Course description:

This course is designed to help students recognize the principles of epidemiology in drug safety and effectiveness evaluation, understand the basic study designs including randomized trials, cohort studies, case-control studies, and case-only designs, threats to validity including selection bias, measurement bias, confounding, and methods for their control. Lectures include recent or ongoing case studies and examples from the literature. The course focuses on methods used in pharmacoepidemiology with the goal of acquiring knowledge to evaluate published literature and to design observational research.

Total course credits: 3

Learning objectives:

At the completion of the course, students should be able to:

- Define the scopes of pharmacoepidemiology and their role in drug safety and effectiveness research
- Critically evaluate epidemiologic studies for potential confounding and selection bias by applying the concept of causal diagrams
- Describe the strengths, limitations and theoretical basis of epidemiologic study designs to assess wanted and unwanted drug effects (i.e., clinical trials, case report/series, case-control studies, cohort studies, and case-only designs)
- Critically analyze published epidemiologic studies for methodological strengths, limitations, data quality, and appropriateness of analytic procedures and interpretation of study findings

Course materials:

Required textbook:

Strom BL, Kimmel SE, Hennessy S. Textbook of Pharmacoepidemiology 2nd Edition. Wiley-Blackwell 2013. (eBook from HSC Library). In addition, relevant readings and assignments will be distributed in advance through the course website.

Recommended textbooks:


Meetings:

Wednesdays, 4:00-7:00 pm; HPNP Room 2309

Instructors:

Wei Liu (wei.liu@ufl.edu)
Office Hours: by appointment

Guest Lecturers

Steven Bird: steven.bird@fda.hhs.gov
Sengwee Darren Toh: Darren_Toh@harvardpilgrim.org

Class format: we will follow a lecture, case discussion/problem analysis format. Question and class discussion are encouraged for this course.

Outcome measures:

Class participation: active learning through class participation and discussion are an important component of the class. Students are expected to participate and attend all classes.

Assignments:

Homework exercise: there will be a homework assignment requires writing exercise covering the contents learnt at the causal inference lecture.

Paper critique: there will be two paper critiques that will examine recent papers on specific areas of drug safety and effectiveness research. Students will critically analyze the study designs and epidemiologic methods used in these papers and will discuss potential public health policy implications of the findings.

Term paper: students will individually write a paper (15 pages maximum, double-spaced) in the format of an article to be submitted for publication to a scientific journal. This paper could be an original drug epidemiology study that you are involved in or planning to be involved. Students should consult the paper topic in advance with the instructor.
Grading: grades are based on a total of 100 points. There is a homework exercise (10 points), 2 paper critiques (30 points), and a final term paper (40 points). Class discussion and participation will be worth 20 points.

Final grades will be assigned according to the following scheme:
A: 93-100
A-: 90-92
B+: 87-89
B: 80-86
C+: 77-79
C: 73-76
C-: 70-72
D: 65-69
E: <65

Late assignment policy: assignments are due at the beginning of the stated class period. The final manuscript is due at 5:00 PM on the indicated date. Late papers will receive either: (1) the class mean, if the actual score is the mean or higher or (2) the actual score, if the score is lower than the class mean. 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 coordinator.

Student responsibility and participation: students are responsible for preparing all assigned readings prior to the lecture. Readings should be brought to class on the day they will be discussed. Students are also encouraged to bring to the attention of the instructor and other class members relevant items of interest.

Academic dishonesty: familiarize yourself with the University's policy regarding academic dishonesty. See the Statements regarding the Student Conduct Code in the 2008-2009 Graduate Catalog. This policy will be strictly enforced. The University’s conduct regulations are available on the Internet at http://oss.ufl.edu/stg/. Please note that the course instructors will closely examine your paper submissions for plagiarism. Please review your notes from our orientations session about academic dishonesty and make sure that you understand the steps needed to avoid plagiarism.

Accommodations for students with disabilities: students requesting classroom accommodation must first register with the dean of Students Office. The Dean of Students Office will provide documentation to the student who must then provide this documentation to the Instructor when requesting accommodation.
Tentative lecture schedule:

**Week 1:** January 4, 2017

**Topics:**
- Introduction to course
- FDA drug approval process
- Basic epidemiology study designs in pharmacoepidemiology
- Case reports, case series, and ecological studies

**Required readings:**
- Textbook of Pharmacoepidemiology (Strom, 2013), Chapter 2

**Instructor:** Liu

**Week 2:** January 11, 2017

**Topics:**
- Causation, statistical association, counterfactual theory
- Causal directed acyclic graphs (DAGs)
- Using causal diagrams to assess bias and confounding in observational studies

**Required readings:**

**Recommended readings:**
- Causal inference textbook (Hernan & Robins), Chapters 1-10

**Week 3:** January 18, 2017

**Topics:**
- Drug utilization research – an overview
- Studying medication adherence and persistence

**Required readings:**

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  http://apps.who.int/medicinedocs/pdf/s4876e/s4876e.pdf

Recommended readings:

Week 4:

January 25, 2017
Topics: Liu
• Randomized safety outcome trials
• Large simple trials in pharmacoepidemiology

Required readings:
• Textbook of Pharmacoepidemiology. (Strom, 2013), Chapter 16

Recommended readings:
• Pharmacoepidemiology. 5th Edition. Chapter 36 The Use of Pharmacoepidemiology to Study Beneficial Drug Effects.

Week 5:

February 1, 2017
Topic: Liu
• Pharmacoepidemiology data sources

Required readings:
• Textbook of Pharmacoepidemiology. (Strom, 2013), Chapter 8

Week 6: February 8, 2017
Topics: Liu
• Cohort studies
• New user design in comparative effectiveness research
Required readings:

Recommended readings:

Week 7: February 15, 2017
Topics: Liu
• Case-control studies
• Efficient cohort sampling
Required readings:
Week 8: February 22, 2017
Topics: 
- Active surveillance of post-marketing drug safety – FDA’s Sentinel System

Required readings:

Recommended readings:

Week 9: March 1, 2017
Topics: 
- Within subject designs: Case-crossover design, self-controlled case series and case-time-control

Required readings:

Recommended readings:
- Hébert C, Delaney JAC, Hemmelgarn B, Lévesque LE, Suissa S. Benzodiazepines and Older Drivers: A Comparison of


Week 10: March 15, 2017
Topics: Liu
- Meta-analysis in drug safety
Required readings:

Week 11: March 22, 2017
Topics: Liu
- Biases in pharmacoepidemiology
Required readings:
- Suissa S. Immortal time bias in observational studies of drug effects. Pharmacoepidemiol drug safety 2007;16:241-249.
Recommended readings:
Week 12: March 29, 2017
Topics: Liu
- Propensity score analyses

Required readings:

Week 13: April 5, 2017
Topics: Liu
- Pregnancy registries
- Drug use during pregnancy

Required readings:

Recommended readings:
- Guidance for industry establishing pregnancy exposure registries.

Week 14: April 12, 2017
Topics: Liu
- Overview of instrumental variable analysis in pharmacoepidemiology
• Therapeutic risk management strategies, evaluation of therapeutic risk management strategies
• Good pharmacoepidemiology practice

**Required readings:**
• Greenland S. An introduction to instrumental variables for epidemiologists.
• Chapter 23. EB Andrews. Evaluation of Therapeutic Risk management Programs.

**Recommended readings:**
• Guidance for Industry and FDA Staff. Best Practice for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data.
• ENCePP Guide on Methodological Standards in Phamacoepidemiology (Revision 3).