PHA5223
Pharmacoepidemiology and Drug Safety

Fall 2023

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 basic understanding of 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 populations.

Teaching Partnership Leaders

Steven M. Smith, PharmD, MPH, FCCP, FAHA

- Email: ssmith@cop.ufl.edu
- Office: HPNP 3316 / DSIT 6014
- Phone: 352-273-5134

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. 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.
2. Maximize the appropriate use of medications in a population.
3. Educate patients and professional colleagues regarding the appropriate use of medications.
4. Use evidence-based information to advance patient care.

Course-Level Objectives

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

1. Identify and distinguish the basics of pharmacoepidemiologic study designs, including cohort study and case-control study.
2. Apply the knowledge of study design to evaluation of drug safety in pharmacoepidemiologic 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 pharmacoepidemiologic 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 V

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.

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

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.]

Table 1.1 Evaluation and Grading

Assessment Item	**Grade Percentage**
iRATs (3 @ 3.33% each)	10%
tRATs (3 @ 3.33% each)	10%

Self-Assessments (2 @ 5% each)	10%
Critical Literature Appraisal	10%
Exam 1	30%
Exam 2	30%
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/

Artificial Intelligence Use

The use of artificial intelligence (AI) text generators such as ChatGPT on assignments, projects, quizzes, and exams is prohibited in this course. Use of AI text generators is considered evidence of academic dishonesty. If a student is uncertain about the use of AI technology, it is the student's responsibility to ask the instructor prior to beginning the assignment or assessment.

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/

Attendance Policy

Attendance is mandatory for active learning sessions such as team-based learning sessions, case discussions, laboratory sessions, and other activities that the instructor designates as required. This course has 4 required ALS sessions. A student who misses greater than 1 session (25% of the required active learning sessions/activities) or laboratory sessions for this course will receive an incomplete in the course and will retake the course during the next offering, resulting in delayed graduation.

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.

Late Assignments

Late assignments are subject to a 20% grade reduction. Assignments submitted more than 1 week late will receive a zero grade.

Accessibility and Belonging Statement

The University of Florida College of Pharmacy strives to stimulate a culture that promotes diversity and inclusion within an exceptional community of students, faculty, and staff. It is our intent that students from all diverse backgrounds and perspectives be well served by this course, that students' learning needs be addressed both in and out of class, and that the diversity that students bring to this class be viewed as a resource, strength, and benefit.

We intend to present materials and activities that are respectful of diversity: gender, sexuality, disability, age, socioeconomic status, ethnicity, race, and culture. Your suggestions are encouraged and appreciated. Please let us know ways to improve the course's effectiveness for you personally or for other students or student groups.

If any of our class meetings conflict with any of your religious events, an excused absence will be provided when requested using the standard UF COP process as detailed in the UF COP Course policies.

If you feel that you have experienced or witnessed any bias/treatment that falls short of these expectations, you may submit a report through the UF COP *Student Mistreatment Report*.

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):

Steven M. Smith, PharmD, MPH, FCCP, FAHA
- Email: ssmith@cop.ufl.edu
- Office: HPNP 3316 / DSIT 6014
- Phone: 352-273-5134

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:

Tianze Jiao, PhD
- Email: tianzejiao@cop.ufl.edu
- Office: HPNP 3321 / DSIT 6301
- Phone: 352-273-9933

Almut Winterstein, RPh, Ph.D., FISPE
- Email: almut@cop.ufl.edu
- Office: HPNP 3336 / DSIT 6310
- Phone: 352-273-6258

Weihsuan Jenny Lo-Ciganic, PhD, MS, MSPharm
- Email: wlociganic@cop.ufl.edu
- Office: HPNP 3338 / DSIT 6008
- Phone: 352-273-6255

Instructional Designer:

Chris Egan, M.Ed., NRP, CHSE, CHSOS
- Email: cegan@ufl.edu
- Phone: 352-294-5636

Academic Coordinator Gainesville Campus:

Ashleigh Langford
- Email: lynn8597@cop.ufl.edu
- Office: HPNP 4309
- Phone: 352-273-6284

Educational Coordinators:

Katie Orben

- Email: korben06@ufl.edu
- Office: Jacksonville Campus
- Phone: 904-244-9590

Jessica Linares

- Email: jnoriegalinares@ufl.edu
- Office: Orlando Campus
- Phone: 407-313-4087

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 B: Course Outline: See Link Below

Date / Time	Mod #	Activity	Activity Title	Contact Time (hr)	Responsible
	1	Module	Module 1: Course Introduction		Steven M Smith
09/08/23	1.1	Lecture Video	Intro to Course	0.14	Steven M Smith
09/08/23	1.2	Lecture Video	Biostatistics, Epidemiological, or Pharmacoeconomic Measures: NAPLEX prep	1.48	Steven M Smith
	2	Module	Module 2: Pharmacoepidemiology Study Design		Steven M Smith
09/11/23	2.1	Lecture Video	What is a Pharmacoepidemiology Study?	0.56	Steven M Smith
09/11/23	2.2	Lecture Video	Cohort Studies	1.88	Steven M Smith
09/12/23	2.3	Lecture Video	Case-Control Studies	0.7	Steven M Smith
09/13/23		Reading (PDF)	Tramadol Use and the Risk of Hospitalization for Hypoglycemia Patients with Non-cancer Pain	1.5	
09/15/23 at 8 - 9:50am		Active Learning Session	Active Learning Session 1: Cohort vs. Case Control - iRAT & tRAT published	2	Steven M Smith
09/15/23		Quiz (iRAT/tRAT)	iRAT & tRAT 1		Steven M Smith
	3	Module	Module 3: Bias & Confounding		Steven M Smith
09/15/23	3.1	Lecture Video	Bias	1	Steven M Smith
09/18/23	3.2	Lecture Video	Confounding	1	Steven M Smith
09/18/23		Reading (PDF)	Association Between Medication Adherence and the Outcomes of Heart Failure	0.5	
	4	Module	Module 4: Artificial Intelligence and Machine Learning in Pharmacy Practice		Jenny Lo Ciganic
09/19/23	4.1	Lecture Video	Artificial Intelligence and Machine Learning in Pharmacy Practice	0.75	Jenny Lo-Ciganic
09/19/23 at 11:59pm		Assignment (Graded)	Assignment: Study Critique Practice (Bias)	2	Steven M Smith
09/19/23 at 11:59 pm		Assignment (Graded)	Assignment: Study Critique Practice (Confounding)	2	Steven M Smith
09/20/23 at 8 - 9:50am		Active Learning Session	Active Learning Session 2: Bias & Confounding	2	Steven M Smith
09/20/23		Quiz (iRAT/tRAT)	iRAT & tRAT 2		Steven M Smith
	5	Module	Module 5: FDA Drug Policy and Role of Pharmacoepidemiology		Almut Gertrud Winterstein
09/20/23	5.1	Lecture Video	Drug Safety	0.84	Almut Gertrud Winterstein
09/21/23	5.2	Lecture Video	FDA Post-Marketing Surveillance	1	Monica Munoz
09/21/23	5.3	Lecture Video	Risk Evaluation and Mitigation Systems (REMS)	0.75	Almut Gertrud Winterstein
	6	Module	Module 6: Outcomes Measurement		Steven M Smith
09/22/23	6.1	Lecture Video	Outcome Measurement	1	Steven M Smith
09/22/23	6.2	Lecture Video	Surrogate and Clinical Endpoints	0.5	Steven M Smith
09/25/23	6.3	Lecture Video	Patient-Reported Outcomes (PROs)	0.5	Steven M Smith

Date / Time	Mod #	Activity	Activity Title	Contact Time (hr)	Responsible
		Optional/Supplemental	eBook Chapter 6 – Outcome Definition and Measurement (Canvas)		
09/26/23		Reading (PDF)	Hormone Replacement Therapy and Adverse Outcomes in Women with Atrial Fibrillation		
09/26/23		Reading (PDF)	Evolocumab Clinical Outcomes in Patients with Cardiovascular Disease (**only read Results Section**)		
09/27/23		Reading (PDF)	Revisiting FDA Approval of Aducanumab by Alexander, et.al	0.2	
09/27/23		Reading (PDF)	Controversy and Progress in Alzheimer's Disease - FDA Approval of Aducanumab by Rabinovici, et.al	0.2	
		Optional/Supplemental	Lecture Study Guide		
09/27/23 at 1 3pm		Exam	Exam 1: Modules 1 5	2	
	7	Module	Module 7: Comparative Effectiveness Research (CER)		Tianze Jiao
09/28/23	7.1	Lecture Video	What is CER?	0.25	Tianze Jiao
		Optional/Supplemental	eBook Chapter 1 – Study Objectives and Questions (Canvas)		
09/29/23	7.2	Lecture Video	Study Design of CER	0.5	Tianze Jiao
		Optional/Supplemental	eBook Chapter 2 – Study Design Considerations (pp. 28-31) (Canvas)		
09/29/23 at 8 - 9:50am		Active Learning Session	Active Learning Session 3: Measuring Outcomes	2	Steven M Smith
09/29/23		Quiz (iRAT/tRAT)	iRAT & tRAT 3		Steven M Smith, Tianze Jiao
10/02/23	7.3	Lecture Video	Bias and Confounding in CER Studies	0.5	Tianze Jiao
		Optional/Supplemental	eBook Chapter 3 – Estimation and Reporting of Heterogeneity of Treatment Effects (Canvas)		
		Optional/Supplemental	eBook Chapter 4 – Exposure Definition and Measurement (Canvas)		
		Optional/Supplemental	eBook Chapter 11 – Sensitivity Analysis (pp. 146-150) (Canvas)		
10/03/23	7.4	Lecture Video	Pragmatic Clinical Trials	0.5	Tianze Jiao
		Optional/Supplemental	Module 7 Study Guide		
10/04/23 at 8 - 9:50am		Active Learning Session	Active Learning Session 4: Selecting Comparator Groups in Pharmacoepidemiological Studies	2	Steven M Smith, Tianze Jiao
10/04/23		Quiz (iRAT/tRAT)	iRAT & tRAT 4		
	8	Module	Module 8: Real World Evidence and Real World Data		Steven M Smith
10/04/23	8.1	Lecture Video	What is Real-World Evidence (RWE) from the perspective of the FDA and pharmaceutical industry?	0.5	Steven M Smith
		Optional/Supplemental	eBook Chapter 8 – Selection of Data Sources (pp. 109-116) (Canvas)		
10/05/23 at		Exam Review	Exam 1 Review		Steven M Smith

Date / Time	Mod #	Activity	Activity Title	Contact Time (hr)	Responsible
9 - 9:30am					
10/05/23		Reading (PDF)	FDA RWE Framework	0.75	
10/05/23	8.2	Lecture Video	What is Real-World Data?	0.5	Steven M Smith
10/05/23		Reading	Real World Data an Opportunity	0.5	
10/06/23	8.3	Lecture Video	Study Designs Unique to RWE		Steven M Smith
10/06/23		Reading (PDF)	Trial Designs RWE	0.5	
10/06/23		Reading (PDF)	Use of Real World Evidence to Drive Drug Development Strategy and Inform Clinical Trial Design	0.75	
10/06/23		Reading (PDF)	Association Between Use of Non Vitamin K oral Anticoagulants with and Without Concurrent Medications and Risk of Major Bleeding in Nonvalvular Atrial Fibrillation	0.5	
	9	Module	Module 9: Critiquing Pharmacoepidemiology and Drug Safety Literature for Decision Making		Steven M Smith
10/09/23	9.1	Lecture Video	Critical Evaluation of the Literature for Pharmacists	0.5	Steven M Smith
10/09/23		Reading (PDF)	Relationship Between Selective Cyclooxgenase-2 Inhibitors and Acute Myocardial Infarction in Older Adults	0.25	
10/09/23		Other	STROBE Checklists	0.1	
10/09/23		Reading (PDF)	A Questionnaire to Assess the Relevance and Credibility of Observational Studies to Inform Health Care Decision Making: An ISPOR-AMCP-NPC Good Practice Task Force Report	0.25	
10/09/23		Reading	Proton Pump Inhibitors and Risk of Dementia (for Critical Literature Appraisal assignment)	0.25	
10/09/23		Reading (PDF)	When and How Can Real World Data Analyses Substitute for Randomized Controlled Trials?	0.75	
10/09/23 at 4:45 - 5pm		Course Evaluation	Course Evaluation		
10/11/23 at 10am 12pm	6 8	Exam	Exam 2: Modules 6 8		
10/13/23		Assignment (Graded)	Assignment: Critical appraisal of a pharmacoepidemiology study		
10/23/23 at 4:30 - 5pm		Exam Review	Final Exam Review		
			Total Hours	36.35	