02/17/2021	8-9	Quiz In-class Graded	Quiz 7		9-10	Stephan Schmidt
02/17/2021	10	Module	Module 10: Principles of Personalized Medicine		11-12	Emily Cicali
02/17/2021	10.1	Video Lecture	Watch: Introduction to Pharmacogenomics	30	11	Emily Cicali

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02/17/2021	10.2	Video Lecture	Watch: Principle of Genetic Medicine, Part 1	60	11	Emily Cicali
02/18/2021	10.3	Video Lecture	Watch: Principle of Genetic Medicine, Part 2	30	11	Emily Cicali
02/18/2021	10.4	Video Lecture	Watch: Database Tools for Pharmacogenomics	60	12	Emily Cicali
02/19/2021	10.5	Video Lecture	Watch: CPIC Guidelines	37	13	Emily Cicali
02/19/2021	10.6	Video Lecture	Watch: Omics and Personalized Medicine	45	14	Emily Cicali
02/23/2021 1:55pm - 3:50pm	10	Active Learning Session--VC	Active Learning Session 8: Module 10	120	11-14	Emily Cicali
02/23/2021	10	Quiz In-class Graded	Quiz 8		11-12	Emily Cicali
02/26/2021	11	Module	Module 11: Pharmacogenomics of Drug Metabolizing Enzymes		15	Emily Cicali
02/26/2021	11.1	Video Lecture	Watch: Pharmacogenomics of Drug Metabolism: Part 1	40	15	Emily Cicali
03/02/2021	11.2	Video Lecture	Pharmacogenomics of Drug Metabolism: Part 2	60	15	Emily Cicali
03/03/2021	11.3	Video Lecture	Pharmacogenomics of Drug Metabolism: Part 3	20	15	Emily Cicali
03/04/2021 TBD	7-10	Active Learning Session--Web	Exam 2 Review	60	8-14	Stephan Schmidt, Emily Cicali
03/05/2021 8:30am - 10:30am	7-10	Exam	Exam 2, Modules 7-10	120	8-14	Stephan Schmidt, Emily Cicali
03/08/2021	12	Module	Module 12: Pharmacogenomics of Drug Transporters		14	Emily Cicali

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03/08/2021	12.1	Video Lecture	Watch: Pharmacogenomics of Drug Transporters, Part 1	38	14	Emily Cicali
03/09/2021	12.2	Video Lecture	Watch: Pharmacogenomics of Drug Transporters, Part 2	30	14	Emily Cicali
03/10/2021 1:55 - 3:50pm	12	Active Learning Session--VC	Active Learning Session 9: Module 11-12	120	14	Emily Cicali
03/10/2021	12	Quiz In-class Graded	Quiz 9		14	Emily Cicali
03/11/2021	13	Module	Module 13: Food-Drug/Drug-Drug Interactions		16	Valvanera Vozmediano
03/11/2021	13.1	Video Lecture	Watch: Food and Herbal Supplement-Based Drug Interactions	35	16	Valvanera Vozmediano
03/12/2021	13.2	Video Lecture	Watch: Enzyme and Transporter Mediated Drug-Drug Interactions	42	16	Valvanera Vozmediano
03/16/2021	14	Module	Module 14: Bioequivalence		17	Valvanera Vozmediano
03/16/2021	14.1	Video Lecture	Watch: Bioequivalence	51	17	Valvanera Vozmediano
03/17/2021 1:55pm-3:50pm	13-14	Active Learning Session--VC	Active Learning Session 10: Modules 13-14	120	16-17	Valvanera Vozmediano
03/24/2021	13-14	Quiz In-class Graded	Quiz 10		16-17	Valvanera Vozmediano
03/18/2021	15	Module	Module 15: Special Patient Populations		18	Valvanera Vozmediano
03/18/2021	15.1	Video Lecture	Watch: Body-size Measure for Normalization	45	18	Valvanera Vozmediano
03/18/2021	15.2	Video Lecture	Watch: Special Patient Populations, Part 1	42	18	Valvanera Vozmediano

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03/19/2021	15.3	Video Lecture	Watch: Special Patient Populations, Part 2	35	18	Valvanera Vozmediano
03/19/2021	15.4	Video Lecture	Watch: Pharmacokinetics and Dosage in Patients with Renal Disease	60	18	Valvanera Vozmediano
03/23/2021 08:30am - 10:25am	15	Active Learning Session--VC	Active Learning Session 11: Modules 15	120	18	Valvanera Vozmediano
03/24/2021	15	Quiz In-class Graded	Quiz 11		18	Valvanera Vozmediano
03/25/2021 TBD	1-15	Active Learning Session--Web	Final Exam Review	60	1-19	Stephan Schmidt, Guenther Hochhaus, Emily Cicali, Valvanera Vozmediano
03/26/2021 08:30am - 10:30am	1-15	Exam	Exam 3, Modules 1-15		1-19	Stephan Schmidt, Guenther Hochhaus, Emily Cicali, Valvanera Vozmediano Esteban
			Total Min	**3283**		
			Total Hours	**54.716**		

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