PHA5223

Pharmacoepidemiology and Drug Safety

Term, 2020
2 Credit Hours – [A-E Grading]

The goal of this course is to familiarize students with the concepts and tools of pharmacoepidemiology and drug safety. Students will develop a base understanding of the evaluation of study designs and drug safety programs, how these fields influence regulation and policy of medications and other treatments, and how to use this information to make evidence-based decisions to achieve positive care outcomes for individual patients or within patient populations.

Teaching Partnership Leaders

Joshua Brown, Pharm.D., Ph.D.
- Email: joshua.brown@cop.ufl.edu
- Office: HPNP 3320
- Phone: 352-294-8593

Office Hours: Mondays 4 – 6 pm (during course dates). Please see Canvas for Zoom meeting ID.

Yu-Jung "Jenny" Wei, M.S., Ph.D.
- Email: jenny.wei@cop.ufl.edu
- Office: HPNP 3321
- Phone: 352-294-5340
- Office Hours: Mondays 10 am – 12 pm (during course dates). Please see Canvas for Zoom meeting ID.

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. EPA A3. Formulate evidence-based care plans in collaboration with an interprofessional team. Utilize clinical guidelines in the development of a pharmacotherapy plan.
2. EPA C2. Recommend solutions to needs in the medication use system and the healthcare system.

Course-Level Objectives

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

1. Identify and distinguish the basics of pharmacoepidemiological study designs, including cohort study and case-control study.
2. Apply the knowledge of study design to evaluation of drug safety in pharmacoepidemiological studies.
3. Analyze the effect bias and confounding may have on the results of a study and understand ways to minimize these threats to validity.
4. Describe comparative effectiveness research (CER) on treatment options and common pitfalls of CER studies.
5. Describe how the pharmacoepidemiological studies and drug safety programs are used to guide federal regulations and other policies for medications and other therapies.
6. Make evidence-based decisions through critical appraisal of the literature to achieve positive care outcomes for individual patients or patient populations.

Course Pre-requisites

1. Completion of all Year 2 Pharm.D. program coursework including milestones.

Course Co-requisites

1. PHA5165L Professional Practice Skills Lab VI

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.

Required Textbooks/Readings

1. There are no required textbooks for this class. Any required readings will be made available on Canvas.
2. • Use UF VPN to access UF Libraries Resources when off-campus.
3. • 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/

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Suggested Textbooks/Readings

Suggested readings will be posted on Canvas.

Other Required Learning Resources

None

Materials & Supplies Fees

None

Student Evaluation & Grading

Evaluation Methods and How Grades are calculated.
[The Canvas© gradebook will be set-up using the percentages below to compute the grade.]

Assessment Item	Grade Percentage
Individual Readiness Assessments [3 @ 2.5% ea.]	7.5%
Team Readiness Assessments [3 @ 4.16% ea.]	12.5%
Self-Assessments [2 @ 5% ea.]	10%
Discussion Board Activity	10%
Exam 1	30%
Exam 2	30%
Total	100%

Table 1.1 Evaluation and Grading Above

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."

Makeup Assignments

Makeup assignments may be required for excused absences from all Active Learning Sessions. Students will be required to complete the makeup assignment within one week of the missed session.

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/

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/.

Appendix A. Course Directory

Teaching Partnership Leader/Course Director(s):

Joshua Brown, Pharm.D., Ph.D.
- Email: joshua.brown@cop.ufl.edu
- Office: HPNP 3320
- Phone: 352-294-8593

Yu-Jung "Jenny" Wei, M.S., Ph.D.
- Email: jenny.wei@cop.ufl.edu
- Office: HPNP 3321
- Phone: 352-294-5340

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

Other Teaching Partnership Faculty Members:

Almut Winterstein, RPh, Ph.D., FISPE
- Email: almut@cop.ufl.edu
- Office: HPNP Room 3336
- Phone: 352-273-6258

Instructional Designer:

Elliot Tordoff, MSc, PGCE
- Email: etordoff@cop.ufl.edu
- Office: HPNP 4309
- Phone: 352-294-5215

Academic Coordinator Gainesville Campus:

Name: Misti Merrill
- Email: mmerrill@cop.ufl.edu
- Office: HPNP 4312
- Phone: 352-294-5617

Absence/Tardy Email: absent3pd@cop.ufl.edu (Visit the course policy site for instructions)

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.

Appendix: Course Outline

Date Recommended Dates for Independent Study	Delivery Date	Mod #	Unit Topic	Contact Time [hr.]a	Responsible
		1	Module 01: Pharmacoepidemiology Study Design		Wei
9/9/20		1.1	Watch: What is Pharmacoepidemiology Study?	0.5	Wei
9/9/20		1.2	Watch: Review of Major Methodology and Terminology	0.5	Wei
9/9/20		1.3	Watch: Cohort Studies	1	Wei
9/10/20		1.4	Watch: Case-Control Studies	1.5	Wei
9/10/20			Read: Article 1 (Canvas)	1.5	Wei
	9/16/20 8:30 - 10:25 am		Active Learning Session 1: Cohort vs. Case Control iRAT & tRAT published	2	Wei
		2	Module 02: Bias		Wei
9/17/20			Watch: Overview of Bias	0.25	Wei
9/17/20			Watch: Selection Bias	0.5	Wei
9/18/20			Watch: Information Bias	0.5	Wei
9/18/20			Watch: Measurement Error	0.25	Wei
9/18/20			Watch: Misclassification	0.5	Wei

	9/22/20 11:59pm		Assignment: Study Critique Practice – Bias	1	Wei
		3	Module 03: Confounding		Wei
09/21/20		3.1	Watch: Review of Confounding	0.5	Wei
09/21/20		3.2	Watch: Confounding in Pharmacoepidemiology	1	Wei
09/21/20		3.3	Watch: Approaches for Handling Confounding	0.5	Wei
			Confounding Supplement		Wei
	9/22/20 11:59pm		Assignment: Study Critique Practice – Confounding	1	Wei
	9/23/20 8:30 - 10:25 am	2-3	Active Learning Session 2: Bias & Confounding	2	Wei
			RAT 2		Wei
		4	Module 04: FDA Drug Policy and Role of Pharmacoepidemiology		Winterstein, Brown
09/24/20			Watch: The U.S. Drug Safety Regulatory Framework and Phase 4 Safety Commitments	0.5	Winterstein, Brown
09/24/20			The U.S. Drug Safety Regulatory Framework and Phase 4 Safety Commitments		Winterstein, Brown
09/25/20			Watch: FDA Post-Marketing Surveillance	1	Winterstein, Brown
	9/28/20 8:30 – 10:00 am		Exam 1: Modules 1-4		
		5	Module 5: Outcomes Measurement		Brown
09/29/20		5.1	Watch: Surrogate vs. Clinical Outcomes	1	Brown
09/29/20		5.2	Watch: Composite Outcomes	0.5	Brown
09/30/20		5.3	Watch: Patient-Reported Outcomes (PROs)	0.5	Brown
			Assignment: Review journal article HRT and Atrial Fibrillation (on Canvas) to prepare for Active Learning Session		Brown
			Assignment: Review journal article HRT and Atrial Fibrillation (on Canvas) to prepare for Active Learning Session #3		
	9/30/20 8:30 - 10:25 am	5	Active Learning Session 3: Measuring outcomes	2	Brown
			iRAT & tRAT 3		Brown
		6	Module 06: Comparative Effectiveness Research (CER)		Brown
10/01/20		6.1	Watch: What is CER?	0.25	Brown
10/01/20			Read: eBook Chapter 1 – Study Objectives and Questions (Canvas)	1	Brown
10/01/20		6.2	Watch: Study Design of CER	0.5	Brown

10/01/20			Read: eBook Chapter 2 – Study Design Considerations (pp. 28-31) (Canvas)		Brown
10/01/20		6.3	Watch: Bias and Confounding in CER Studies	0.5	Brown
10/02/20			Read: eBook Chapter 3 – Estimation and Reporting of Heterogeneity of Treatment Effects (Canvas)	1	Brown
10/02/20			Read: eBook Chapter 4 – Exposure Definition and Measurement (Canvas)	0.75	Brown
10/02/20			Read: eBook Chapter 11 – Sensitivity Analysis (pp. 146-150) (Canvas)	0.25	Brown
10/02/20		6.4	Watch: Pragmatic Clinical Trials	0.5	Brown
10/02/20		6.5	Watch: Real-World Applications of CER	0.5	Brown
		7	Module 7: Real-World Evidence and Real-World Data		Brown
10/02/20		7.1	Watch: What is Real-World Evidence (RWE) from the perspective of the FDA and pharmaceutical industry?	0.5	Brown
10/05/20			Read: eBook Chapter 8 – Selection of Data Sources (pp. 109-116) (Canvas)	0.5	Brown
10/05/20			FDA RWE Framework (Canvas)		
10/05/20		7.2	Watch: What is Real-World Data?	0.5	Brown
10/05/20			Real world data an opportunity (Canvas)		
10/05/20		7.3	Study Designs Unique to RWE		
10/06/20			Trial Designs RWE (Canvas)		
10/06/20			Watch: Pharmacist Careers in Drug Safety	0.5	Brown
	09/28/20	8	Module 8: Critiquing Pharmacoepidemiology and Drug Safety Literature for Decision-Making		Brown
10/06/20			Watch: Critical Evaluation of the Literature for Pharmacists	0.5	Brown
10/06/20			Read: Article 2 (Canvas) When and How Can Real World Data Analyses Substitute for Randomized Controlled Trials?	0.75	Brown
10/06/20			Read: Article 3 (Canvas) A Questionnaire to Assess the Relevance and Credibility of Observational Studies to Inform Health Care Decision Making	0.75	Brown
10/06/20			Read: Article 4 and use for Discussion Board Activity Below	0.25	Brown
			Assignment: Discussion Board Activity		Brown
	10/7/20 8:30 - 10:25 am	6-7	Active Learning Session 4: Decision-making using Real-World Evidence and Comparative Effectiveness Research	2	Brown
	10/12/20 8:30 - 10 am	1-8	Exam 2: Modules 5-7		Brown, Wei
				Total Hours 33.5	