

**University of Hawaii at Manoa
John A. Burns School of Medicine
Dr. James Davis and Dr. A. Katz**

Course Number:642

Course Title:

Applied Clinical Epidemiology and Biostatistics

Course Credit:

3 credits

Prerequisite:

BIOMED 640, 642

Placement in Curriculum:

Applied Clinical Epidemiology and Biostatistics is the introductory course in epidemiology and intermediate course in biostatistics in the Masters in Clinical Research curriculum. The course is preparation for more advanced courses.

Course Description:

To teach epidemiologic and biostatistical methods in clinical research within an integrated framework, and to develop proficiency with computer software for performing the analysis of clinical datasets

Clinical Epidemiology and Biostatistics will introduce epidemiologic and biostatistical methods as applied to clinical research. The epidemiology lectures will cover study design, bias and causal associations, screening tests, measures of disease occurrence and disease association; the different mechanisms of bias in clinical research (selection, measurement, and confounding); and randomized clinical trials. Research implications of evidence-based clinical medicine, including the specifications of diagnostic tests, screening tests, and prognostic tests will be addressed..

Students will be taught epidemiologic measures such as relative risks and odds ratios and how to interpret these measures and their 95% confidence intervals in the context of clinical studies. Students will learn how to interpret screening tests in terms of reliability, validity, sensitivity, specificity, and positive and negative predictive values. The epidemiology lectures will teach the difference between “observational” and “experimental studies,” and have a substantial emphasis on the design of randomized clinical trials. Blinding, interventions and controls; measuring outcomes and adverse effects; follow-up, compliance and postrandomization problems; ethical issues; and working with pharmaceutical companies will also be addressed.

The biostatistics section will include both lectures and computer applications. Students will learn how to analyze studies of differing designs, including randomized trials, cross-over trials, sequential clinical trials, single-subject designs, cohort studies, nested case-control studies, case-cohort designs, and case-crossover designs. For traditional cohort and case-control studies the students will learn methods of stratified analysis

Learning Outcomes:

At the conclusion of the course student will be able to::

- Identify two types of descriptive study and list the strengths and weaknesses of each
- Differentiate “observational” from “experimental” studies
- Identify two analytic observational epidemiologic study designs and list the strengths and weaknesses in each.
- Define relative risk (RR) and odds ratio (OR) and be able to interpret calculated RR or OR in the context of comparison study.
- Interpret 95% confidence intervals for RR or OR calculations
- Given a summary description of an analytic study:
- Describe random allocation, blinding, and intent-to-treat analysis in the context of a randomized controlled trail (RCT)
- Define and interpret the following terms: reliability; validity; sensitivity; specificity; positive and negative predictive value
- Define information bias, selection bias, and confounding and give examples of each.
- List and describe the criteria used to assess whether a statistically significant association between an independent and dependent variable is causal.
- Differentiate causal, indirect, and artifactual associations, and give examples of each.
- Understand the concepts and assumptions on which introductory statistical tests are based
- Recognize the types of numeric data
- Learn how to select the correct statistical method to analyze the data
- Know how to interpret the results of statistical tests
- Understand how to apply statistical methods in clinical studies
- Proficiently use at least one computer data analysis program

Topical Outline:

Epidemiology topics:
Introduction to study design
Descriptive studies
Cohort studies

Case-control studies
Association and causation
Interpretation of screening tests
Randomized clinical trials
Biostatistics topics:
Introductory statistical methods
Data analysis using SAS
Analysis of designed experiments
Stratified analysis
An introduction to regression analysis

Required Texts:

The 11 part “Epidemiology Series” on randomized trials published in Lancet, 2002, Fletcher RH, Fletcher SW, Wagner EH. Clinical epidemiology: the essentials, 3rd ed., Baltimore: Williams & Wilkins, and Walker GA. Common statistical methods for clinical research: with SAS examples.

Learning Experiences:

Lecture, discussion, practicum

Evaluation

Examination	40%
Analysis project	60%

Students will be evaluated by formal tests, by write-ups of analyses assignments, and by writing a proposal for a secondary analysis that the students will perform in the next semester