

PGS 384 T, Unique # 58355 , Advanced Epidemiology (pharmacoepidemiology)

Fall 2016

Draft (7/18/16)

In Austin room PHR 2.208; In San Antonio - TBD

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Twice weekly: Monday and Wednesday

Class: North Pharmacy Building, PHR 2.208

10:00-11:30

San Antonio, TBD

Office: North Pharmacy Building PHR 3.210A

Goals: To review selected chapters in Strom's Textbook of Pharmacoepidemiology, in order to gain a better appreciation of the area, and explore, through readings, topic areas that a researcher in the area should be aware of when reading, interpreting, designing, conducting, teaching about, or evaluating pharmacoepidemiology studies. Paper required. In class presentations - many, if not daily.

Format: Seminar style – review of chapters, with additional resources to illustrate key points, and extensive discussion to aid in understanding of the presented topics. The format will be a mixture of seminar, instructor-led discussion, student-led discussion, and student presentations.

Grade based on in class presentations (90%) and course paper (10%).

Texts: Textbook of Pharmacoepidemiology, 2<sup>nd</sup> ed. by Brian L Strom, Stephen E Kimmel, Sean Hennessy (eds) (paperback available - 2013) John Wiley & Sons, Ltd.; ISBN: 978-1-118-34486-6

Barnsandnobel.com - \$76.49 (paperback); Nook \$51.99 (Accessed 5/12/2016)

Amazon.com - \$69.32 (paperback); also Kindle -\$68.76 (Accessed 5/12/2016)

Also at UT CO-OP

At UT Life Sciences Library – and on-line – free

<http://catalog.lib.utexas.edu/search~S29?/XPharmacoepidemiology&searchscope=29&SORT=D/XPharmacoepidemiology&searchscope=29&SORT=D&SUBKEY=Pharmacoepidemiology/1%2C61%2C61%2CB/frameset&FF=XPharmacoepidemiology&searchscope=29&SORT=D&2%2C2%2C>

Pharmacoepidemiology, 5<sup>th</sup> edition by Brian L. Strom, Stephen E Kimmel and Sean Hennessy (Mar 5, 2012) Amazon.com - \$289.37; Barnsandnobel.com - \$290.10; Nook \$217.49 (Accessed 5/6/12/16)

At UT Life Sciences Library – and on-line – free

<http://catalog.lib.utexas.edu/search~S29?/XPharmacoepidemiology&searchscope=29&SORT=D/XPharmacoepidemiology&searchscope=29&SORT=D&SUBKEY=Pharmacoepidemiology/1%2C61%2C61%2CB/frameset&FF=XPharmacoepidemiology&searchscope=29&SORT=D&4%2C4%2C>

Advantage – additional references; somewhat more in depth

In text: Selected chapters – which one should we cover if we have time? Definitely the methods chapters, and ... you tell me what you would like to cover.

I expect everyone will present at least 3 or 4 chapters over the semester. Class: each person will prepare a Power Point presentation, handout, and obtain selected key referenced articles to hand out. Present a ‘class’ on the selected chapter, and lead discussion. Include current paper(s) as appropriate.

Current issues/topics to explore; review of some ‘classic’ papers/issues.

To know about: Division of Pharmacoepidemiology & Pharmacoeconomics, Department of Medicine, Brigham and Women’s Hospital, Harvard Medical School (programs in SAS, R, etc.)

<http://www.drugapi.org/dope-downloads/#Pharmacoepidemiology%20Toolbox>

Draft schedule -

AUG 24 – no class (work on presentations)

AUG 29 – no class (work on presentations)

AUG 31 – no class (work on presentations)

SEP 5 – holiday, no class (work on presentations)

SEP 7 – no class (work on presentations)

SEP 12 – introduction to course, assignment selection (hope all were made in summer)

Chapter 1: What is Pharmacoepidemiology? – Jim

Current topics to explore – these will be each week

SEP 14 – Chapter 3. - Sample Size Considerations – Shannon

Using negative controls in observational research - Matt

Current topics to explore -

SEP 19 – Chapter 4- Basic principles of Clinical Pharmacology Relevant to Pharmacoepidemiologic Studies

SEP 21 – Chapter 11: How Should One Perform Pharmacoepidemiologic Studies Choosing Among the Available Alternatives

NOTE: Class in PHR 2.114 (Austin) this day

SEP 26 - Chapter 8- Overview of Automated Databases in Pharmacoepidemiology

SEP 28 – Chapter 17: Pharmacoeconomics: Economic Evaluation of Pharmaceuticals

OCT 3 –Chapter 21 - Advanced Approaches to Controlling Confounding - Matt

OCT 5 –Chapter 20- Studies on Medication Adherence - Shannon

OCT 10 –15: Bioethical Issues in Pharmacoepidemiologic Research - Matt

OCT 12 – Chapter 16 – The use of RCTs for pharmacoepidemiologic studies

OCT 17 – Chapter 19 – The use of meta-analysis in pharmacoepidemiology

OCT 19 – Chapter 13 – Assessing Causality of Case Reports of Suspected Adverse Events - Matt

OCT 24 – Chapter 18 – Using high-quality QoL measurements in pharmacoepidemiologic research

OCT 26 – Chapter 7 – Postmarketing Spontaneous Pharmacovigilance Reporting System - Matt

OCT 31 – Chapter 14 – Molecular pharmacoepidemiology (ISPOR Europe)

NOV 2 – Chapter 23 - The future of pharmacoepidemiology (ISPOR Europe)

NOV 7 -

NOV 9 –

NOV 14 – (I will be out of town, PRIM&R) -

NOV 16 – (I will be out of town, PRIM&R)

NOV 21 –

NOV 23 – Thanksgiving Holiday break – no class

NOV 28 – presentations -

NOV 30 – presentations –

DEC 5 – no class (ASHP Midyear)

Other topics may include – comparative effectiveness, Immortal time bias, wedge randomization, current diseases, classic papers, case-control studies, cohort studies, case-cohort studies, case-crossover studies, case-chaos studies, case-time-control studies, risk windows, Webber effect, etc.

University recommended materials:

“Campus Carry: Students should familiarize themselves with the information provided by the University regarding the implementation of “Campus Carry” legislation. You will find an information sheet specifically for students (as well as sheets for parents, visitors, faculty, and staff) at <http://campuscarry.utexas.edu/info-sheets>."

**Qualified Students with Disabilities:** The University of Texas at Austin provides upon request appropriate academic accommodations for qualified students with disabilities. For more information, contact the Division of Diversity and Community Engagement, Services for Students with Disabilities, 471--6259, <http://www.utexas.edu/diversity/ddce/ssd/>. It is the student’s responsibility to inform faculty at the beginning of each semester to arrange for appropriate accommodations when necessary.

Notice regarding academic dishonesty. UT Honor Code (or statement of ethics) and an explanation or example of what constitutes plagiarism (Link to University Honor Code: <http://registrar.utexas.edu/catalogs/gi09-10/ch01/index.html>)

Notice regarding accommodations for religious holidays. By UT Austin policy, you must notify me of your pending absence at least fourteen days prior to the date of observance of a religious holy day. If you must miss a class, an examination, a work assignment, or a project in order to observe a religious holy day, you will be given an opportunity to complete the missed work within a reasonable time after the absence.

**Use of E--Mail for Official Correspondence to Students:** E-mail is recognized as an official mode of university correspondence; therefore, you are responsible for reading your e-mail for university and course-related information and announcements. You are responsible to keep the university informed about changes to your e-mail address. You should check your e-mail regularly and frequently to stay current with university related communications, some of which

may be time critical. You can Find UT Austin's policies and instructions for updating your e-mail address at <http://www.utexas.edu/its/help/utmail/1564>.

Regarding emergency evacuation from the Office of Campus Safety and Security, 512-471-5767, <http://www.utexas.edu/safety/> Occupants of buildings on The University of Texas at Austin campus are required to evacuate buildings when a fire alarm is activated. Alarm activation or announcement requires exiting and assembling outside. Familiarize yourself with all exit doors of each classroom and building you may occupy. Remember that the nearest exit door may not be the one you used when entering the building. Students requiring assistance in evacuation shall inform their instructor in writing during the first week of class. In the event of an evacuation, follow the instruction of faculty or class instructors. Do not re-enter a building unless given instructions by the following: Austin Fire Department, The University of Texas at Austin Police Department, or Fire Prevention Services office. Link to information regarding emergency evacuation routes and emergency procedures can be found at: [www.utexas.edu/emergency](http://www.utexas.edu/emergency)

Behavior Concerns Advice Line (BCAL): If you are worried about someone who is acting differently, you may use the Behavior Concerns Advice Line to discuss by phone your concerns about another individual's behavior. This service is provided through a partnership among the Office of the Dean of Students, the Counseling and Mental Health Center (CMHC), the Employee Assistance Program (EAP), and The University of Texas Police Department (UTPD). Call 512---232---5050 or visit <http://www.utexas.edu/safety/bcal>.