Abstracts of Presentations

1. Mark Becker, Georgia State University

Everything I Need to Know I Learned in UM – Biostatistics

Reflections on how the department's unique culture provides valuable lessons and a model for others to emulate.

2. Richard Cornell, University of Michigan

It is a pleasure to visit with alums and faculty members of the Department of Biostatistics, past and present, and to observe the extent to which the department has grown and matured. Its impact has been great both in terms of the careers of its graduates and in terms of its impact on graduate education and research in public health and medicine. When I came here in 1971 the department's research was centered in epidemiology. Its doctoral program was in jeopardy because the National Institute of General Medical Sciences discontinued support for graduate programs in biostatistics. Only two students advanced from the masters program into the doctoral program that year. During the years that followed we broadened the scope of applied research to other programs in the School of Public Health and the Medical School, widened the base of support for graduate students, strengthened the research and Ph. D. programs in Biostatistics, and added the weekend program in clinical research. I am glad to see that these efforts have been improved and expanded in the years that have followed.

3. Dianne Finkelstein, Harvard University

A Simple Derivation of a Score Test from Missing Data with Applications to Interval Censored Failure Time Data

Often clinical and laboratory studies result in missing and censored data. For example, for clinical studies that monitor patients for disease progression, visits will be missed, resulting in censored data. The analysis of these studies can become cumbersome in the context of such incomplete data. I will present a simple method for deriving a score test from incomplete data. It uses a very intuitive technique of calculating the expected complete data score conditional on the observed incomplete data (CEST). I will apply the method to develop a test for the association of a longitudinal marker and failure data from incomplete data. The work was motivated by data from an observational study of patients with diabetes.

4. Debashis Ghosh, Pennsylvania State University

Survival analysis with instrumental variables

Recently, interest has rekindled in the use of instrumental variables for resolving associations that are subject to confounding in epidemiologic and more generally nonrandomized studies. While the concept of instrumental variables dates back to the early 20th century, its methodological development has been primarily in the econometric literature. To extend its use to biostatistical settings, it is important to have methods available that can model the types of response variables that exist there. In this talk, we focus on the use of instrumental variables in survival analysis applications. Two types of models,

proportional hazards and quantile regression, using instrumental variables are formulated. Some methods are described, and simulation studies are used to assess the performance of the methodology.

5. Joel Greenhouse, Carnegie Mellon University

The Role of Meta-Analysis in Assessing Adverse Drug Effects

Meta-analysis is an essential methodology for synthesizing evidence, particularly in the biomedical and social sciences. Quantitative research synthesis is frequently used to accumulate evidence about questions of interest; it can also be used to investigate the generalizability of research results, and to investigate alternative explanations for observed associations. Some even argue that meta-analysis can be used to establish causal effects. In this talk, we discuss the role of meta-analysis in the assessment of drug safety considerations and consider the strengths and weaknesses of evidence generated from research synthesis. As a case study to help illustrate some of these issues, we consider the evidence from a meta-analysis of randomized controlled trials that the FDA used to inform their decision to issue a black box warning concerning the risk of suicidality in children who use antidepressants.

6. Beth Hauser, Duke University

UM Biostatistics—Where the "Bio" is not silent

One of the most important aspects of the UM Biostatistics training philosophy is the attention paid to the biological context in which biostatistical methods will be used. I was grateful for the opportunity to completely submerge myself in statistical genetics, while at the same time gaining a broad understanding of the field of biostatistics. I am even more grateful now as I try to balance the need to understand the genetics context of my work with applying novel and not so novel biostatistical concepts. I will discuss how the lessons learned as a UM Biostat student are helping me today.

7. J. Richard Landis, University of Pennsylvania

Developing a Biostatistics Program: Challenges of the Past -- Visions for the Future

This talk will explore key development issues over the past decade at the University of Pennsylvania, as well as current challenges facing Biostatistics programs in academic medical centers more widely. Using many practical examples, I will highlight general principles related to the development and sustainability of a vital biostatistics program within a complex academic medical center environment. Issues to be addressed include recruitment and retention of outstanding faculty, promoting effective balance between collaborative and methodological research, launching and sustaining a nationally competitive graduate (PhD, MS) training program, recruiting and retaining excellent biostatistical analyst / programmer, data management and project management research staff. The parallel issues of promoting and deploying a leading-edge research IT infrastructure, as well as biomedical informatics methods and tools, within a rapidly changing research landscape will also be highlighted.

Major challenges facing biostatistics programs include cultivating a new generation of biostatistical scientists with the technical breadth, as well as the leadership skills, to guide multidisciplinary research teams within the evolving clinical and translational science award (CTSA) paradigm of NIH Roadmap research, pursuing new partnership approaches with industry for graduate education that includes

collaborative approaches to scientific inquiry, and promoting research teams within the academic health system to harvest the research potentials of enterprise-wide clinical practice data.

8. Danyu Lin, University of North Carolina at Chapel Hill

On the Relative Efficiency of Using Summary Statistics vs Individual Level Data in Meta-analysis

Meta-analysis is widely used to synthesize the results of multiple studies. Although meta-analysis is traditionally carried out by combining the summary statistics of relevant studies, advances in technologies and communications have made it increasingly feasible to access the original data on individual participants. We investigate the relative efficiency of analyzing original data versus combining summary statistics under the fixed-effects approach. We show that, for all commonly used parametric and semiparametric models, there is no asymptotic efficiency gain by analyzing original data if the parameter of main interest has a common value across studies, the nuisance parameters have distinct values among studies, and the summary statistics are based on maximum likelihood. We also assess the relative efficiency of the two methods when the parameter of main interest has different values among studies or when there are common nuisance parameters across studies. We conduct simulation studies to evaluate the theoretical results and provide applications to genetic association studies. Finally, we assess the theoretical properties of the random-effects approach to meta-analysis.

9. Xihong Lin, Harvard University

Statistical Issues and Challenges in Analyzing High-throughput 'Omics Data in Population-Based Studies

With the advance of biotechnology, massive "omics" data, such as genomic and proteomic data, become rapidly available in population based studies to study interplay of genes and environment in causing human diseases. An increasing challenge is how to analyze such high-throughput "omics" data, interpret the results, make the findings reproducible. We discuss several statistical issues in analysis of high-dimensional "omics" data in population based "omics" studies. We present statistical methods for analysis of several types of "omics" data, including incorporation of biological structures in analysis of data from genome-wide association studies, analysis of genetic pathway data and gene selection, and analysis of genome-wide DNA methylation data and study of genes and environment. Data examples are presented to illustrate the methods. Strategies for interdisciplinary training in statistical genetics, computational biology and genetic epidemiology will also be discussed.

10. Tom Ten Have, University of Pennsylvania

Heterogeneity at Michigan and Beyond

We review heterogeneity ranging from a rich history of diverse but parallel methods by UM biostatistics faculty to challenging methodological issues of causal inference related to treatment heterogeneity in randomized trials.

The analytic techniques focus on reducing the bias in effectiveness trials due to time-varying post-baseline factors such as treatment non-adherence, early non-response, and comorbidities. These methods include standard regression, principal stratification, and semi-parametric approaches that reflect the current heterogeneity of UM biostatistics faculty. In spite of their apparent differences, there are some relationships between the methods that may illuminate the answers to clinical questions

about treatment heterogeneity. Distinctions among these methods involve efficiency and assessment of assumptions.

11. Lee-Jen Wei, Harvard University

Prediction Versus Association with Working Models

Abstract TBA

12. Robert Wolfe, University of Michigan

Biostatistics at the University of Michigan

I discuss probability theory, individuals, wisdom, uncertainty, causal mechanisms, regression models, instrumental variables, graduate School, Michigan, students, clients

13. Careers Roundtable

Four distinguished alumni and leaders in their respective fields -- Robert Kasprzyk, the Dow Chemical Company; Keith Rust, Westat Inc.; Edward Vonesh, Northwestern University and Vonesh Statistical Consulting, and George Williams, Amgen Inc. -- discuss their careers, and provide perspectives and advice on career options for biostatistics students.

14. Yes! There is a Life After the OJOC!

Talks by distinguished alumni of the Clinical Research and Statistical Analysis On-Job On-Campus Program at the University of Michigan