SPPH 580B
Selected Topics in Pharmacoepidemiology

Primary Instructor: Dr. Mahyar Etminan
Scientist, Center for Clinical Epidemiology and Evaluation
Vancouver Hospital
Tel: 875-4111 (66681), 778 846-9604
Email: mahyar.etminan@vch.ca

Week 1 January 8

Title: Review of pharmacoepidemiologic concepts; case-control studies

This lecture will consist of a brief overview of basic epidemiologic concepts pertaining to both methodology and analysis of pharmacoepidemiologic studies. Some of the concepts discussed include: review of case-control and cohort studies, rate ratios, odds ratios, and method of analysis for pharmacoepidemiologic studies including Poisson, Cox and Logistic regression.

Assigned Readings:


Week 2 January 15

Title: Methodologic and analytical concepts in case-control and cohort studies

Whether to use a case-control or a cohort design when addressing a specific drug related question is a controversial topic in pharmacoepidemiology. Using examples in the literature, this lecture will address reasons as to why studies that address the same question but use a different study design (case-control or cohort) may yield different results. There will also be a discussion on the types of drug related questions that may be more suited to either study design.
Assigned Readings:


Week 3 January 22

Title: **Confounding by indication**

Confounding by indication refers to a phenomenon where a drug can act as a marker for a clinical characteristic or medical condition triggering the use of that drug and thus increasing the risk for a harmful outcome. Controlling for confounding by indication remains one of the challenges of pharmacoepidemiology. This lecture will use published studies where confounding by indication may have been present. Various methods of controlling for this type of confounding including use of propensity scores will also be discussed.

Assigned Readings:


Week 4 January 29

Title: **Databases in pharmacoepidemiology**

This lecture will discuss the set up of various administrative and clinical databases that may be used for pharmacoepidemiologic research.

Assigned Readings:

Week 5

*Title: Harm Benefit in drug studies*  
February 5

Week 6  
February 12

*Title: Addressing drug exposure in pharmacoepidemiologic studies: focus on time-dependent covariates*

This lecture will discuss the importance of defining the time dependency of prescription drug use including use of time-dependent analysis (time dependent Cox model) as well as a time-matched case control design.


Week 7  
**Reading break**

Week 8  
February 26

*Title: Analysis of case-control studies*

This will be an in class analysis of a case-control study. Students will be familiar with a SAS dataset on a recently analyzed case-control study. Time will be spent on basics of SAS programming as well as concepts discussed in previous lectures.

Week 9

*Title: Bias in pharmacoepidemiology*  
March 5

Addressing bias is one of the important aspects of epidemiologic research. Pharmacoepidemiologic studies, especially those that use administrative data, may face biases that arise as a result of the time-dependent nature of the exposure and complexity of large administrative databases. Several types of biases have been identified that may be unique to pharmacoepidemiology including protopathic as well as “immortal” time bias. Different types of bias will be discussed in this lecture with an emphasis on immortal time bias.

*Assigned Readings:*


Week 10 March 17

**Title: Using Bayesian statistics in addressing confounding in observational studies**

Title: Uncontrolled confounding, Bayesian sensitivity analysis, and instrumental variable methods.

Week 10 March 19

**Title: Novel approaches in assessing confounding in pharmacoepidemiology**

One of the limitations of randomized trials is their inability to predict the degree of adherence to a specific drug therapy. This lecture will focus on several methods of quantifying adherence to drug therapy using large administrative databases. An example of a recent project looking at adherence to obesity medications in British Columbia will also be discussed in more detail.

Assigned Readings:


Week 11 March 26

**Title: Novel study designs in Pharmacoepidemiology: Case-cross over and case-time-control studies**

Risk associated with some drugs may not resemble a regular pattern. For example, there may be periods where the risk is high and other times where the risk is low. Also, some drugs are not taken on a regular basis and may be only used transiently. When addressing
adverse events associated with drugs that are used transiently and also resemble an irregular risk pattern, classic case-control or cohort studies may not be the optimal study designs to address these questions. In such circumstances, the case-cross over and case-time control studies may be used. Methodology for both of these designs will be discussed using examples from the literature.

Assigned Readings:


Week 12 April 2

**Final Projects Presentations**

Upon selecting a research question in the area of pharmacoepidemiology, students will address important areas related to methodology and analysis of their research question using concepts discussed throughout the course. Students will present their topic in a 20 minute presentation and will submit a 15-20 page (double space) term paper.

**Grading:**

50% Participation

50% Final Project