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**PHA 6891 Introduction to Pharmacoepidemiology**  
**3 Semester Credit Hours**

**Course Purpose:**

This course will introduce students to basic epidemiology principles with a particular focus on how they are applied to pharmaceuticals. The course will provide a basic understanding of causation, measures of disease occurrence and causal effect, types of epidemiology studies, biases in study design, data analysis (including methods to control confounding), and use of epidemiology in clinical settings.

**Course Faculty and Office Hours:**

Professor: Christian Hampp, PhD, FISPE  
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Christian Hampp is an employee of the US Food and Drug Administration. The views expressed are his own and do not represent the views of the FDA or the U.S. Government.

**Office Hours**

Dr. Hampp – Contact by email

**Place and Time of Class Sessions**

The first online live class will be held on a Sunday evening (8/19/2018) from 8:00 p.m. to 9:30 p.m. EST and all subsequent live classes will be held on Wednesday evenings from 8:00 p.m. to 9:30 p.m. EST. Exam review sessions will be offered on the Thursdays before the Midterm and Final exam, with voluntary attendance.

A recorded lecture will be posted each week and will contain new content. Questions on the recorded lecture content can be asked at the next live session.

**Course Objectives**

Upon completion of this course, the students will:

- Understand the concepts of epidemiologic thinking and causation.
- Understand common measures of disease frequency and measures of effect.
- Describe the main types of epidemiologic studies.
- Understand the concepts of both bias and random error along with ways to control or assess their impact.
- Describe clinical trials and observational pharmacoepidemiologic studies.
- Understand data analysis including methods to control for confounding.
- Understand the concepts of biologic interaction and the use of regression models.

**Pre-Requisite Knowledge and Skills**

None

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## Course Structure & Outline

### Course Structure:

- Learning activities include mandatory readings and live online lectures.
- Assignments (4) and Exams (midterm and final) are posted and submitted online.
- Weekly questions based on recorded lecture material will be posted at the end of the recorded lecture and answers are to be emailed to the presenter.

### Textbook:

Rothman, KJ. Epidemiology – An Introduction. 2<sup>nd</sup> Edition

ISBN: 978-0-19-975455-7

Publisher: Oxford University Press

Publication Date: 2012

### Active Learning Requirements

Students will be required to complete:

1. 4 assignments,
2. short weekly questions based on that week's recorded session,
3. a midterm exam and,
4. a final exam.

### Student Evaluation & Grading

#### Evaluation Methods:

Assignments	40%
Weekly Quiz Questions	10%
Midterm Exam	25%
Final Exam	25%

#### Grading Scale:

95-100 = A
90-94 = A-
86-89 = B+
83-85 = B
80-82 = B-
76-79 = C+
73-75 = C
70-72 = C-
66-69 = D+
63-65 = D
60-62 = D-
<60 = E

### Class Attendance Policy

Attendance in live class sessions is mandatory. Student should, whenever possible, anticipate upcoming absences and contact the instructor to make prior arrangements for make-up work. Students must contact the instructor as soon as possible following any unanticipated absence.

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Recorded lecture will contain new material and must be reviewed. Questions on the recorded material can be asked at the next live session.

**Quiz/Exam Policy**

Assignments and Exams will be posted and a due date will be clearly specified. If any special circumstances are anticipated that will require special consideration they must be discussed with the faculty beforehand.

**Make-up Quiz/Exam Policy**

Any special requests are to be discussed with faculty beforehand.

**Policy on Old Quizzes and Assignments**

Students will not be provided with old quizzes or assignments.

**Assignment Deadlines**

Late assignments will not be accepted unless previous special arrangements have been made with faculty.

**General College of Pharmacy Course Policies**

The College of Pharmacy has a website that lists course policies that are common to all courses. This website covers the following:

1. University Grading Policies
2. Academic Integrity Policy
3. How to request learning accommodations
4. Faculty and course evaluations
5. Student expectations in class
6. Discussion board policy
7. Email communications
8. Religious holidays
9. Counseling & student health
10. How to access services for student success

Please see the following URL for this information:

<http://www.cop.ufl.edu/wp-content/uploads/dept/studaff/policies/General%20COP%20Course%20Policies.pdf>

**Complaints**

Should you have any complaints with your experience in this course please visit:

<http://www.distancelearning.ufl.edu/student-complaints> to submit a complaint.

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**Other Course Information:  
Lecture Schedule:****Week I** Rothman Chapters 1 & 3*Overview:*

The purpose of this week's material is to introduce the concepts of epidemiologic thinking and causation.

*Learning Objectives:*

- Understand the history of pharmaco-epidemiology and how it fits within epidemiology.
- Obtain a basic understanding of confounding
- Understand crude vs. age-specific (or age-stratified) rates
- Understand average age at disease onset vs. risk of disease between groups of the same age
- Understand causal mechanism and component causes
- Understand what is meant by strong and weak causes
- Distinguish between induction period and latency period
- Distinguish between initiators and promoters
- Distinguish between generalization in Epidemiology (or scientific generalization) and statistical representativeness
- Understand the differences between external and internal validity.

**Week II** Rothman Chapter 4*Overview:*

The purpose of this week's material is to introduce common measures of disease frequency and measures of effect.

*Learning Objectives:*

- Understand risk, incidence rate, and prevalence
- Understand implications of competing risks and loss to follow-up on risk estimates
- Understand case fatality rate
- Understand when the equation "risk = incidence\*time" is valid
- Understand concept of survival analysis
- Understand the concepts behind the Kaplan Meier curve and how to interpret it.
- Differentiate epidemics and outbreaks
- Differentiate incidence proportion and prevalence proportion
- Understand factors that affect prevalence
- Understand when the equation "prevalence = incidence\*proportion" is valid
- Understand why a crossover study is not a counterfactual
- Understand relationship between risk ratio and relative effect
- Understand when a risk ratio will be approximately equal to the rate ratio
- Understand why the terms risk ratio and rate ratio are preferred to relative risk
- Understand the concept of attributable fraction

**Week III** Rothman Chapter 5*Overview:*

The purpose of this week's material is to introduce the main types of epidemiologic studies.

*Learning Objectives:*

- Understand when a cohort study is an experiment (or trial)
- Understand the concept of population at risk
- Understand why a study might only look at the first occurrence of an event
- Describe two ways to handle person-time in a exposed cohort during the induction period
- Distinguish between retrospective and prospective cohort studies
- Describe advantages and disadvantages of a case-control study
- Describe the odds ratio obtained in a case-control study

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- Describe risk set sampling
  - Describe three methods for selecting controls in a case-control study
  - Compare and contrast case-cohort and density case control studies
  - Describe the rare disease assumption for a case-control study
  - Describe a case-crossover study
  - Compare and contrast cohort and case-control studies

**Week IV** Rothman Chapters 7 & 8

*Overview:*

The purpose of this week's material is to introduce the concepts of both bias and random error along with ways to control or assess their impact.

*Learning Objectives:*

- Compare and contrast systemic and random error
- Describe the three broad types of bias and subtypes of selection and information bias
- Distinguish between differential and nondifferential misclassification bias and the impact of each on the direction of the bias introduced
- Describe confounding by indication
- Describe requirements for a variable to be a confounder and the direction of the bias introduced by confounding
- Describe two methods for preventing confounding in study design and the advantage of randomization over restriction
- Describe the two main roles of statistics in the analysis of epidemiologic data
- Define confidence interval and p-value
- Describe why it is a fallacy to infer a lack of association from a p-value
- Describe the two pieces of information provided by a confidence interval for a relative risk

**Week V** Chapters 9 & 10

*Overview:*

The purpose of this week's material is to continue last week's discussion of confidence intervals and p-values and to introduce methods to control for confounding

*Learning Objectives:*

- Be able to name the distribution models underlying the estimate of confidence intervals for risk and incidence rate data
- When given appropriate data, be able to estimate risk and its confidence interval
- When given appropriate data, be able to estimate incidence rate and its confidence interval
- When given appropriate data, be able to estimate and interpret the risk difference, risk ratio, incidence rate difference, incidence rate ratio, odds ratio and their respective confidence intervals
- Explain how stratification can control confounding and the key assumption regarding variability of the confounder within each category of the stratification variable
- Compare and contrast the two methods of aggregating information across strata
- When given appropriate data, be able to estimate and interpret pooled risk difference, risk ratio, incidence rate difference, and incidence rate ratio and their respective confidence intervals
- Understand the concept of residual confounding
- Explain how choice of weights impacts standardized rates and reasons why standardization may be preferred over pooling
- Understand the concept of a Standardized Mortality (or Morbidity) Ratio (SMR)
- When given appropriate data and weights, calculate standardized rates
- Explain how to measure confounding
- Explain why stratification is preferred over multivariable modeling
- Describe the difference between confounding and effect modification.

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**Week VI** Rothman Chapters 11 & 12*Overview:*

The purpose of this week's material is to introduce biologic and statistical interaction and explain the use of regression models

*Learning Objectives:*

- Explain effect measure modification and why the term "measure" is important
- Be able to provide an example of biologic interaction
- In the case of 2 interacting causes, describe the 4 classes of causal mechanism into which all casual mechanisms of the disease must fall
- In the case of 2 interacting causes, describe how to partition the risk into the 4 classes of causal mechanism
- Describe the 2 reasons for models in epidemiology
- Describe why the generalized linear model is sometimes transformed using the logarithm
- Describe the impact of logarithmic transformation on the interpretation of the coefficient for an independent variable
- Describe the type of transformation typically used when analyzing case-control data
- Describe why a multivariable model is preferable to stratification
- Describe the potential danger of using a multivariable model without first using stratification
- Describe the basic principles for using models in causal research
- Know whether it is appropriate to include predictors that are not causally related to the outcome in a model being used for risk prediction in an individual

- **Week VII** Rothman Chapter 13

*Overview:*

The purpose of this week's material is to introduce key aspects of a clinical trial and introduce the concepts of sensitivity and specificity

*Learning Objectives:*

- Distinguish sensitivity and specificity and situations in which each should be maximized
- Describe the effect of changes in disease prevalence on predictive value
- Describe the benefit of a survival curve over a case fatality rate
- Describe the benefits of a randomization, blinding, and placebo use in a clinical trial
- Evaluate why accepted conclusions of several observational studies were later rebutted by randomized clinical trials

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**Appendix A. Schedule of Course Activities/Topics**

<b>Activity</b>	<b>Reading + Lecture</b>	<b>Live Online Class (8:00 – 9:30 p.m. EST)</b>	<b>Assignment</b>	<b>Assignment Due (11:59 p.m., your time zone)</b>
Week I	Chapter 1 (live)	Aug 19 (Sun)	Assignment 1	Aug 27
	Chapter 3 (recorded)		Lecture questions	Aug 27
Week II	Chapter 4a (live)	Aug 29 (Wed)	Assignment 2	Sept 3
	Chapter 4b (recorded)		Lecture questions	Sept 3
Week III	Chapter 5 (live)	Sept 5 (Wed)		
	Exam Review (live)	Sept 6 (Thu)		
Midterm Exam	Posted: Sep 7, 6:00 a.m. EST; Due: Sep 9, 11:59 p.m., your time zone			
Week IV	Chapter 7 (live)	Sept 12 (Wed)	Assignment 3	Sept 17
	Chapter 8 (recorded)		Lecture questions	Sept 17
Week V	Chapter 9 (live)	Sept 19 (Wed)		
	Chapter 10 (recorded)		Lecture questions	Sept 24
Week VI	Chapter 11 (live)	Sept 26 (Wed)	Assignment 4	Oct 1
	Chapter 12 (recorded)		Lecture questions	Oct 1
Week VII	Chapter 13 (live)	Oct 3 (Wed)		
	Exam Review (live)	Oct 4 (Thu)		
Final Exam	Posted: Oct 5, 6:00 a.m. EST; Due: Oct 7, 11:59 p.m., your time zone			