

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

**Course Number:**643

**Course Title:**

Applied Biostatistics in Clinical Research

**Course Credit:**

3 credits

**Prerequisite:**

Applied Clinical Epidemiology and Biostatistics

**Placement in Curriculum:**

Applied Biostatistics in Clinical Research will follow, the course in applied epidemiologic and biostatistical methods. It may be taken before or along with Clinical Research Methods

**Course Description:**

Applied Biostatistics in Clinical Research will combine a didactic introduction to multivariable regression with the hands on analysis of a clinical dataset. The lectures will introduce the regression methods for normally distributed, binary, and count data, as well as for time-to-event data. The lectures will cover both model building and model evaluation. To complement the lectures, each student will perform the secondary analysis of a clinical dataset. The datasets will be created from administrative (claims) data. Students will be given the opportunity to select (or suggest) a topic that interests them. Students can elect to analyze clinical outcome or health service research data. The students will be asked to further review the literature, then to design analyses that answer a clinical hypothesis. Analyses will include descriptive statistics and multivariable regression models. The students will be taught basic data management skills as needed to perform their analyses. The students will be required to include at least one analysis using each of the regression methods they are taught. Instruction in multiple predictor analyses as a tool for control of confounding and for constructing predictive models. Topics will include linear regression and logistic regression. Statistical packages will be used throughout. multivariable statistical analysis that includes instruction in survival analysis and analysis of repeated measures and clustered data. The course culminates with student presentations of statistical analyses of their own research projects. Instruction in advanced topics in biostatistics including individualized instruction in biostatistical methods pertaining to the scholars' research projects will be included. Exams will emphasize questions based on the analysis of their own and other student projects. The final will be a seminar presenting their research findings.

**Learning Outcomes:**

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

- Understand how analyzing longitudinal data differs from cross-sectional data analysis
- Define the concepts of hazard and cumulative hazard

- Use the Kaplan-Meier method of estimating survivor functions
- Understand the proportional hazard assumption
- Include time-dependent covariates in regression models
- Identify nested (multilevel) relations and model them appropriately
- Interpret regression coefficients from survival and multilevel analyses
- Analyze data with repeated measurements on the study participants
- Understand random effects and their implications for longitudinal analyses
- Design and perform the analysis of a secondary dataset
- Present analysis results at a seminar
- Write-up a research analysis in a manuscript form

### **Topical Outline:**

Exploratory analysis of longitudinal data  
 Multilevel models of change  
 Handling repeated measurements  
 Incorporating time-dependent covariates  
 Discrete time hazard models  
 Descriptive analysis of continuous time-to-event data  
 Fitting proportional hazard regression models  
 Extensions of regression models to non-proportional hazards  
 Practicum

### **Required Text:**

*Applied Longitudinal Data Analysis: Modeling Change and Event Occurrence* by JD Singer and JB Willet, Oxford University Press, 2003

### **Learning Experiences:**

Lecture, discussion, practicum

### **Evaluation**

Examination	30%
Analysis project	70%