

Invited Sessions

Thursday and Friday, January 21–22, 2010

Mixed-Treatment Meta-Analysis for Promoting Comparative Effectiveness Research

Organizer: Chris Schmid, Tufts University-New England Medical Center

Speakers: **Georgia Salanti—University of Ioannina, Greece**

How Multiple-Treatments Meta-Analysis Can Challenge and Advance the Existing Clinical Evidence

Stephanie Chiang—AHRQ

Comparative Effectiveness Research: Finding the Best Evidence to Answer Questions

Christopher Schmid—Tufts University

Multiple-Treatment Meta-Analysis for Categorical Outcomes

Alex Sutton—University of Leicester, UK

The Use of Multiple Treatment Comparisons in Health Technology Assessment

Novel Methods for Using Decision Models in Economic Evaluation and Research Priority Setting in Healthcare

Organizer: Anirban Basu, The University of Chicago

Speakers: **Nicola Cooper—University of Leicester, UK**

Integration of Meta-Analysis and Economic Decision Modeling for Evaluating Diagnostic Tests

Lou Garrison—University of Washington

The Value of Information in Benefit-Risk Analysis for Regulatory Approval

David Meltzer—The University of Chicago

Applications of Decision Modeling to Assess the Value of Clinical Research

Statistical Issues in Drug Safety

Organizer: Robert Gibbons, University of Illinois at Chicago

Speakers: **Sharon-Lise Normand—Harvard Medical School**

Meta-Analysis and Medical Technology Safety

Robert Valuck—University of Colorado, Denver

Studying Drug Safety: From RCTs to OCER

Robert Gibbons—University of Illinois at Chicago

Post-Approval Drug Safety Surveillance

Incorporating Adaptive/Dynamic Treatment Strategies in Clinical Trial Designs

Organizer and Chair: Anirban Basu, The University of Chicago

Speakers: **Marie Davidian—North Carolina State University**

Introduction to Dynamic Treatment Regimes, Challenges, and Benefits

Susan Murphy—University of Michigan

Constructing Dynamic Treatment Regimes Using STAR*D and CATIE

Michael R. Kosorok—The University of North Carolina at Chapel Hill

Reinforcement Learning Strategies for Clinical Trials in Non-Small Cell Lung Cancer

The Magic with Missing Data Methods: Is There More to the Prestige?

Organizer: Recai M. Yucel, University of Albany

Speakers: **Xiao-Li Meng—Harvard University**

What Happens When Imputation Model and Analysis Procedure Are Uncongenial?

Yulei He—Harvard Medical School

Posterior Predictive Checking of Imputation Models

Geert Molenberghs—Universiteit Hasselt, Belgium

Incomplete Data: Analysis and Sensitivity Analysis

Discussant: **Joseph L. Schafer—The Pennsylvania State University**



PLENARY SPEAKER

Carolyn Clancy

Director, Agency for Healthcare Research and Quality

Thursday, January 21, 8:30 a.m. – 10:00 a.m.

Data Confidentiality: Do We Really Want to Disturb a Sleeping Bear?

Organizer: Ofer Harel, University of Connecticut

Speakers: **Jerome Reiter—Duke University**

Using Multiple Imputation to Protect Participants' Confidentiality When Sharing Data

Adam Smith—The Pennsylvania State University

Pinning Down 'Privacy' In Statistical Databases

Ofer Harel—University of Connecticut

Assessing Privacy Using the Area Under the Receiver-Operator Characteristic Curve

Discussant: **Robert Aseltine—University of Connecticut Health Center**

Beyond Simple Randomized Trials: Health Services Research Within the VA Healthcare System

Organizer and Chair: Roslyn A. Stone, University of Pittsburgh

Speakers: **Kara Zivin—University of Michigan**

The Use of Antipsychotics in Veterans with Dementia: Did the Black Box Warnings Have Any Impact?

Leslie L. Taylor—VA Puget Sound Healthcare System

Causal Inference in Randomized Encouragement Design Studies

with Non-Compliance and Non-Ignorable Missing Outcomes:

The Effects of Physician Adherence on Medical Outcomes of Veterans with Chronic Heart Failure

Kevin Lynch—University of Pennsylvania

Adaptive Designs In Substance Abuse Research, with Applications to VA and Non-VA Research

Alexander H. Sox-Harris—Center for Health Care Evaluation

Multi-Level Modeling (and Thinking) in the Development and Validation of Health Care Quality Measures for Substance Abuse Disorder Treatment

Discussant: **Xiao-Hua (Andrew) Zhou—University of Washington**

Challenges in the Design of Health Services Research Studies

Modeling Efforts to Inform Healthcare Initiatives and Policy

Organizers: Marc Elliott, RAND, and Steven B. Cohen, AHRQ

Speakers: **Steven B. Cohen—Agency for Healthcare Research and Quality**

Issues of Data Capacity and Statistical Quality to Support Health Care Modeling and Microsimulation Efforts

Beth McGlynn—RAND Corporation

Using the Compare Microsimulation Model to Evaluate Health Reform Legislation: Challenges and Contributions

A. Bowen Garrett—Health Policy Center, Urban Institute

The Health Insurance Policy Simulation Model and Its Applications

Discussant: **Michael L. Cohen—National Academy of Sciences**

Topic-Contributed Sessions

Thursday, January 21, 2010

Modern Methods in Health Disparities Research

Organizer: Amelia M. Haviland—RAND Corporation

Speakers: Marc N. Elliott—RAND Corporation

Using Administrative Data To Identify Spanish-Preferring Seniors

Claude M. Setodji—RAND Corporation

Improving Health Outcome Estimates in Small Populations: A Smoothing Across Time in Repeated Cross-Sectional Data

Robin M. Weinick—RAND Corporation

Using Standardized Encounters to Understand Disparities in Patient Experiences

Amelia M. Haviland—RAND Corporation

Disparities in Immunization Rates for Seniors by Hispanic Ethnicity and Spanish-Language Preference

Beth Ann Griffin—RAND Corporation

How Robust Is the Association Between Neighborhood Socioeconomic Status and Coronary Heart Disease Among Women?

Quantitative Models for Health Care Reform

Organizer: Arlene Ash, Boston University

Speakers: Arlene Ash—Boston University

The Role of Mathematical Modeling in Health Care Reform

Randall P. Ellis—Boston University

Bundled Payments to Primary Care Physicians Using a Risk-Adjusted Primary Care Activity Level (PCAL) Model

James Burgess—Boston University

Using Flexibility-Based Weights to Calculate a Composite Measure of Quality

Workshops

Wednesday, January 20, and Friday, January 22, 2010

WK1 Bayesian Adaptive Methods for Clinical Trials

8:30 a.m.–5:15 p.m., January 20

Bradley Carlin, University of Minnesota • Peter Muller, University of Texas MD Anderson Cancer Center • Scott Berry, Berry Consultants

This full-day course introduces Bayesian methods, computing, and software and then elucidates their use in phase I, II, and III trials. Descriptions are included for how the methods can be implemented in WinBUGS, R, and BRugs, the version of the BUGS package callable from within R.

Session 1—8:30 a.m.–10:15 a.m.

Introduction to Hierarchical Bayes Methods and Computing

Bayesian inference: point and interval estimation, model choice

Bayesian computing: MCMC methods, Gibbs sampler, Metropolis-Hastings algorithm

Hierarchical modeling and meta-analysis

Principles of Bayesian clinical trial design: predictive probability, indifference zone, Bayesian and frequentist operating characteristics (power, type I error)

Session 2—10:30 a.m.–12:15 p.m.

Bayesian Design and Analysis for Phase I Studies

Rule-based designs for determining the MTD (e.g., 3+3)

Model-based designs for determining the MTD (CRM, EWO, TITE monitoring, toxicity intervals)

Dose ranging and optimal biologic dosing

Efficacy and toxicity

Examples and software

Session 3—1:30 p.m.–3:15 p.m.

Bayesian Design and Analysis for Phase II Studies

Standard designs: Phase IIA (single-arm) vs. phase IIB (multi-arm)

Predictive probability-based methods

Sequential stopping for futility, efficacy

Multi-arm designs with adaptive dose allocation

Hierarchical phase II models and examples

Decision theoretic methods

Session 4—3:30 p.m.–5:15 p.m.

Bayesian Design and Analysis for Phase III Studies

Confirmatory trials

Adaptive confirmatory trials: adaptive sample size, futility analysis, arm dropping

Modeling and prediction

Examples from FDA-regulated trials

Seamless phase II-III trials

Multiplicity and subset analysis

Summary and floor discussion

Special Panel Discussion

Putting the Research into Comparative Effectiveness Research

10:15 a.m.–12:15 p.m., January 22, 2010

Health care systems worldwide grapple with the need to offer the best health care to all citizens at an affordable price. Development of rigorous methods and well-defined metrics to measure and compare the outcomes and costs of competing interventions and policies remain the core of health policy statistics. This panel, comprising representatives from three health care systems—American, Canadian, and British—will discuss the contributions of methods research to the health policy debate and solutions to the knowledge gaps that could most inform the public debate.

Organizer

Thérèse Stukel, Institute for Clinical Evaluative Sciences, Canada

Moderator

Christopher Schmid—Tufts University School of Medicine

Speakers

Jean Slutsky—Center for Outcomes and Evidence, Agency for Healthcare Research and Quality

Kalipso Chalkidou—NICE International, UK NHS NICE

Merrick Zwarenstein—Centre for Health Services Sciences, Sunnybrook Health Sciences Centre

WK2 Estimating Treatment Effects Using Longitudinal Observational Data

8:30 a.m.–10:15 a.m., January 20

Miguel Hernán, Harvard School of Public Health • Robert Obenchain, Risk Benefit Statistics, LLC

Organizer: Douglas E. Faries, Eli Lilly and Company

This workshop will demonstrate how to implement techniques for the assessment of causal treatment effects in longitudinal observational data. Also demonstrated will be how to implement newer local control and trajectory analysis techniques applied to assessing treatment effects in observational data.

WK3 Reducing the Impact of Selection Bias with Propensity Scores

10:30 a.m.–12:15 p.m., January 20

Thomas Love, Case Western Reserve University

This intermediate-level workshop demonstrates effective strategies for using propensity score methods to address the potential for selection bias in observational studies comparing exposures.

WK4 Microsimulation Modeling

1:30 p.m.–3:15 p.m., January 20

Carolyn Rutter, Center for Health Studies, Group Health Cooperative

This workshop will present current uses of microsimulation models, including estimation of cost effectiveness and population effects of cancer screening intervention, though the focus will be on population-based microsimulation of cancer incidence and mortality.

WK5 Cluster Randomized Trials in Health Policy Research

3:30 p.m.–5:15 p.m., January 20

Thomas Love, Randall Cebul, and Neal Dawson, Case Western Reserve University

Electronic medical records (EMRs) with sophisticated clinical decision support (CDS) functions are common in health systems that have affiliated clinical practice sites. Cluster-randomized trials (CRTs) of different approaches to CDS are made by EMRs in these systems by enabling identification of patients and problem areas that might benefit from CDS. Course leaders will illustrate key points by highlighting an AHRQ-supported CRT of CDS in diabetes across two organizations and 24 practice sites, and a small-group interactive task completed during the session will motivate the presentation.

FREE

WK6 The Medical Expenditure Panel Survey (MEPS): A National Data Resource to Inform Health Policy

1:45 p.m.–3:30 p.m., January 22

Jeffrey A. Rhoades, Agency for Healthcare Research and Quality

This workshop will address the use of the Medical Expenditure Panel Survey Household Component (MEPS HC) public use data files by the health services research community and provide the knowledge necessary to formulate research plans using the various MEPS HC files and linkage capabilities.