

PHA 6268 Pharmacoepidemiology and Drug Safety

Fall, 2021

3 Credit Hours – [A-E Grading]

This course is intended for students with an introductory background in epidemiology who are interested in a research career in pharmacoepidemiology. The goal of the course is to apply epidemiology concepts and methodology into research and evaluation of medication- or medical device-related outcomes. Students will be exposed to several transcending concepts throughout the course that include real-world data sources, study design and measurement, bias and confounding, analytical approaches, and practical research applications.

Course Coordinators

Weihuan 'Jenny' Lo-Ciganic, MSPharmD, MS, PhD

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Office Hours: By Zoom appointment ONLY

Using the Canvas discussion board for general course-related questions are preferred. For any specific individual issues, please contact the course coordinator via your email.

Class Meeting Times

You are expected to read all the required readings and take the quiz for each module before watching the lecture recording. The lecture recordings were recorded from 2020 Fall course, and each module's recording will be released after you finished quizzes. You can watch at your own pace.

Course-Level Objectives

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

1. Understand epidemiologic methods to the study of medication or medical device use and their effects.
2. Design studies that address pharmacoepidemiology questions and incorporate techniques that reduce systematic bias and confounding to increase the validity of causal inferences.
3. Highlight the processes and considerations involved in evidence synthesis to evaluate the effects of pharmacologic and other drug-related interventions.
4. Compare and contrast the purpose and application of pharmacoepidemiology research in different settings and countries.
5. Appreciate and apply emerging methodologies in pharmacoepidemiology research, including machine learning

Course Pre-requisites

1. PHA 6935 Introduction to Pharmacoepidemiology or PHC 6001 Principles of Epidemiology in Public Health or PHA 5244 Principles of Evidence-Based Practice
2. Other equivalent coursework will be evaluated on a case by case basis by the course coordinators.

Course Outline

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.

See the complete course outline in Appendix A. Please note that given the current changing circumstances due to COVID-19, class times and order of topics might need to be adjusted as necessary. The course coordinators will provide additional information on the Canvas site and through email if any changes are made to the schedule.

Required Textbook

Students are not required to purchase textbooks, as they are available through the UF library.

- Strom BL, Kimmel SE, Hennessy S. **Pharmacoepidemiology. Fifth edition.** Hoboken, N.J.; 2012. E-book is available through the UF Library
- Rothman KJ, Greenland S, Lash TL. **Modern Epidemiology. Third edition.** Wolters Kluwer Health/Lippincott Williams & Wilkins; 2008. E-book is available through the UF Library

Use [UF VPN to access UF Libraries Resources](#) when off-campus.

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
iRATs [15 @ 2% each] (Lowest graded RAT of 16 will be dropped)	30%
Attendance by completion of reviewing lecture recordings	15%

Final Project Assignment <ul style="list-style-type: none"> • Background and Significance 5% • Preliminary Methods 5% • Final Abstract 5% • Final written report 20% • Final oral presentation 5% 	40%
Professional Development Activities [3 @ 5% each]	15%
Total	100%

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."

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

Class Attendance Policy

Attendance to class is mandatory and a component of the class participation/attendance grading component for the course. Missing attendance due to unforeseen and distressing events (serious illness, a death in the family, computer hardware/software failure, etc.) will be treated on a case-by-case basis by the course coordinators. Unless excused by the coordinators prior to the start of the class, all students are encouraged to turn on their webcams when participating in online Zoom sessions.

Late Assignment Policy

Late submissions will result in a grade of zero for the assignment. Delays due to unforeseen and distressing events (serious illness, a death in the family, computer hardware/software failure, etc.) will be treated on a case-by-case basis by the course coordinators.

Educational Technology Use

The following technology below will be used during the course and the student must have the appropriate technology and software: Canvas™ Learning Management System. For technical support, navigate to [Educational Technology and IT Support Contact Information](http://curriculum.pharmacy.ufl.edu/current-students/technical-help/) at this URL: <http://curriculum.pharmacy.ufl.edu/current-students/technical-help/>

Students Requiring Accommodations

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the disability Resource Center by visiting <https://disability.ufl.edu/students/get-started/>. It is important for students to share their accommodation letter with their instructor and discuss their access needs, as early as possible in the semester.

Course Evaluations

Students are expected to provide feedback on the quality of instruction in this course by completing online evaluations at <https://gatorevals.aa.ufl.edu/>. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at <https://gatorevals.aa.ufl.edu/>.

University Honesty Policy

UF students are bound by The Honor Pledge which states, “We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: “On my honor, I have neither given nor received unauthorized aid in doing this assignment.” The Honor Code specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel.

Software Use

All faculty, staff, and students of the University are required and expected to obey the laws and legal agreements governing software use. Failure to do so can lead to monetary damages and/or criminal penalties for the individual violator. Because such violations are also against University policies and rules, disciplinary action will be taken as appropriate. We, the members of the University of Florida community, pledge to uphold ourselves and our peers to the highest standards of honesty and integrity.

Student Privacy

There are federal laws protecting your privacy about grades earned in courses and on individual assignments. For more information, please see: <http://registrar.ufl.edu/catalog0910/policies/regulationferpa.html>

Campus Resources:

- **U Matter, We Care:** If you or a friend is in distress, please contact umatter@ufl.edu or 352 392-1575 so that a team member can reach out to the student. **Counseling and Wellness Center:** <http://www.counseling.ufl.edu/cwc> and 392-1575. **University Police Department** at 392-1111 (or 9-1-1 for emergencies), or www.police.ufl.edu

Other Academic Resources

- **Library Support,** <http://cms.uflib.ufl.edu/ask>. Various ways to receive assistance with respect to using the libraries or finding resources. **Writing Studio,** 302 Tigert Hall, 846-1138. Help brainstorming, formatting, and writing papers. <https://writing.ufl.edu/writing-studio/>

Appendix A – Course Outline and Faculty

Week	Date	Topic	Faculty
1	Aug 24	Study Design Overview in Pharmacoepidemiology	Dr. Juan Hincapie-Castillo (UF)
2	Aug 31	Advanced Drug Utilization Research*	Dr. Juan Hincapie-Castillo (UF)
3	Sep 7	Control for Confounding (Propensity Scores)*	Dr. Jenny Lo-Ciganic (UF)
4	Sep 14	Active Surveillance in the US – FDA Sentinel	Dr. Judith Maro (Harvard Medical School and Harvard Pilgrim Health Care Institute)
5	Sep 21	Medication Adherence	Dr. Sabina Nduaguba (UF)
5*	Optional	Group-Based Trajectory Models*	Dr. Jenny Lo-Ciganic (UF)
6	Sep 28	Pharmacoepidemiology in Industry: Post-Marketing Safety Commitments	Dr. Caitlin Knox (Regeneron Pharmaceuticals)
7	Oct 5	Introduction to Machine Learning in Pharmaceutical Outcomes Research I	Dr. Jenny Lo-Ciganic (UF)
8	Oct 12	Introduction to Machine Learning in Pharmaceutical Outcomes Research II	Dr. Jenny Lo-Ciganic (UF)
9	Oct 19	Medical Device Pharmacoepidemiology	Dr. Fei Huang (Health Economics and Outcomes Research Analytics, Philips Health)
10	Oct 26	Self-Controlled Drug Safety Studies	Dr. Kenneth Man (University College London School of Pharmacy)
11	Nov 2	Spontaneous Pharmacovigilance Reporting Systems – FAERS	Dr. Monica Munoz (Food and Drug Administration)
12	Nov 9	Pharmacoepidemiology in Regulatory Settings: Evolving Role of RWE	Dr. Donna Rivera (Food and Drug Administration)
13	Nov 16	Pharmacoepidemiology from European Perspective	Dr. Vicki Osborne (Drug Safety Research Unit, UK)
14	Nov 30	Traditional and Network Meta-Analysis*	Dr. Sabina Nduaguba (UF) Dr. Jenny Lo-Ciganic (UF)
15	Dec 7	Drug Safety Policy Evaluation, REMS, and Patient Registries	Dr. Juan Hincapie-Castillo (UF)
16	Dec 14	Final project presentations	Dr. Jenny Lo-Ciganic (UF)

*Hands-on experience included