



PHRD 550: Pharmacoepidemiology
3 Units
Fall 2022
Monday 5:00PM-7:00PM

Location: Online (Zoom)-live classroom sessions

Instructor: Dima M Qato, PharmD, MPH, PhD
Office: CHP #236C
Office Hours: by appointment
Contact Info: qato@usc.edu

Course Description

This course is intended to provide an overview of pharmacoepidemiology and discuss key concepts and principles in the study of the utilization, safety, and effectiveness of medications in large populations. Pharmacoepidemiology applies the methods of epidemiology to the content area of clinical pharmacology. This course introduces students to pharmacoepidemiologic methods, including study designs, data sources, measurement of medication use and outcomes, sources of, and techniques to reduce, bias and confounding. This course will integrate priority areas in the field and review examples of current research and evaluate their public health and policy implications. Intended audience includes graduates students in public health and pharmacy (e.g., MS, MPH, PhD), pharmacy and medical students as well as well as working professionals.

Learning Objectives: Upon successful completion of this course,

1. To provide students with an introduction to basic principles of pharmacoepidemiology necessary for conducting and interpreting pharmacoepidemiologic research.
2. To understand the role of pharmacoepidemiology in pharmacovigilance and the evaluation of drug safety post-approval, including the role of REMS, Black-Box warnings and other risk mitigation strategies.
3. To evaluate various studies investigating the safety and effectiveness of medications and explain their strengths and weaknesses.
4. To understand research methods, data sources and study designs, and analytic techniques to address confounding and bias, often employed in pharmacoepidemiologic research.
5. To increase awareness and understanding of novel applications of pharmacoepidemiology in health disparities research, including equitable access and safe use of essential medicines in the U.S. and globally.

Prerequisite(s): Graduate student in pharmacy or public health (e.g. MS, MPH or PhD), medical or pharmacy student (2nd to 4th year), or others with permission of instructor.

Recommended Preparation: Introductory epidemiology or biostatistics course is recommended.

Course Notes: Students will be given a letter grade at the end of the course. Links to the lectures and slides are posted on Blackboard a few days prior to the lecture. Students are expected to have read assigned readings and reviewed the lecture prior to the zoom class session. Students are expected to regularly participate in classroom discussions and post questions/queries in the Blackboard discussion window. The course will consist of 50 minute lecture with 15-20 minute discussion followed by another 50 minute lecture and 15-20 minutes discussion. Short 5-minute breaks between each session.

All students are required to have their webcam on during the zoom session.

Course Syllabus: The syllabus may be updated and reposted on Blackboard during the semester. When this occurs, students will be notified in class. Students are expected to check the course Blackboard site regularly (at least 2-3 times/week) to be aware of the most current syllabus and any announcements.

Technological Proficiency and Hardware/Software Required

Students will need to have access to a laptop or desktop computer with Zoom and webcam enabled and Blackboard. Each student is required to be signed into their Zoom account on their computer before the class session begins.

Required Readings and Supplementary Materials

Required Textbook

Pharmacoepidemiology 6th Edition by Brian L. Strom (Editor), Stephen E. Kimmel (Editor), Sean Hennessy (Editor). Wiley-Blackwell, Paperback, 1208 pages, ISBN-13: 978-1119413417.; 6th edition (December 16, 2019). Available in bookstore or can be ordered online.

Required Readings

Additional readings and articles will be posted on Blackboard.

Recommended Textbooks

Pharmacoepidemiology and Therapeutic Risk Management. Abraham G Hartzema, Hugh H Tilson, K Arnold Change, (eds). 1050 pages. ISBN 978-0-929375-30-4.

Description and Assessment of Assignments

Weekly quizzes: Beginning the 3rd week of classes, a short weekly quiz administered via Blackboard will be administered based on material/readings from the prior week/weeks. A total of ten quizzes will be administered throughout the semester.

Active Class Participation: Active class participation will be assessed for every class and includes participating in discussions during live sessions and responding to queries related to a news story posted on the Blackboard discussion board (e.g., initiating a post/response). Class participation may also include the instructor's assessment of your preparedness for class which will be assessed through class participation and question/answer session.

Assignments: There will be a total of four assignments; two of each of the below.

1. To critically evaluate a scientific article (list of journal articles posted on Blackboard). This assignment is required twice throughout the semester. Guidelines will be posted on Blackboard.
2. Design a pharmacoepidemiology study to address a priority public health problem related to access, safety or effectiveness of medications. This assignment is required twice throughout the semester. Instructor approval of topic required. This is intended to be a short proposal (500-750 words).

Final Paper: All students are required to complete a final paper (~3000-3,500 words) on a pharmacoepidemiology topic. The paper should focus on a contemporary 2015 or later topic. The paper should provide a history of the evidence to the current state of knowledge. The paper should indicate an understanding of the advantages and disadvantages of specific studies based on their methodology, provide a summary of the evidence, discuss the limitations of the existing evidence and whether and how these limitations can be addressed, and propose possible approaches to overcome evidence gaps based on existing or new data. List of potential topics:

- Montelukast and neuropsychiatric adverse effects in children
- Antidepressants and suicidality in children/adolescents
- Polypharmacy and dementia in older adults
- Drug-Drug interactions and Preventable Adverse Drug Events in the Elderly
- CNS stimulants and sudden cardiac death in children/adolescents
- Polypharmacy, opioids and overdoses (fatal and non-fatal)

COURSE GRADING

	Points	% of Grade
Weekly Quizzes- 10 quizzes/15 points each	150	15%
Active Class Participation*	150	15%
Assignments – Four assignments/75 points each	300	30%
Final Paper	400	40%
TOTAL	1000	

Grading Scale: Course final grades will be determined using the following scale

- A 95-100
- A- 90-94
- B+ 87-89
- B 83-86
- B- 80-82
- C+ 77-79
- C 73-76
- C- 70-72
- D+ 67-69
- D 63-66
- D- 60-62
- F 59 and below

Assignment Submission Policy

Assignments are submitted on Blackboard, including the Discussion Board.

Grading Timeline

Grading and feedback, when applicable, for assignments, quizzes, and final paper will be completed within 1-2 weeks of submission.

CLASSROOM DISTRACTIONS

Do not take class time to do homework from other classes or view social media. Cellphones should be turned off or set to “silent” during class time. Failure to comply with these rules will adversely affect participation grade for class session.

ATTENDANCE POLICY

Students are expected to attend every class and for the duration of the class. Failure to attend class, arriving late or lack of active participation could affect your course grade. Students are expected to notify instructor by email of any anticipated absence or reasons for tardiness. Students that do not have their webcam on are considered not actively participating.

LATE OR MAKE-UP WORK

Late work will be accepted if and only if an extension request has been submitted to the instructor and if that request has been approved at least 24-hours before due date/deadline for assignments and final paper. Extensions will only be granted for legitimate and/or reasonable circumstances. If submission is late without permission, the grade will be affected by 10% per day (<24 hours). Quizzes are usually given during the first 20 minutes of class and cannot be made up on a later date.

Course Schedule:*

Weekly Lesson	Topics	Speaker/Instructor	Readings	Assignments
Week 1 8/22/22	What is Pharmacoepidemiology? <ul style="list-style-type: none"> Pharmacoepidemiology vs. epidemiology vs. clinical pharmacology Example case studies (e.g. HRT and MI) Basic principles (causality, associations, strength of the evidence) 	Dima Qato	Textbook: Chapter 1	None
Week 2 8/29/22	Application of Pharmacoepidemiology: Drug utilization research	Christopher Rowan	Readings Posted	None
Week 3 9/5/22	Labor Day-No Class			
Week 4 9/12/22	Pharmacoepidemiology study designs <ul style="list-style-type: none"> Case reports/case series Ecological studies Cross-sectional studies Case-control Studies Nested Case control studies Cohort studies 	Dima Qato	Textbook: Chapter 2	Quiz 1
Week 5 9/19/22	Bias and confounding <ul style="list-style-type: none"> Selection bias Indication bias Immortality time bias Reverse causality 	Gregory Calip	Textbook Chapters 4-5/Assigned Readings	Quiz 2/ Assignment 1
Week 6 9/26/22	Addressing Bias and confounding <ul style="list-style-type: none"> Propensity scores New user designs Active-comparator vs. negative control Difference-in-Difference approach/ITS 	Katharine Ozenberger	Textbook Chapters 4-5	Quiz 3
Week 7 10/3/22	Data sources <ul style="list-style-type: none"> Claims/administrative Medical records Surveys Critical assessment of data sources Exposure and Outcome Measurement <ul style="list-style-type: none"> Baseline risk/status Drug effectiveness (e.g. heterogeneity of treatment effect) Drug exposure (e.g. adherence) 	Dima Qato	Textbook: Chapters 6, 8-9	Quiz 4
Week 8 10/10/22	Applications of Pharmacoepidemiology: Drug safety surveillance and pharmacovigilance	Dima Qato	Readings posted	Quiz 5/ Assignment 2
Week 9 10/17/22	Application of Pharmacoepidemiologic methods to study the adverse effects of polypharmacy and drug-drug interactions	Katharine Ozenberger	Readings posted	Quiz 6
Week 10 10/24/22	Application of PE in the study of health inequities (e.g., access and safety)	Dima Qato	Readings posted	Quiz 7/Assignment 3
Week 11 10/31/22	Application of PE: drug effectiveness (e.g., CVD prevention, cancer treatment)	Dima Qato	Readings posted	Quiz 8

Week 12 11/7/22	Applications of PE: drug safety (e.g., bleeding risk, cancer risk)	Gregory Calip	Readings posted	Quiz 9
Week 13 11/14/22	FDA and drug safety regulations <ul style="list-style-type: none"> REMS Black-box warning Post-marketing regulations 	Dima Qato	Readings posted	Assignment 4
Week 14 11/21/22	Existing and novel measures of medication use <ul style="list-style-type: none"> Pharmacy Quality Alliance CMS Medicare Part-D Measures Measures of unsafe use/polypharmacy Known vs. unknown Adverse Effects 	Dima Qato	Readings Posted	Quiz 10
Week 15 12/5/22	Study Day for Final			
FINAL 12/12/22	Final Paper Due by <u>12/12/22 by 5PM PT.</u>			Refer to the final exam schedule in the <i>USC Schedule of Classes</i> at classes.usc.edu .

Additional readings may be posted on Blackboard. Quizzes are completed during the first 20 minutes of class. Assignments are due the following week by 5PM PT Wednesday. For example Assignment 1 is assigned 9/15/22 and is due by 9/21/22 5PM PT.

*Syllabus/schedule subject to change

Academic Conduct:

Plagiarism – presenting someone else’s ideas as your own, either verbatim or recast in your own words – is a serious academic offense with serious consequences. Please familiarize yourself with the discussion of plagiarism in SCampus in Part B, Section 11, “Behavior Violating University Standards”

policy.usc.edu/scampus-part-b. Other forms of academic dishonesty are equally unacceptable. See additional information in SCampus and university policies on [Research and Scholarship Misconduct](#).

Students and Disability Accommodations:

USC welcomes students with disabilities into all of the University’s educational programs. The Office of Student Accessibility Services (OSAS) is responsible for the determination of appropriate accommodations for students who encounter disability-related barriers. Once a student has completed the OSAS process (registration, initial appointment, and submitted documentation) and accommodations are determined to be reasonable and appropriate, a Letter of Accommodation (LOA) will be available to generate for each course. The LOA must be given to each course instructor by the student and followed up with a discussion. This should be done as early in the semester as possible as accommodations are not retroactive. More information can be found at osas.usc.edu. You may contact OSAS at (213) 740-0776 or via email at osasfrontdesk@usc.edu.

Support Systems:

Counseling and Mental Health - (213) 740-9355 – 24/7 on call
studenthealth.usc.edu/counseling

Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention.

National Suicide Prevention Lifeline - 1 (800) 273-8255 – 24/7 on call
suicidepreventionlifeline.org

Free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week.

Relationship and Sexual Violence Prevention Services (RSVP) - (213) 740-9355(WELL), press "0" after hours – 24/7 on call

studenthealth.usc.edu/sexual-assault

Free and confidential therapy services, workshops, and training for situations related to gender-based harm.

Office for Equity, Equal Opportunity, and Title IX (EEO-TIX) - (213) 740-5086

eeotix.usc.edu

Information about how to get help or help someone affected by harassment or discrimination, rights of protected classes, reporting options, and additional resources for students, faculty, staff, visitors, and applicants.

Reporting Incidents of Bias or Harassment - (213) 740-5086 or (213) 821-8298

usc-advocate.symplicity.com/care_report

Avenue to report incidents of bias, hate crimes, and microaggressions to the Office for Equity, Equal Opportunity, and Title for appropriate investigation, supportive measures, and response.

The Office of Student Accessibility Services (OSAS) - (213) 740-0776

osas.usc.edu

OSAS ensures equal access for students with disabilities through providing academic accommodations and auxiliary aids in accordance with federal laws and university policy.

USC Campus Support and Intervention - (213) 821-4710

campussupport.usc.edu

Assists students and families in resolving complex personal, financial, and academic issues adversely affecting their success as a student.

Diversity, Equity and Inclusion - (213) 740-2101

diversity.usc.edu

Information on events, programs and training, the Provost's Diversity and Inclusion Council, Diversity Liaisons for each academic school, chronology, participation, and various resources for students.

USC Emergency - UPC: (213) 740-4321, HSC: (323) 442-1000 – 24/7 on call

dps.usc.edu, emergency.usc.edu

Emergency assistance and avenue to report a crime. Latest updates regarding safety, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible.

USC Department of Public Safety - UPC: (213) 740-6000, HSC: (323) 442-120 – 24/7 on call

dps.usc.edu

Non-emergency assistance or information.

Office of the Ombuds - (213) 821-9556 (UPC) / (323-442-0382 (HSC)

ombuds.usc.edu

A safe and confidential place to share your USC-related issues with a University Ombuds who will work with you to explore options or paths to manage your concern.

Occupational Therapy Faculty Practice - (323) 442-3340 or otfp@med.usc.edu

chan.usc.edu/otfp

Confidential Lifestyle Redesign services for USC students to support health promoting habits and routines that enhance quality of life and academic performance.