

EPID-0590
"Readings/Research Topics
in Epid"

University of Medicine and Dentistry of New Jersey
School of Public Health

Course Syllabus

Pharmacoepidemiology & Therapeutic Risk Management (3 credits)
Spring Session, 2009

I. General Information Time: Tue: 6:10pm-9:00pm Location: SPH

Instructor:

Zdravko Vassilev, MD, MPH
Medical Director, Epidemiology
Covance Inc., Princeton, NJ, 08540
Phone: (609) 452-4442
Fax: (609) 520-0597
E-mail: zdravko.vassilev@covance.com

Textbooks (Recommended):

Textbook of Pharmacoepidemiology, Strom BL and Kimmel S (edited),
2007 Wiley Publisher.
Manual of Drug Safety and Pharmacovigilance, Colbert BL, 2007 Jones
and Bartlett Publishers

II. Course Objectives

This course is designed to introduce students to the basic concepts and methods of pharmacoepidemiology and drug safety. At the conclusion of the course, students should be able to:

- Define the scope of pharmacoepidemiology, pharmacovigilance and their role in drug safety research
- Describe and explain the main pharmacoepidemiological study designs and their major strengths and weaknesses
- Explain the foregoing epidemiology methods and concepts in analyzing, determining, and preventing drug-related problems. Describe Risk Minimization Action Plans (RiskMAPs) and drug post-marketing surveillance
- Critically review and interpret the medical and epidemiological literature related to studies on adverse drug reactions, drug safety, and pharmacovigilance

III. Teaching Format

New material will be presented in informal lectures. The main emphasis will be put on students' hands-on experience through discussions and in-class assignments, case studies, and critical reading of relevant literature. Participation in class discussions is mandatory. Students will be expected to read the assigned material prior to the lecture or the class discussion.

IV. Student Evaluation

Grades will be based on the following:

- | | |
|--------------------------------|-----|
| • Mid-term exam | 30% |
| • Final exam | 30% |
| • Written critique of articles | 20% |
| • Class participation | 20% |

Examinations

Two exams will be given during this course. The exams may consist of multiple choice, True-False, short answer questions, and statistical computations, and will be administered at the scheduled times. Students should bring a calculator for exams.

Written critique

In the second half of the course, students will complete 1 critique of a recent paper published in one of the pharmacoepidemiologic journals. Students will receive a handout with guidelines how to evaluate an epidemiologic paper. Full credit will be awarded if the critiques are completed and turned in on time. No credit will be given if the critiques are turned in 24 hours past the due date. The critiques will be discussed in class in one of the following sessions.

V. Course Schedule

DATE	TOPIC
Thu, Week 1	Introduction to Course: What is Pharmacoepidemiology, Drug safety, and Pharmacovigilance
Thu, Week 2	Study Designs in Pharmacoepidemiology Sample Size Considerations
Thu, Week 3	Basic Principles of Clinical Pharmacology used in Pharmacoepidemiology
Thu, Week 4	Bias and Confounding in Pharmacoepidemiology. Causality
Thu, Week 5	Drug Safety, Spontaneous Adverse Event Reporting
Thu, Week 6	Sources of Pharmacoepidemiology Data Risk Evaluation and Mitigation Strategy
Thu, Week 7	<u>MID-TERM EXAM</u>
Thu, Week 8	Randomized Clinical Trials. Utilization of Observational and Interventional Studies in Pharmacoepidemiology
Thu, Week 9	Bioethical Issues in Pharmacoepidemiology
Thu, Week 10	Molecular Pharmacoepidemiology
Thu, Week 11	Pharmacoeconomic Studies
Thu, Week 12	Quality-of-Life Measurements in Pharmacoepidemiology. Registries of Patient Outcomes
Thu, Week 13	<u>FINAL EXAM</u> : Covers entire course

V. Grading

Letter grades are awarded in this course as follows below, and will appear on the student's official transcript.

- A Represents achievement that is outstanding relative to the level necessary to meet course requirements. (90-100 points)
- B+ (86-89 points)
- B Represents achievement that is significantly above the level necessary to meet course requirements. (80-85 points)
- C+ (76-79 points)
- C Represents achievement that meets the course requirements in every respect. (70-75 points)
- F Represents failure and signifies that the work was completed but not at a level of achievement worthy of credit (<70 points)
- I An incomplete grade ("I") is permitted only in cases of exceptional circumstances and following consultation with the instructor.