This course adheres to the items listed in the College of Pharmacy Central Syllabus: https://docs.google.com/a/umn.edu/document/d/1artQ5e1rbzxe8iEtWo7BE8k8snZAEgMMz_QcW8yJ-II/edit?pli=1

Meeting Times & Locations

<table>
<thead>
<tr>
<th>Day</th>
<th>Time</th>
<th>Duluth Room</th>
<th>Twin Cities Room</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monday</td>
<td>3:30 – 5:30pm</td>
<td>LSci 144</td>
<td>7-193/195</td>
</tr>
</tbody>
</table>

Course Website: http://moodle.umn.edu

Instructional Team

If you need assistance with the course, contact one of the Teaching Assistants.

Technology Help, Duluth: 218-726-8847  itsshelp@d.umn.edu
Technology Help, Twin Cities: 612-301-4357  help@umn.edu

Faculty Office Hours: by appointment

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Investigator, Chronic Disease Research Group

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Epidemiologist, NxStage
Email: EWeinhandl@gmail.com

Akeem A. Yusuf, B.Pharm., Ph.D.
Adjunct Assistant Professor, Pharmaceutical Care & Health Systems, MN College of Pharmacy
Pharmacoepidemiologist, Chronic Disease Research Group.
Course Description

Course content: Pharmacoepidemiology is the study of the uses and effects of drugs in patient populations. The science of pharmacoepidemiology borrows from pharmacology and epidemiology. This course will introduce students to the field of pharmacoepidemiology including study methodology, relevant statistics, data sources, measurement of treatments and outcomes, sources of bias and control of confounding, techniques to reduce bias and confounding, survival analysis and regression techniques, interpretation of results, and drug safety surveillance and risk management.

Course format: This course is mainly lecture-based. Students are expected to prepare for each class, as debate and discussion of various concepts presented in class will take place. Near the end of the course, students will be expected to use information gained throughout the course to compose a written critique of a pharmacoepidemiology study and then orally present their critique in class.

Prerequisites

- 2nd, 3rd or 4th year pharmacy students. First year students may enroll with permission of course directors. First year students will need to show that they have had previous relevant courses in epidemiology, or public health.

Requirements

Course Materials

Required

Optional

Computer / Technology Requirements

- The University of Minnesota computer requirements are listed here: http://www1.umn.edu/moodle/start/technical.html

Attendance Policy

Students are expected to attend every class for which they are registered. Students are expected to attend classes on the campus where they are enrolled. Instructors may choose to take attendance. When a student is unable to attend a class for health or family reasons, the instructor must be informed in advance.
Goals & Objectives

Course Goals
Main course concepts:
   The aim of the course is to help students acquire a basic understanding of the concepts and practice of pharmacoepidemiology.

Learning Objectives
1. Discuss the concept of pharmacoepidemiology
2. Compare and contrast typical pharmacoepidemiologic study designs and explain their strengths and weaknesses
3. Discuss the roles that pharmacoepidemiology studies have had in the past regarding drug use and health outcomes and the future roles that pharmacoepidemiology can play in drug safety surveillance and comparative drug effectiveness and safety
4. Debate the threats to validity that are possible in pharmacoepidemiology studies and the variety of solutions available to avert or control for these threats
5. Using the information provided by the text, lectures, and assigned readings, compose a written critique of a recently-published pharmacoepidemiology study and orally present this critique in class
Assessments and Grading

Assignments and learning activities

Graded Assessments

- Class participation/attendance (20%)
- Midterm exam – multiple choice, short answer/essay (40%)
- End-of-semester written critique (20%)
- End-of-semester oral presentation [slides, 15-20 minutes] (20%)

The midterm exam, written critique, presentation and class participation/attendance will be graded by the course directors.

Thorough reading of assigned readings prior to class, attendance and class participation is expected. The student will take the midterm exam, select one study from recently-published pharmacoepidemiology studies, compose a written critique of the study and orally present this critique in class. The student must also prepare a list of questions to ask of other presenters at their oral presentations.

Course Letter Grades

<table>
<thead>
<tr>
<th>Grade</th>
<th>A</th>
<th>A-</th>
<th>B+</th>
<th>B</th>
<th>B-</th>
<th>C+</th>
<th>C</th>
<th>C-</th>
<th>D</th>
<th>F</th>
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<tbody>
<tr>
<td>%</td>
<td>&gt;93</td>
<td>90-92</td>
<td>87-89</td>
<td>83-86</td>
<td>80-82</td>
<td>77-79</td>
<td>73-76</td>
<td>70-72</td>
<td>60-69</td>
<td>&lt;60</td>
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</table>

Late paper or presentation material submission

Late papers or late presentation materials will be assessed a penalty. Your grade will be reduced by 5% for each day that your materials are late.

Re-grade Policy:

There will be no re-grades in this class.

Minimum Passing Level: C-
## Schedule

| Week 1 |  
| --- | --- |
| **Date** | **Sept 14** |
| **What is Pharmacoepidemiology?** | **Akeem Yusuf** |
| **What is Pharmacoepidemiology?** | **Akeem Yusuf** |
| • Distinction between pharmacoepidemiology, epidemiology, and clinical pharmacology | |
| • Historical Background | |
| • Potential Contributions | |

**Required Reading:** Pharmacoepidemiology Text
- Chapter 1 (pages 3-16)
- Chapter 4 (pages 40-41)

**Optional Readings:**

| Week 2 |  
| --- | --- |
| **Date** | **Sept 21** |
| **Interpretation of pharmacoepidemiology studies** | **Akeem Yusuf** |
| • Basic principles of epidemiology relevant to pharmacoepidemiology studies | |
| o Causality and associations | |
| o Hypothesis testing | |
| o Power calculations | |
| o P-values and confidence intervals | |
| • Interpretation of results (RR, HR, absolute risk reduction, numbers needed to treat) | |

**Required Reading:** Pharmacoepidemiology Text
- Chapter 2 (pages 17-18, 20-21)
- Chapter 3 (pages 30-33)
- Chapter 5 (pages 57-58)

| Week 3 |  
| --- | --- |
| **Date** | **Sept 28** |
| **Study Designs 1** | **Wendy St. Peter** |
• Basic features, strengths and weaknesses of pharmacoepidemiology study designs
  o Case reports and case series
  o Ecological studies
  o Cross-sectional studies
  o Case-control studies
  o Nested-case control studies
  o Cohort studies

Required Reading: Pharmacoepidemiology Text
• Chapter 2 (pages 22-29)

Required Reading: Other
• Etminan M & Samii A. Pharmacoepidemiology I: A review of pharmacoepidemologic study designs. Pharmacotherapy 2004;24:964. Read pages 964-966 (don’t read section on case-crossover studies) and 968 (confounding bias only).
• Etminan M. Pharmacoepidemiology II: the nested case-control study-a novel approach in pharmacoepidemiologic research. Pharmacotherapy 2004;1105-1109.

Bring a hardcopy to class or be able to access electronically in class for an exercise
• Johnsen SP. Risk of hospitalization for myocardial infarction among users of rofecoxib, celecoxib and other NSAIDs. Arch Intern Med 2005;165;978-984.
• Block GA. Cinacalcet hydrochloride treatment significantly improves all-cause and cardiovascular survival in a large cohort of hemodialysis patients. Kidney International 2010;78:578-89.

Week 4

Date
Oct 5

Study Designs 2
Wendy St. Peter
• Special applications of pharmacoepidemiology
  o Studies of drug utilization
  o Comparative effectiveness and safety research
  o Pharmaceutical reimbursement policy

Required Reading: Pharmacoepidemiology Text
• Chapter 22 (pages 339-346, 393-401)

Week 5

Date
Oct 12

Sources of Data and Data Extraction
Patrick Gleason, Kevin Bowen & Cathy Starner
• Spontaneous reporting systems
• Administrative datasets (Medicare, commercial)
• Data registries (Organ transplant, cancer, etc…)
• Publically available survey data (NHANES, etc…)
• Medical records (Structured data, Unstructured Data)
• Critical assessment of data sources
### Week 6

**Date**  
Oct 19

**Measurement of treatments and outcomes**  
Patrick Gleason, Kevin Bowen & Cathy Starner

- Disease occurrence  
- Drug effectiveness versus efficacy  
  - Treatment effect heterogeneity  
- Drug exposure  
  - Intent-to-treat versus as-treated  
  - First fill, days’ supply, adherence, persistence  
- Outcomes  
  - Clinical outcomes  
  - Economic outcomes  
  - Patient-reported outcomes

**Required Reading:** Pharmacoepidemiology Text

- Chapter 8 (Pages 118-122)  
- Chapter 9 (pages 123-173)

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### Week 7

**Date**  
Oct 26

**Bias, confounding and control of confounding, validity**  
Holly Epperly Budlong

- Types of bias  
  - Selection bias  
  - Indication bias  
  - Measurement bias  
  - Information bias  
  - Misclassification (disease or exposure)  
  - Immortality bias  
  - Lead time bias  
- Validity  
  - Face validity  
  - Internal validity  
  - External validity

**Required Reading:**

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### Week 8

**Date**  
Nov 2

**Principles of survival analysis and other regression techniques**

**Akeem Yusuf**

- Kaplan-Meier
- Cox Regression
- Poisson Regression

**Required Reading:**

### Week 9

**Date**  
Nov 9

**Midterm Exam**

### Week 10

**Date**  
Nov 16

**Analytic approaches for improved confounding control 1**

**Akeem Yusuf**

- Efficient cohort sampling
- New user designs
- Sensitivity analyses
- Measured vs. Unmeasured confounding
- External validation

**Required Reading:**  **Pharmacoepidemiology Text**
- Chapter 21 (Pages 324-330, 333)

**Optional Readings:**

### Week 11

**Date**  
Nov 23

**Analytic approaches for improved confounding control 2**

**Eric Weinhandl**
- Propensity score approaches

**Required Reading:**
- Glynn RJ et al. Indications for propensity scores and review of their use in pharmacoepidemiology. Basic and Clinical Pharmacology and Toxicology 2006;98;253-259

### Week 12

**Date**
- Nov 30

**Drug Safety Surveillance and Risk Management**
- Holly Epperly Budlong

- **Drug Safety**
  - Drug-drug interactions
  - Adverse drug events
  - Classification criteria
  - Errors of omission
  - Errors of commission

- **Signal sources and generation**
- **Signal identification**
- **Signal detection algorithms**
- **Dis-proportionality Analysis**

**Required Reading:** Pharmacoepidemiology Text
- Chapter 22 (pages 370-378, 384-392)

### Week 13

**Date**
- Dec 7

**Oral Presentations**

### Week 14

**Date**
- Dec 14

**Oral Presentations and Course Evaluation**