Introduction to Epidemiologic Research Methods
Wednesdays, 3:00-5:30

Primary Instructor: Co-Instructor
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Course Materials
Primary texts for this course:
• Miguel Hernán and James M. Robins. Causal Inference. Unpublished text.

We will also be using material from several other sources for lectures and may put materials from these sources on the course website from time to time:
• Dr. Robert Dubrow’s Course Reading Packet from the Yale Principles of Epidemiology I course, 2007.
• Additional readings throughout semester

Articles, problem sets, and case studies will be distributed on our course website, accessible via a course website.

Course Objectives:
The overall objective of this course is to provide students with an introduction to epidemiologic research methods. The course will also focus on select topics in pharmacoepidemiology, including study design considerations, common data sources for pharmacoepidemiologic studies, and confounding in pharmacoepidemiology. A common theme of the pharmacoepidemiology lectures will be the practice of epidemiology in highly regulated environments. A clinical background is not required.

We will discuss epidemiologic concepts in the context of drug studies that have led to increased public awareness (and confusion), such as Vioxx and risk of death, SSRIs and risk of teen suicide, aspirin and risk of CVD v. bleeding. The content of this course is appropriate for a wide audience of students interested in medication development and use, including those with undergraduate or graduate degrees, practicing clinicians, or those working (or interested in working) in regulatory agencies or the biopharmaceutical industry.

By the end of this introductory course, students should be sufficiently familiar with epidemiologic research methods to begin to apply these methods to their own work. Specifically, through class lecture, discussion, and problem sets, students will:

1) Develop a strong foundation in epidemiologic concepts
a. Understand and apply key terms and topics including measures of disease occurrence and association, confounding, bias, notable historical frameworks of causation, effect modification, and random error
b. Interpret and estimate effect measure modification and interaction; understand differences between confounding, effect measure modification, interaction, and mediation
c. Perform and interpret basic epidemiological calculations, including crude and standardized measures of disease frequency and their confidence intervals, along with crude, stratified, and matched measures of association and their confidence intervals
d. Conduct and interpret basic epidemiologic data analyses, including correlation, t-tests, and chi-squared tests for unmatched and matched data
e. Understand and apply study designs; describe strengths, weaknesses, and principal uses of different study designs:
   i. Descriptive studies – distributions of disease/events by person, place and time
   ii. Association studies, including experimental, cohort, case-control, cross-sectional, and ecological
f. Identify basic design strategies to improve study accuracy and efficiency (e.g., matching, stratification)

2) Understand issues specific to pharmacoepidemiologic studies
   a. Define what pharmacoepidemiology is, including basic principles and terminology common to pharmacoepidemiologic studies
   b. Cite advantages and disadvantages of common data sources in pharmacoepidemiology
   c. Understand the difficulty of confounding in pharmacoepidemiologic studies
   d. Understand the role of passive and active safety surveillance in pharmacoepidemiology

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<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Required reading</th>
</tr>
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<tbody>
<tr>
<td>Class 1</td>
<td>a) Class overview / Introduction to epidemiology</td>
<td>Szklo, Ch 1; Modern Epi, Ch 6</td>
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<td>b) Overview of study designs</td>
<td>Koepsell, Ch 10</td>
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<td>c) Measurement issues in exposure and disease assessment</td>
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<td>Class 2</td>
<td>a) Quantifying disease occurrence</td>
<td>Szklo, Ch 2</td>
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<td>- prevalence and incidence</td>
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<td>- morbidity and mortality</td>
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<td>b) Screening</td>
<td>Szklo, Ch 8 Section 8.3-8.5</td>
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<td>Class 3</td>
<td>Descriptive studies (including spatial epidemiology and age-period-cohort analyses)</td>
<td>Szklo, Ch 1</td>
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<td>b) Data sources in pharmacoepidemiology</td>
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### Class 5
- **a)** Intro to causation and causal inference
  - Szklo, Ch 10 Section 10.1-10.2; Modern Epi, Ch2
- **b)** Intro to Directed Acyclic Graphs (DAGs)
  - *In-class exercise: Practicing DAGs*
  - H&R, Ch 6

### Class 6
- **Measures of association & causation**
  - Szklo, Ch 3
  - *In-class exercise: Basic calculations*

### Class 7
- **a)** Selection bias
  - Szklo, Ch 4
- **b)** Information bias (including misclassification of exposure & outcome; conceptual v. operational definitions)
  - H&R, Ch 9; Savitz, Ch 8 & 9 (optional)
- **c)** Random error (and statistics)
  - H&R, Ch 10

### Class 8
- **a)** Confounding
  - Szklo, Ch 5; H&R, Ch 7
- **b)** Effect measure modification
  - H&R, Ch 4&5; Rothman Intro, Ch 9 (optional)

### Class 9
- **a)** Clinical trials (Experimental study design)
  - H&R, Ch 2; Koepsell, Ch 13
  - Koepsell, Ch 14;
- **b)** Cohort study designs
  - Koepsell, Ch 12
  - *In-class exercise: Basic issues in designing a study - small group sections*

### Class 10
- **a)** Case-control and related study designs
  - H&R, Ch 3; Koepsell, Ch 15
  - Koepsell, Ch 12
- **b)** Cross-sectional and ecological study designs
  - *In-class exercise: Basic issues in designing a study - small group sections*

### Class 11
- **Bias and confounding in studies of the effects of drugs or vaccines**
  - Ray WA, Thapa PB, Gideon P. Misclassification of current benzodiazepine exposure by use of a single baseline measurement and its


Dore DD, Seeger JD, Chan KA. Use of a claims-based active drug safety surveillance system to assess the risk of acute pancreatitis with exenatide or sitagliptin compared to metformin or glyburide. Curr Med Res Opin. 2009;25(4):1019-27.
