

Topics in Clinical Epidemiology
Clinical Research Skills Development Core
Course director: Peter Imrey, PhD
January 14 – April 29, 2010
7:00 – 9:00 a.m.

Epidemiology is concerned with learning about what causes, predicts, prevents, and ameliorates diseases and their progression from information on who gets sick and who doesn't – that is, from non-random patterns of disease distribution in groups. Epidemiology is distinguished from other medical disciplines by its focus on patterns in groups and its integration of medical knowledge with the biostatistical language and tools needed to study such patterns. Clinical epidemiology is that branch of epidemiology particularly concerned with the study of clinical populations, including determinants of disease progression and the evaluation of diagnostic tools, prognostic tools, and therapies. The research methods of clinical epidemiology, applied with sound clinical understanding, constitute the scientific underpinning of evidence-based medicine.

The course introduces the technical language and research methods of epidemiology. Topics will include measures of disease frequency and association, which comprise a critical technical vocabulary for clinical research; sources of spurious statistical associations, including bias and confounding; basic concepts of observational cohort and case-control study design and analysis; fundamentals of understanding clinical trials; evaluation of diagnostic tests and disease screening programs; effect modification and statistical interaction; and brief introductions to meta-analysis and clinical decision analysis. Classes will be primarily in lecture-discussions, with copious use of examples from contemporary and historical clinical research and some research case-based discussions. Assigned portions of a paper text, computer-based interactive text, and clinical research papers will be important for genuine understanding and retention of the material.

Provisional Outline

1. Introductory Case Studies
2. Basic Concepts
3. What Happens, How Often? Describing Natural History and Clinical Course Using Frequencies
4. How Long, How Often? Describing Natural History and Clinical Course Using Time Intervals
5. Design Structure of Cohort and Case-Control Observational Studies
6. Basic Analyses of Cohort Studies and Controlled Clinical Trials
7. Basic Analysis of Case-Control Observational Studies
8. Threats to Research Validity, With Emphasis on Observational Research
9. Assessing Accuracy of Diagnostic and Screening Tests
10. Does Screening for Early Detection Reduce Mortality or Morbidity?
11. Understanding Stratification, Effect Modification, Confounding, and Statistical Adjustment
12. Functional Anatomy of Clinical Trials I
13. Functional Anatomy of Clinical Trials II
14. Multivariable Modeling From 30,000 Feet
15. Meta Analysis
16. Clinical Decision Analysis (schedule permitting)

Resources:

Gordis, L. Epidemiology, 4th edition. Philadelphia: WB Saunders; 2008.
Kleinbaum DG. ActivEpi 2.0 on CD-ROM. Version 3. New York: Springer-Verlag, 2008.