Confronting statistical challenges of using electronic health record data to conduct health research

Meet Our Speakers

Denise Boudreau, RPh, PhD, is a Senior Scientific Investigator at Group Health Research Institute and an affiliate Associate Professor in the Departments of Pharmacy and Epidemiology at the University of Washington. She has been engaged in a wide array of pharmacoepidemiology and drug safety projects across various national networks over the past decade. She has extensive experience working with health plan data/claims and also brings expertise in the areas of observational study design, managed care, drug safety, and clinical pharmacy. Dr. Boudreau has led or been a co-investigator across numerous HMO Research Network (HMORN) collaborative groups including the HMORN Center for Education and Research on Therapeutics (CERT), Cancer Research Network, Cardiovascular Disease Research Network, and Coordinated Clinical Studies Network. She was the Group Health site PI for the HMORN CERT from 2004-2007, and she currently participates as the HMORN Steering Committee Representative on the FDA Sentinel Initiative, as well as leads and participates in numerous Sentinel activities.

Andrea Cook, PhD, is an Associate Investigator in the Biostatistics Unit at Group Health Research Institute and an Affiliate Associate Professor of Biostatistics at the University of Washington. She received her PhD from the Department of Biostatistics at Harvard School of Public Health in 2005. Dr. Cook’s research focuses on developing methods for longitudinal, spatial, and multi-level data, with application in areas such as breast cancer screening, obesity control and prevention, emergency resuscitation, alternative medicine, and drug and vaccine safety. She has expertise in methods for both randomized clinical trials and complex observational studies, particularly those that use large health care databases. Dr. Cook provides national leadership for the NIH’s Health Care Systems Research Collaboratory as a Coordinating Center co-investigator and member of the Biostatistics Core. She has also lead multiple methods task orders for the Food and Drug Administration’s (FDA) Mini-Sentinel Initiative, a pilot project to facilitate development of an active surveillance system for monitoring the safety of all FDA-regulated medical products using a distributed electronic health care database network.
Susan Ellenberg, PhD, is Professor of Biostatistics, Department of Biostatistics and Epidemiology, Perelman School of Medicine at the University of Pennsylvania. Dr. Ellenberg’s research has focused on practical problems and ethical issues in designing, conducting and analyzing data from clinical trials, including surrogate endpoints, data monitoring committees, clinical trial designs, adverse event monitoring, vaccine safety and special issues in cancer and AIDS trials. She serves as senior statistician for three multicenter clinical trials and directs the Biostatistics Core of the Penn Center for AIDS Research. Previously, she was Associate Dean for Clinical Research, overseeing the human subjects protections programs, training and centralized research support of the Perelman School of Medicine. Dr. Ellenberg is a Fellow of the American Statistical Association, the Society for Clinical Trials and the American Association for the Advancement of Science, and is an elected member of the International Statistical Institute. Her book, *Data Monitoring Committees in Clinical Trials: A Practical Perspective*, co-authored with Drs. Thomas Fleming and David DeMets, was named WileyEurope Statistics Book of the Year for 2002; a second edition is in preparation.

Sarah Greene, MPH, is an Associate Director with the CER Methods and Infrastructure Program at the Patient-Centered Outcomes Research Institute (PCORI). She is responsible for providing intellectual and organizational leadership for the program, primarily working with awardees on PCORI’s National Patient-Centered Clinical Research Network. For the past two decades, Greene has worked in patient-centered communication, health literacy, quality of cancer care, and optimization of multi-site collaboration. Most recently, as a healthcare strategy consultant for Group Health Cooperative, she led initiatives on improving patient service, cancer outcomes measurement, and branding. At the Group Health Research Institute, she served leadership roles on federally funded consortium projects, including the Cancer Research Network, Cancer Communication Research Center, and the HMO Research Network. As a member of the Clinical & Translational Science Awards consortium, Greene chaired the national Community Partners Integration work group. Greene has authored numerous manuscripts focused on development and implementation of multicenter research, and she created ResearchToolkit.org, which focuses on resources related to conduct of health research studies.

Susan Gruber, PhD, MPH, MS is the Senior Director for Methods Research for the IMEDS Program at the Reagan-Udall Foundation for the FDA. She is also a visiting scientist in the Department of Epidemiology at Harvard School of Public Health. Dr. Gruber’s work focuses on initiating and facilitating methods development for detecting safety signals in electronic health data. She is also involved in several joint projects with investigators at the FDA, including developing longitudinal data-adaptive causal inference methodology to assess drug safety. Prior to obtaining her PhD in Biostatistics, Dr. Gruber worked as a computer scientist, and taught classes at De Anza College in Cupertino, California.
Sebastien Haneuse, PhD, is an Associate Professor of Biostatistics at the Harvard School of Public Health, with doctoral training from the University of Washington. His primary research interests are in the use of electronic medical records for public health and medical research and on observational study design. Substantively, his collaborative work focuses on health outcomes following bariatric surgery and understanding variation in end-of-life quality of care.

Sebastien Haneuse, PhD

Patrick Heagerty, PhD is Professor and Chair of the Department of Biostatistics at the University of Washington (UW). He also directs the Center for Biomedical Statistics, responsible for coordinating biostatistical collaboration in Seattle and the greater Northwest region of Washington, Wyoming, Alaska, Idaho, and Montana. Dr. Heagerty received a BS from Cornell University, an MS in Mathematics and Statistics from the State University of New York at Albany, and a PhD in Biostatistics from Johns Hopkins University. He is an elected fellow of the American Statistical Association and has won numerous other awards for his research focusing on methods for the analysis of longitudinal data and on the evaluation of biomarkers. He has also taught from middle school to graduate school, and was named the UW School of Public Health's Outstanding Teacher in 2009.

Patrick Heagerty, PhD

Miguel Hernan, MD, ScM, DrPH, conducts research on how to do research. His focus is on methods for causal inference, including comparative effectiveness of policy and clinical interventions. Together with collaborators in several countries, he investigates the optimal way to treat and prevent HIV infection, cancer, and cardiovascular disease. He teaches core courses at the Harvard School of Public Health, where he is a Professor in the Departments of Epidemiology and Biostatistics, and at the Harvard-MIT Division of Health Sciences and Technology. He is Editor of Epidemiology, Associate Editor of the American Journal of Epidemiology and of the Journal of the American Statistical Association, and an elected Fellow of the American Association for the Advancement of Science.

Miguel Hernan, MD, DrPH
Rebecca A. Hubbard, PhD, is an Associate Investigator at the Group Health Research Institute and an Affiliate Associate Professor in the Department of Biostatistics at the University of Washington. She received her PhD in Biostatistics from the University of Washington and completed post-doctoral training at the National Alzheimer's Coordinating Center at the University of Washington. Dr. Hubbard's research focuses on development and application of statistical methodology for studies using observational data from electronic medical records (EMR). This work encompasses evaluation of screening and diagnostic test performance, methods for comparative effectiveness studies, and health services research. Dr. Hubbard's methodological research emphasizes development of statistical tools for inference using EMR data with application to studies of cancer screening, aging and dementia, pharmacoepidemiology, and behavioral health.

Lisa A. Jackson, MD, MPH, is a senior scientific investigator in the Group Health Research Institute and is a Research Professor in the Department of Epidemiology and an Adjunct Research Professor in the Department of Medicine at the University of Washington. For the past 20 years Dr. Jackson has been involved in clinical and epidemiologic studies of vaccine safety and efficacy. She is the Principal Investigator at Group Health of the CDC-sponsored Vaccine Safety Datalink Project and of the NIH-sponsored Vaccine and Treatment Evaluation Unit. She has authored over 140 peer-reviewed publications and 14 book chapters and is a past member of the FDA Vaccines and Related Biological Products Advisory Committee and the National Vaccine Advisory Committee. Dr. Jackson received her medical degree from the University of Virginia School of Medicine, Charlottesville, and her master of public health degree from the University of Washington School of Public Health and Community Medicine.

Ken Kleinman, ScD, holds an undergraduate degree in sociology and anthropology from Oberlin College and a doctorate in biostatistics from the Harvard School of Public Health. Since 2000 he has been on the faculty of the Harvard Medical School Department of Population Medicine, working mainly on federally funded research. The subject areas of this work have varied from real-time surveillance of doctor visits to detect disease outbreaks to observational epidemiology to describing the relationship between maternal diet and offspring health to trials of changing antibiotic prescribing behavior of pediatricians to describing the public health impact of payment policy changes. His methodological interests center on clustered and otherwise correlated data, longitudinal repeated measurements, and methods for missing data. He has served on several NIH study sections and is a standing member of PCORI's review panels. He also writes books and a blog about SAS and R statistical software and tries to keep statistical analysts flexible in their tool use.
David Madigan, PhD, is Executive Vice President and Dean of the Faculty of Arts & Sciences at Columbia University in New York City. He received a bachelor’s degree in Mathematical Sciences and a Ph.D. in Statistics, both from Trinity College Dublin. He has previously worked for AT&T Inc., Soliloquy Inc., the University of Washington, Rutgers University, and SkillSoft, Inc. He has over 120 publications in such areas as Bayesian statistics, text mining, Monte Carlo methods, pharmacovigilance and probabilistic graphical models. He is an elected Fellow of the American Statistical Association, the Institute of Mathematical Statistics, and the American Association for the Advancement of Science. He recently completed a term as Editor-in-Chief of Statistical Science and is the current editor of Statistical Analysis and Data Mining.

Diana Miglioretti, PhD, is the Dean’s Professor in Biostatistics in the Department of Public Health Sciences, School of Medicine at the University of California, Davis. She also serves as a Senior Investigator in the Biostatistics Unit at Group Health Research Institute, where she is co-principal investigator for the Breast Cancer Surveillance Consortium (BCSC)—a network of mammography registries linked to tumor and pathology registries that comprise the largest and most comprehensive collection of breast cancer screening data in the nation. Through the BCSC, Dr. Miglioretti leads collaborative research on breast cancer screening and radiation exposure from medical imaging. Her statistical expertise includes multilevel and latent variable models, longitudinal and clustered data analysis, and the evaluation of screening and diagnostic tests. Dr. Miglioretti serves as an instructor at the Radiological Society of North America’s (RSNA) annual workshop in clinical trials methodology, which aims to prepare radiologists to develop clinical research protocols and apply for funding. Among her many professional memberships are the American Association for Cancer Research, the International Biometrics Society Eastern and Western North America regions (ENAR and WNAR), and the American Statistical Association, for whom she served as a Council of Sections representative in Biometrics.

Jennifer Nelson, PhD, is Director of Biostatistics and a Senior Investigator in the Biostatistics Unit at Group Health Research Institute and an Affiliate Associate Professor of Biostatistics at the University of Washington. She received her PhD from the Department of Biostatistics at the University of Washington in 1999. Dr. Nelson’s research focuses on methods to assess drug and vaccine safety and effectiveness, and she has published over 50 studies in this area. She is particularly interested in addressing methodological challenges in post-licensure drug and vaccine safety studies that use large observational health care databases. Dr. Nelson provides national leadership as the Methods Core Co-Lead and Senior Statistician for the Food and Drug Administration’s (FDA) Mini-Sentinel Initiative, a pilot project to facilitate development of an active surveillance system for monitoring the safety of all FDA-regulated medical products. She is an invited member of the Vaccines Sub-Committee of the International Society for Clinical Biostatistics (ISCB), a group established to facilitate collaboration among statisticians working in vaccine research and to disseminate statistical methods for vaccine research worldwide.
Robert Platt received his PhD in Biostatistics in 1996, and since then has been on faculty at McGill University. He is currently Professor in the departments of Epidemiology, Biostatistics, Occupational Health, and Pediatrics. His primary research interest is in statistical methods for epidemiology, with applications in pharmacoepidemiology and drug safety and in perinatal epidemiology. His methodologic interests are in causal inference and prediction tools. He has made important contributions to the study and use of marginal structural models in pharmacoepidemiology, and to statistical methods for meta-analysis and network meta-analysis. He is principal investigator on grants from the Canadian Institutes of Health Research and Natural Sciences and Engineering Council of Canada, and co-investigator/subcontractor on multiple CIHR and NIH grants, and is leader of the methods team on the Canadian Network for Observational Drug Effect Studies. He also directs the biostatistics and data management core facility at the McGill University Health Centre Research Institute. Dr. Platt has published over 220 articles, one book, and several book chapters on methods and substantive issues in epidemiology.

Ross Prentice, PhD, is a Member in, and former Director of, the Public Health Sciences Division of the Fred Hutchinson Cancer Research Center, and is Professor of Biostatistics at the University of Washington. He served as Principal Investigator of the Clinical Coordinating Center for the Women's Health Initiative from 1992-2011. His personal research is mainly in the area of statistical methods development for population science research. Research support includes an NCI program grant, currently in its thirty seventh year, that includes an emphasis on research designs and strategies for studies of diet, nutrition and chronic disease, including the strategy of strengthening observational studies through the inclusion of objective (biomarker) measures of nutrition and activity. He is a Member of the Institute of Medicine, and served on its Food and Nutrition Board. Honors include the Marvin Zelen Leadership Award from Harvard University, the Prentice Professorship for Biostatistical Collaboration at the University of Washington, the Research Excellence in Epidemiology and Prevention Award from the AACR and ACS, and the COPSS President’s and R.A. Fisher Lectureship awards from the joint statistical societies.

Bruce M. Psaty, MD, PhD, is a Professor of Medicine, Epidemiology, and Health Services; Co-Director of the Cardiovascular Health Research Unit at the University of Washington; an Investigator at Group Health Research Institute, Group Health Cooperative; and a practicing general internist at Harborview Medical Center, Seattle, WA. He received his MD and PhD in English language and literature from Indiana University and his MPH in epidemiology from the University of Washington. His research interests include cardiovascular epidemiology, epidemiological methods, myocardial infarction, stroke, hypertension, diabetes, drug safety, pharmaco-epidemiology, genetics, genomics, and pharmacogenetics. Dr. Psaty is the principal investigator on several large epidemiologic studies and has had major roles as a cardiovascular disease epidemiologist at the coordinating centers of NIH-funded multi-center studies, including the Cardiovascular Health Study, the Multi-Ethnic Study of Atherosclerosis, and the CHARGE (Cohorts for Heart and Aging Research in Genomic Epidemiology) consortium. He also teaches and mentors students, fellows and junior faculty in medicine and epidemiology. Dr. Psaty has published more than 700 articles, editorials and commentaries. He also serves on the editorial board of several journals, and is a contributing writer at JAMA.
Jonathan Schildcrout, PhD, is an associate professor in the Department of Biostatistics at the Vanderbilt University School of Medicine. His methodological research interests involve longitudinal data with specific emphasis on unplanned and planned biased selection at the level of subjects and at the level of observation times within subjects. He has worked on a variety of collaborative research projects including evaluation of a pre-emptive genotyping program for personalizing cardiac medication treatments, examination of the mechanisms by which high body mass impacts kidney function after thoracic surgery, and the role of social and environmental factors on outcomes and readmission risk in patients with acute coronary syndrome.

William Vollmer, PhD, is a biostatistician and health services researcher with a longstanding interest in the epidemiology and management of asthma and chronic obstructive pulmonary disease as well as the non-pharmacologic control of blood pressure and weight. In recent years his research has increasingly shifted to the conduct of large, pragmatic trials designed to improve chronic disease management. He recently directed a randomized trial involving three Kaiser Permanente regions that used a mixed methods approach to test the impact, relative to usual care, of two organizational approaches to improving adherence to statins, ACE inhibitors, and angiotensin receptor blockers among over 25,000 patients with diabetes or cardiovascular disease. Prior to that he led a similar study focused on improving adherence to inhaled corticosteroids among patients with persistent asthma. Dr. Vollmer now serves as the lead statistician on two large, cluster randomized, pragmatic trials that are being conducted as part of the NIH Collaboratory. One is testing a strategy to reduce opioid use among chronic pain patients through the better integration of primary and specialty care services. The other is testing the impact of a program to improve colorectal cancer screening among Federally Qualified Health Clinics serving lower income, economically disadvantaged populations.

Scott L. Zeger, PhD, is Professor of Biostatistics at the Johns Hopkins Bloomberg School of Public Health and is the University’s Vice Provost who directs the Johns Hopkins Individualized Health Initiative. From 2008-2013, he was Vice Provost for Research to represent the university in all matters related to the research and scholarship of its faculty and students. He conducts statistical research on regression analysis for correlated responses as occur in surveys, time series, longitudinal or genetics studies. For the past two years, Dr. Zeger has led Hopkins inHealth, a signature initiative of the Rising to the Challenge Campaign that combines the assets of Johns Hopkins University, Health System and Applied Physics Laboratory to bring modern biological and data sciences to the practice of American medicine and public health. Professor Zeger has been elected Member of the National Academy of Sciences’ Institute of Medicine, Fellow of the American Association for the Advancement of Science and of the American Statistical Association. He is a member of the Springer-Verlag editorial board for statistics and was the founding co-editor of the Oxford University Press journal Biostatistics.
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