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

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-Une 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:
- Xiaoli 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

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

PLENARY SPEAKER
Carolyn Clancy
Director, Agency for Healthcare Research and Quality
Thursday, January 21, 8:30 a.m. – 10:00 a.m.
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, EWOC, 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

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 data. Also demonstrated will be how to implement newer local control and trajectory analysis techniques applied to assessing treatment effects in observational data.

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-support 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.

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.