

National Institutes of Health and
Agency for Healthcare Research and Quality

Conference on
**METHODOLOGICAL
CHALLENGES IN COMPARATIVE
EFFECTIVENESS RESEARCH**

December 2-3, 2010 | Masur Auditorium, Building 10 (Clinical Center), NIH Campus, Bethesda Maryland

SPEAKER LIST AND BIOGRAPHIES

David Atkins, MD, MPH

Director
Quality Enhancement Research Initiative
Health Services Research & Development
U.S. Department of Veterans Affairs

Dr. David Atkins is the Director of the Quality Enhancement Research Initiative (QUERI) program in the Office of Research and Development of the Veterans Health Administration. In that role, he oversees a network of 10 research centers dedicated to studying and improving the implementation of new practices to improve the quality of care in the VA health system. Before coming to the VA, Dr. Atkins spent 12 years at Agency for Healthcare Research and Quality, providing scientific oversight to their work on evidence-based practice, clinical prevention, care management, and comparative effectiveness. He is a board certified general internist and clinical epidemiologist. He received his MD from Yale University, completed his residency at Univ. of Pittsburgh Medical Center, and received his MPH from U. Washington where he completed a Primary Medicine Fellowship. He has published widely on issues of clinical prevention, comparative effectiveness, translating evidence into practice, and implementation research.

Peter Bach, MD, MAPP

Director
Center for Health Policy and Outcomes
Memorial Sloan-Kettering Cancer Center

Dr. Bach directs the Center for Health Policy and Outcomes at Memorial Sloan-Kettering Cancer Center, where he is a pulmonary and critical care physician and a Full Member with Tenure of title. His work focuses on improving the quality of cancer care for disadvantaged patients in Medicare, on epidemiological and statistical methods that can be used to assess healthcare systems quality and organization, on developing approaches to creating new clinical evidence of effectiveness for therapies and devices in typical clinical care settings, Medicare payment reform, and the assessment of cancer prevention and screening strategies.

His work has been continuously funded by the NIH for the last decade, during which time he has published more than 75 scientific papers, including more than 20 articles in the *New England Journal of Medicine*, *JAMA*, and the *Annals of Internal Medicine*. He is also a frequent contributor to the opinion, editorial, and perspective sections of both medical journals and the lay media, the latter including the *New York Times*, the *Wall Street Journal*, and National Public Radio.

His research has documented that low quality of care contributes to excess mortality for African Americans with cancer, that limited access to high quality primary care physicians may reduce care quality for minority groups, that care fragmentation in the Medicare program may drive up costs while impeding the development of effective pay-for performance programs, and that CT screening for lung cancer may not benefit patients, but instead harm them by prompting over-treatment without reducing the risk of serious illness or death. He was the senior author on the NQF white paper on the development of quality and efficiency measures for cancer care.

Dr. Bach holds and has held several health care policy appointments. In 2005 and 2006 he served as Senior Adviser to the Administrator of the Centers for Medicare and Medicaid Services (CMS) in Washington, DC, where he oversaw the agency's cancer initiatives, including the 2005 and 2006 Oncology Demonstration Projects, directed the agency's evidence development work through conditional coverage (i.e. Coverage under Evidence Development, "CED"), and played a central role in articulating the agency's data policy, including the release of Part D data to the research community. At that time he also served as the Administrator's liaison to other branches of HHS, including the FDA, NIH, OHRP and AHRQ.

He is a member of the Institute of Medicine's National Cancer Policy Forum, the Committee on Performance Measurement for the National Committee on Quality Assurance, the Health Information Technology advisory group to the President's Council on Science and Technology Policy (PCAST), and the Committee on Geographic Variation in Health Care Spending of the Institute of Medicine, and a principal or sub on contracts with NCI, ASPE, and CMS covering various aspects of quality and performance measure development and testing. He is the former incumbent of the Frederick R. Adler Junior Faculty Chair, and a recipient of the Boyer award for clinical research.

Dr. Bach is a graduate of Harvard College, the University of Minnesota Medical School, and the University of Chicago School for Public Policy. He completed his medical residency and sub-specialty fellowship at the Johns Hopkins Hospital in Baltimore, MD. During the 1994 Rwandan Civil War he provided medical care to refugees in Goma, Zaire.

Jesse A. Berlin, ScD

Vice President

Epidemiology

Johnson & Johnson Pharmaceutical Research and Development

Jesse Berlin received his doctorate in Biostatistics from the Harvard School of Public Health in 1988. In 1989 he joined the faculty at the University of Pennsylvania, in a unit that became the Center for Clinical Epidemiology and Biostatistics, under the direction of Dr. Brian Strom.

Dr. Berlin spent several years as Director of Biostatistics for the University of Pennsylvania Cancer Center, followed by assuming the role of Faculty Director of the Biostatistics and Epidemiology Consulting Center. At the end of the summer of 2004, Dr. Berlin left Penn to join Johnson and Johnson Pharmaceutical Research and Development, where he is currently Vice President of Epidemiology. His group is involved throughout the drug development process and in the design and interpretation of post-approval studies.

He has authored or coauthored over 230 publications in a wide variety of clinical and methodological areas. Dr. Berlin has experience in both the application of meta-analysis and the study of meta-analytic methods as applied to both randomized trials and epidemiology. He has served as a consultant on meta-analysis for the Australian government, and has served on two Institute of Medicine Committees examining the association between exposure to chemicals contained in Agent Orange and risk of a wide variety of diseases. He currently serves on an Institute of Medicine Committee developing recommendations for the use of systematic reviews in clinical effectiveness research, and on the Scientific Advisory Committee to the Observational Medical Outcomes Partnership, a public-private partnership aimed at understanding methodology for assessing drug safety in large, administrative databases. Dr. Berlin was a co-chair of a committee established by PhRMA (Pharmaceutical Research and Manufacturers' Association) that proposed standards for safety evaluation during drug development: the Safety Planning, Evaluation, and Reporting Team (SPERT), and has presented on this topic in a variety of international settings.

William C. Black, MD

Professor of Radiology
Department of Radiology
Dartmouth-Hitchcock Medical Center

Dr. Black is a practicing radiologist with clinical expertise in chest radiology and research interest in screening and cost-effectiveness analysis. He has demonstrated how advances in diagnostic imaging distort the clinician's perception of the prevalence of disease, its natural history, and its response to medical intervention. He has also written extensively about the problem of overdiagnosis in cancer screening and the design of randomized control trials for cancer screening with imaging tests. Currently, Dr. Black is a co-investigator of the National Lung Screening Trial (NLST), an NCI funded multi-center randomized controlled trial of screening for lung cancer with chest CT versus chest radiography. He has been particularly involved with the selection of study endpoints, image interpretation, and cost-effectiveness analysis. Dr. Black is also a co-principal investigator on the CER GO Grant Comparative Effectiveness of Advanced Imaging in Cancer, which includes an analysis of medical utilization related to incidental findings in the NLST.

Francis S. Collins, MD, PhD

Director
National Institutes of Health

Francis S. Collins, M.D., Ph.D., was officially sworn in on Monday, August 17, 2009 as the 16th director of the National Institutes of Health (NIH). Dr. Collins was nominated by President Barack Obama on July 8, and was unanimously confirmed by the U.S. Senate on August 7.

Dr. Collins, a physician-geneticist noted for his landmark discoveries of disease genes and his leadership of the Human Genome Project, served as director of the National Human Genome Research Institute (NHGRI) at the NIH from 1993-2008. With Dr. Collins at the helm, the Human Genome Project consistently met projected milestones ahead of schedule and under budget. This remarkable international project culminated in April 2003 with the completion of a finished sequence of the human DNA instruction book.

In addition to his achievements as the NHGRI director, Dr. Collins' own research laboratory has discovered a number of important genes, including those responsible for cystic fibrosis, neurofibromatosis, Huntington's disease, a familial endocrine cancer syndrome, and most recently, genes for type 2 diabetes and the gene that causes Hutchinson-Gilford progeria syndrome.

Dr. Collins has a longstanding interest in the interface between science and faith, and has written about this in *The Language of God: A Scientist Presents Evidence for Belief* (Free Press, 2006), which spent many weeks on *The New York Times* bestseller list. He is the author of a new book on personalized medicine, *The Language of Life: DNA and the Revolution in Personalized Medicine* (HarperCollins, 2010).

Dr. Collins received a B.S. in chemistry from the University of Virginia, a Ph.D. in physical chemistry from Yale University, and an M.D. with honors from the University of North Carolina at Chapel Hill. Prior to coming to the NIH in 1993, he spent nine years on the faculty of the University of Michigan, where he was a Howard Hughes Medical Institute investigator. He is an elected member of the Institute of Medicine and the National Academy of Sciences. He is the recipient of the Presidential Medal of Freedom (2007) and the National Medal of Science (2009). On April 22, 2010, Dr. Collins was a co-recipient of the Albany Medical Center Prize in Medicine and Biomedical Research.

Dean A. Fergusson, MHA, PhD

Senior Scientist and Acting Director
Clinical Epidemiology Program
Ottawa Hospital Research Institute
Associate Professor, Departments of Medicine, Surgery,
and of Epidemiology and Community Medicine
University of Ottawa

Dr. Fergusson is a Senior Scientist and Director, Clinical Epidemiology Program, at the Ottawa Hospital Research Institute. He is also the Director of the University of Ottawa Centre for Transfusion Research and an Associate Professor in the University of Ottawa's Departments of Medicine, Surgery, and of Epidemiology and Community Medicine. He holds a PhD (Honours) in Epidemiology and Biostatistics from McGill University and a Masters of Health Administration from the University of Ottawa. In 2006, he was awarded a \$250,000 New Investigator salary award from the Canadian Institutes of Health Research. In 2008, he was awarded the Michael Smith, Promising Scientist Award by the OCRI Life Sciences Achievement Awards and the Dr. Michel Chrétien Researcher of the Year Award from the Ottawa Health Research Institute.

Dr. Fergusson's clinical research interests are mainly in the field of transfusion medicine but include respirology and nephrology. Specifically, he has focused much of his research on transfusion alternatives and the effectiveness of blood products. His research interests also extend to the methodology and ethics of clinical trials and systematic reviews.

Dr. Fergusson is a principal investigator on a number of large, peer-reviewed clinical trials in transfusion medicine including "Blood Conservation Using Antifibrinolytics: Randomized Trial in High-Risk Cardiac Surgery (BART)", Age of Red Blood Cells in Premature Infants (ARIP), "Age of Blood Evaluation (ABLE)". Dr. Fergusson has also contributed over 200 articles, abstracts, and book chapters to the medical literature.

Christopher B. Forrest, MD, PhD

Mary D. Ames Professor of Pediatrics
Children's Hospital of Philadelphia
University of Pennsylvania School of Medicine

Christopher Forrest is the Mary D. Ames Professor of Pediatrics at the Children's Hospital of Philadelphia and University of Pennsylvania School of Medicine. He holds an adjunct appointment in the Department of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health. His academic focus is on pediatric population sciences, transforming children's health, and informatics innovations in healthcare delivery. He has authored numerous scientific manuscripts and reviews, and his research is supported by a broad mix of funders, including the National Institutes of Health, the Centers for Disease Control and Prevention, the California Healthcare Foundation, the Commonwealth Fund, and the Robert Wood Johnson Foundation. He leads several large, multi-institutional research efforts that include development and application of child-reported health and well-being outcome measures, child health services research, and using EHR data to transform care. Dr. Forrest and colleagues formed the Pediatric EHR Data Sharing Network (PEDSNet), which includes children's hospitals and physician practices dedicated to leveraging their EHR data for research and practice improvement. He currently chairs the Executive Committee of the NIH's PROMIS research network, which is developing a standardized approach and tool set for obtaining patient reported outcomes.

Dr. Forrest received his BA and MD degrees at Boston University as part of a dual-degree program. He trained in pediatrics at CHOP, where he also served as Chief Resident. Chris completed a PhD in Health Services Research at Johns Hopkins School of Public Health.

Constantine A. Gatsonis, PhD

Professor of Medical Science
Director, Center for Statistical Sciences
Brown University

Dr. Constantine Gatsonis is Henry Ledyard Goddard University Professor of Medical Science (Biostatistics) and founding Director of the Center for Statistical Sciences at Brown University. Dr. Gatsonis is a leading authority on the evaluation of diagnostic and screening tests and has extensive involvement in the development of methods for medical technology assessment and health services and outcomes research. He is the founding editor-in-chief of the journal *Health Services and Outcomes Research Methodology*. Dr. Gatsonis' currently research portfolio in Comparative Effectiveness Research is focused on the evaluation of diagnostic and screening tests. His work includes both methodologic and substantive research projects addressing the role of diagnostic imaging in cancer and cardiovascular disease. He served on the IOM Committee on Comparative Effectiveness Research Prioritization and led the organizing of the RSNA/ NIBIB Workshop on Comparative Effectiveness Research for diagnostic imaging earlier this year.

Dr. Gatsonis is Network Statistician of the American College of Radiology Imaging Network (ACRIN), a NCI funded collaborative group conducting multi-center studies of diagnostic imaging and image-guided therapy for cancer. He is the chief statistician of the Digital Mammography Imaging Screening Trial (DMIST), of ACRIN's arm of the National Lung Screening Trial (NLST) and of several other studies of the role imaging for diagnosis and staging, monitoring, and prediction of response to therapy. A growing component of ACRIN's research agenda is focused on CER.

A major focus of the research publications and current interests of Dr. Gatsonis is on Bayesian inference and its applications to problems in biostatistics, with emphasis on the evaluation of diagnostic imaging and health services and outcomes research. He has long-term involvement in methodologic work on hierarchical regression models and their applications to the study of variations in the utilization, outcomes, and quality of health care, the study of variability in diagnostic performance among radiologists and institutions and to meta-analysis of studies of diagnostic test performance. Dr. Gatsonis has also published on statistical methods for the analysis of correlated ROC data, the design of reader studies, group sequential designs for ROC studies, predictive ROC curves, and on broader issues of study design in diagnostic test evaluation.

Dr. Gatsonis has served on the IOM Immunization Safety Review Committee, the NAS Committee on Identifying the Needs of the Forensic Sciences Community (co-Chair); the NAS Committee to Study Engineering Aviation Security Environments, the NAS Committee on Applied and Theoretical Statistics, the Commission on Technology Assessment of the American College of Radiology, the Research Development Committee of the Radiology Society of North America, the HSDG Study Section of the Agency for Health Care Policy Research, review panels of the Center for Devices and Radiological Health of FDA and technical expert panels for HCFA/CMS. He is an associate editor of the *Annals of Applied Statistics*, *Bayesian Analysis*, *Statistics and Probability Letters*, and *Clinical Trials* and an editor of the *Diagnostic Test Accuracy Reviews* of the Cochrane Collaboration. Dr. Gatsonis was elected fellow of the American Statistical Association and the Association for Health Services Research. He received his BA in mathematics, magna cum laude, from Princeton and his PhD in mathematical statistics from Cornell.

Steven Goodman, MD, MHS, PhD

Professor
Oncology, Pediatrics, Epidemiology, and Biostatistics
Johns Hopkins Bloomberg School of Public Health
Editor-in-Chief, *Clinical Trials*, Journal of the Society for Clinical Trials
Senior Statistical Editor, *Annals of Internal Medicine*

Steven N. Goodman, M.D., M.H.S., Ph.D., is Professor of Oncology in the Division of Biostatistics of the Johns Hopkins Kimmel Cancer Center, with joint appointments in the departments of Pediatrics, Biostatistics, and Epidemiology. Dr. Goodman received a B.A. from Harvard, an M.D. from NYU, trained in Pediatrics at Washington University in St. Louis, and received an M.H.S. in Biostatistics and Ph.D. in Epidemiology from Johns Hopkins University. Since 2004 he has been the editor of *Clinical Trials: Journal*

of the *Society for Clinical Trials*, and is a Senior Statistical Editor at the *Annals of Internal Medicine*, where he has been since 1987.

He has served on numerous IOM committees, including Immunization Safety, Veterans and Agent Orange, Alternative Models to Daubert Standards, Treatment of PTSD in Veterans, and he currently co-chairs the Committee on Ethical and Scientific Issues in Studying the Safety of Approved Drugs. He serves as a member and scientific co-advisor to the Medical Advisory Panel of the National Blue Cross/Blue Shield Technology Evaluation program. At Johns Hopkins he is on the core faculties of the Center for Clinical Trials, the Berman Bioethics Institute, and the Graduate Training Program in Clinical Investigation. He was a co-director of the Johns Hopkins Evidence-based Practice Center, and a member of CMS's Medical Coverage Advisory Commission. He teaches and writes extensively on evidence evaluation and inferential, methodological, and ethical issues in epidemiology and clinical research.

Sheldon Greenfield, MD

Donald Bren Professor of Medicine
Executive Director, Health Policy Research Institute
University of California, Irvine

Sheldon Greenfield, MD, an internationally recognized leader in quality of care and health services research, and is the Donald Bren Professor of Medicine and Executive Director of the Health Policy Research Institute, University of California at Irvine. Dr. Greenfield's research has focused on primary care outcomes, quality of chronic disease care, patient participation in care, and assessment of comorbidity. He was the 1995 recipient of the PEW Health Professions Commission Award for lifetime achievement in Primary Care Research.

Dr. Greenfield is a recipient of the Glaser Award of the Society of General Internal Medicine and the 1999 Novartis Global Outcomes Leadership Award. Dr Greenfield was elected to the Institute of Medicine in 1996. He was Chair of the IOM report *Cancer Patient to Cancer Survivor; Lost in Transition* and was also the Chair of the National Diabetes Quality Improvement Alliance. Last year he was Co-Chair of the IOM Committee on setting National Priorities for Comparative Effectiveness Research. He is currently Chair of an IOM committee to standardize Clinical Practice Guidelines. He is the current Chair of the National Quality Forum Advisory Panel for Diabetes and Chronic Kidney Disease, and a member of the NQF Outcomes Steering Committee.

Frank E. Harrell, Jr., PhD

Professor and Chairman
Department of Biostatistics
Vanderbilt University School of Medicine

Dr. Harrell received his PhD in Biostatistics from the University of North Carolina in 1979. He was on the faculty of Duke University for 17 years and of the University of Virginia for 7 years. He founded the Division of Biostatistics and Epidemiology at the University Of Virginia School Of Medicine in 1996 and the Department of Biostatistics at Vanderbilt University in 2003. He has taught biostatistics and research methodology to hundreds of physicians since 1980 and has been a mentor or co-mentor to several physician investigators. He is an Associate Editor for *Statistics in Medicine*, and his specialties are development of accurate prognostic and diagnostic models, model validation, clinical trials, observational clinical research, technology evaluation, quantifying predictive accuracy, and missing data imputation.

Dr. Harrell is a Fellow of the American Statistical Association and is the 2008 Mitchell Lecturer for the Department of Statistics, Glasgow University. He is an FDA expert consultant and a member of the NIH Biostatistical Methods and Research Design Study Section. He is the leader of the Design, Biostatistics, and Clinical Research Ethics program for the Vanderbilt NIH CTSA and is the director of the Statistics and Methodology Core for the Vanderbilt Kennedy Center for Research on Human Development. He is the author of the first and third most cited papers (on development of prognostic models) in the 26 year history of *Statistics in Medicine* and has 195 peer-reviewed publications. His latest areas of emphasis are pharmaceutical safety, flexible Bayesian clinical trial design and Bayesian analysis, and graphical and tabular methods for reporting analyses from clinical trials.

Miguel Hernán, MD, DrPH

Associate Professor of Epidemiology
Harvard School of Public Health
Member of the Affiliated Faculty
Harvard-MIT Division of Health Sciences and Technology

Miguel Hernan is Associate Professor of Epidemiology at the Harvard School of Public Health. His research is focused on the development and application of methods for causal inference, including comparative effectiveness of policy and clinical interventions. He is Associate Director of HSPH Program on Causal Inference in Epidemiology and Allied Sciences, member of the Affiliated Faculty of the Harvard-MIT Division of Health Sciences and Technology, and an Editor of the journal *EPIDEMIOLOGY*.

Mark A. Hlatky, MD

Professor of Health Research and Policy
Professor of Medicine (Cardiovascular Medicine)
Stanford University School of Medicine

Dr. Hlatky is a cardiologist with major research interests in clinical trials, clinical research methods, outcomes research, and comparative effectiveness research. Dr. Hlatky has participated in several large, multicenter randomized clinical trials, including studies of coronary revascularization, treatment of acute myocardial infarction, hormone therapy to prevent cardiovascular disease, and management of life-threatening ventricular arrhythmias. He has also conducted large outcomes research studies of sudden cardiac death, implantable cardioverter defibrillators, and the initial clinical presentation of coronary artery disease. He served as Director of the Stanford-UCSF Evidence-based Practice Center, and of Stanford's Donald W Reynolds Cardiovascular Clinical Research Center, which encompasses basic laboratory, genetic, and epidemiologic studies of coronary disease. He is currently the Director of the Stanford-Kaiser Cardiovascular Outcomes Research Center, which is sponsored by the American Heart Association and is examining the comparative effectiveness of treatments for ischemic heart disease and heart failure.

Marshall M. Joffe, MD, MPH, PhD

Associate Professor of Biostatistics
Department of Biostatistics and Epidemiology
Center for Clinical Epidemiology and Biostatistics
University of Pennsylvania School of Medicine

Marshall M. Joffe is Associate Professor of Biostatistics in the Department of Biostatistics and Epidemiology and the Center for Clinical Epidemiology of Biostatistics of the University of Pennsylvania School of Medicine. He came there after receiving a Ph.D. in Epidemiology from UCLA and receiving postdoctoral training at Harvard. His independent work centers on causal inference, with particular attention to the effects of time-varying treatments and exposures. Current areas of interest include inference for causal effects when standard assumptions are inappropriate, and the use of surrogate outcomes in randomized trials and observational studies. He collaborates extensively with investigators in nephrology and other areas.

William Lawrence, MD, MS

Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

William Lawrence, MD, MS is a general internist with extensive experience in evidence-based medicine, health outcomes research, and simulation modeling. Dr. Lawrence completed an Internal Medicine Residency and General Internal Medicine Fellowship at the University of Wisconsin. He has conducted clinical practice and clinical research as a faculty member in the Department of Medicine at the University of Wisconsin and in the Departments of Medicine and Oncology at Georgetown University. He is currently a Medical Officer in the Center for Outcomes and Evidence at the Agency for Healthcare Research and Quality (AHRQ). In this role, Dr. Lawrence works in the Effective Health Care Program as a project officer working with Evidence-Based Practice Centers and Developing Evidence to Inform

Decisions about Effectiveness (DEcIDE) Centers, and he provides clinical and methodologic expertise to the program. Dr. Lawrence also works with the Research Initiative on Clinical Economics on methodologic issues in clinical economic evaluations, including value of information analysis.

David Meltzer, MD, PhD

Associate Professor
Department of Medicine
Associated Faculty Member
Harris School and the Department of Economics
The University of Chicago

David O. Meltzer MD, PhD is Associate Professor in the Department of Medicine, Department of Economics and the Harris School of Public Policy Studies at the University of Chicago. Meltzer's research explores problems in health economics and public policy with a focus on the theoretical foundations of medical cost-effectiveness analysis and the cost and quality of care, especially in teaching hospitals. Meltzer is currently completing a randomized trial comparing the use of doctors who specialize in inpatient care ("hospitalists") with traditional physicians in six academic medical centers and is Director of the AHRQ-funded Hospital Medicine and Economics Center for Education and Research in Therapeutics (CERT) at the University of Chicago.

Dr. Meltzer received his MD and PhD in economics from the University of Chicago and completed his residency in internal medicine at Brigham and Women's Hospital in Boston. He is Director of the Center for Health and the Social Sciences and Chief of the Section of Hospital Medicine at the University of Chicago, where he also directs the Program on Outcomes Research Training and the MD/PhD program in the social sciences. Dr. Meltzer is the recipient of numerous awards, including the National Institute of Health Medical Scientist Training Program Fellowship, the National Science Foundation Graduate Fellowship in Economics, the University of Chicago Searle Fellowship, the Lee Lusted Prize of the Society for Medical Decision Making, the Health Care Research Award of the National Institute for Health Care Management, the Eugene Garfield Award from Research America and the Robert Wood Johnson Generalist Physician and Investigator Awards. Dr. Meltzer is a research associate of the National Bureau of Economic Research, elected member of the American Society for Clinical Investigation, and past president of the Society for Medical Decision Making. He has served on panels examining the future of Medicare for the National Academy of Social Insurance and the Department of Health and Human Services (DHHS) and U.S. organ allocation policy for the Institute of Medicine (IOM). He recently served on an IOM panel examining the effectiveness of the U.S. drug safety system and currently serves on The DHHS Secretary's Advisory Committee on Healthy People 2020, which aims to establish health objectives for the U.S. population.

Cynthia Mulrow, MD, MSc, MACP

Senior Deputy Editor
Annals of Internal Medicine
Clinical Professor of Medicine
University of Texas Health Science Center at San Antonio

Cynthia Mulrow is Clinical Professor of Medicine at the University of Texas Health Science Center at San Antonio and Senior Deputy Editor of the *Annals of Internal Medicine*. Dr. Mulrow's expertise is in clinical methodology, information synthesis, and clinical guidelines. She is a member of the American Society for Clinical Investigation (ASCI) and the Institute of Medicine (IOM) and currently serves on the IOM Board on Health Care Services. She was previously Director of the San Antonio VA Cochrane Center, Program Director of the Robert Wood Johnson Foundation's Generalists Physician Scholars Program and Director of the San Antonio Evidence-based Practice Center. Dr. Mulrow has served on several editorial boards including the *British Medical Journal* and the *American Journal of Medicine*. She was a member of the U.S. Preventive Services Task Force and has served on guideline development panels for RAND and AHRQ. She currently participates in multiple groups that develop reporting standards for medical research including CONSORT (reporting standards for trials), PRISMA (reporting standards for systematic reviews), and STROBE (reporting standards for observational studies).

Doug Owens, MD, MS

Professor of Medicine
Stanford University

Douglas K. Owens, MD, MS, is general internist and a Senior Investigator at the Center for Health Care Evaluation at the VA Health Care System, Palo Alto, and a Professor of Medicine and of Health Research and Policy at Stanford University, where he directs the Program on Clinical Decision Making and Guideline Development at the Center for Primary Care and Outcomes Research (PCOR). Dr. Owens also directed the Stanford University-UCSF Evidence-Based Practice Center funded by the Agency for Healthcare Research and Quality (AHRQ) that performed comparative effectiveness research and systematic reviews. His research expertise includes the decision sciences, evidence synthesis, cost-effectiveness analysis and guideline development. He has evaluated the comparative effectiveness and cost effectiveness of a wide variety of interventions in infectious disease, cardiology, oncology and preventive medicine. Dr. Owens was the Chair of the Clinical Guideline Committee of the American College of Physicians (ACP).

Dr. Owens received a Research Career Development Award and an Advanced Research Career Development Award from the Department of Veterans Affairs. He is a past President of the Society for Medical Decision Making. Dr. Owens was elected to the American Society for Clinical Investigation (ASCI), and the Association of American Physicians (AAP). In 2007, Dr. Owens received the VA Under Secretary's Award for Outstanding Achievement in Health Services Research. The award is the highest honor that VA gives for achievement in health services research. In 2010, he received the John Eisenberg Award from the Society for Medical Decision Making for sustained leadership in translating medical decision making research into practice.

Steven D. Pearson, MD, MSc, FRCP

President
Institute for Clinical & Economic Review
Massachusetts General Hospital
Harvard Medical School

Steven D. Pearson, MD, MSc, FRCP is the Founder and President of the Institute for Clinical and Economic Review (ICER) at Massachusetts General Hospital. ICER is a leader in bringing stakeholders together to develop methods and policies to improve the use of evidence in the health care system. Dr. Pearson also serves as Visiting Scientist in the Department of Bioethics at the National Institutes of Health, and is a Lecturer in the Department of Population Medicine at Harvard Medical School. He attended UCSF School of Medicine and completed his residency in internal medicine at Brigham and Women's Hospital in Boston. An internist, health services researcher, and ethicist, he has served in many advisory and leadership roles in academia and government. From 2005-2006 Dr. Pearson was Special Advisor, Technology and Coverage Policy, within the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services. He has also served as Senior Fellow at America's Health Insurance Plans, and as the Vice Chair of the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) from 2007-2009. Dr. Pearson continues today to serve in various roles related to comparative effectiveness research and policy, including the Board of Directors of HTAi, the AcademyHealth Methods Council, the Quality Alliance Steering Committee, and the National Institutes of Health Comparative Effectiveness Research Steering Committee. His published work includes numerous articles and commentaries on the role of evidence in the health care system, and the book *No Margin, No Mission: Health Care Organizations and the Quest for Ethical Excellence*.

David F. Penson, MD, MPH

Professor of Urologic Surgery
Director, Center for Surgical Quality and Outcomes Research
Vanderbilt University Medical Center

David F. Penson, MD, MPH received his residency training in surgery and urology at the University of California, Los Angeles from 1991 through 1997. Upon completing this, Dr. Penson was simultaneously awarded an AFUD Health Policy Research Scholarship and a Robert Wood Johnson Clinical Scholars

Fellowship at Yale University. As a fellow, he studied clinical epidemiology and health services research and obtained a Masters in Public Health. He is currently Professor of Urologic Surgery at Vanderbilt University and is Director of the Center for Surgical Quality and Outcomes Research in the Vanderbilt Institute for Medicine and Public Health. Dr. Penson also maintains a clinical practice in urologic oncology at Vanderbilt University Medical Center.

Dr. Penson's research interests include long-term survivorship in prostate cancer and the disease's impact on quality of life. His research has been funded by the National Cancer Institute, the Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality (AHRQ). He is the Principal Investigator of the Prostate Cancer Outcomes Study (PCOS), a large population-based study of prostate cancer survivors that includes the longest longitudinal health-related quality of life follow-up in the field. Results from the PCOS have appeared in such journals as *JAMA*, *Medical Care* and *JNCI*. Dr. Penson was recently awarded a highly coveted CHOICE grant from AHRQ to study the comparative effectiveness of therapies for localized prostate cancer. In addition to prostate cancer, Dr. Penson has published on a wide range of other topics, including kidney, testicular and bladder cancer, female urology, cryptorchidism, infertility and erectile dysfunction. His work has been published in a variety of journals, including the *New England Journal of Medicine*, *JAMA*, and *JNCI*. Dr. Penson's research and clinical efforts were recognized by the American Urological Association (AUA) in 2006, when he received the prestigious Gold Cystoscope award, given annually to the urologist who has contributed the most to the specialty in the first 10 years after completing his/her residency.

Dr. Penson also maintains a strong interest in health policy and quality improvement in urology. He was awarded the AUA's first Gallagher Health Policy Fellowship in 2007. In addition, Dr. Penson chaired the AUA's Quality Improvement and Patient Safety Committee from 2006 to 2009 and currently serves as the Vice-Chairman of the AUA's Health Policy Council, the parent committee responsible for all policy activities in the AUA. He was instrumental in the development of the AUA and AMA PCPI's prostate cancer performance measures which were included in the 2007 Medicare PQRI initiative. He is currently the AUA's representative to the National Quality Forum and the American College of Surgeons Commission on Cancer.

Bruce M. Psaty, MD, PhD

Professor
Medicine and Epidemiology
Cardiovascular Health Research Unit
University of Washington

Bruce M. Psaty, MD, PhD, MPH, 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 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, hypertension, diabetes, epidemiological methods, drug safety, pharmacoepidemiology, 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 Women's Health Initiative. Recently, he collaborated with investigators from other cohort studies to establish the CHARGE (Cohorts for Heart and Aging Research in Genomic Epidemiology) consortium, which has published more than 40 meta-analyses of genome-wide association studies of a variety of phenotypes. Dr Psaty has served on various NIH working groups, data-safety monitoring committees, review groups and study sections, including as chair of the NIH Cardiovascular Disease and Sleep Epidemiology Study Section (2004-2006), Institute of Medicine's Committee on the Assessment of the US Drug Safety System (2005-2006), the Executive Committee of the National Heart, Lung and Blood Institute's Strategic Planning Effort (2006-2007), and the Scientific Advisory Board of the Netherlands Biobank Infrastructure. In 2005, he received the University of Washington Outstanding Public Service Award for his work on drug safety. The American Heart Association's Epidemiology and Prevention Council selected Dr Psaty as the Remington Methodology Lecturer (2004) and as the Ancel Keys Memorial Lecturer (2009). Elected memberships include American Epidemiological Society, Association of American Physicians, and fellow

of the American Heart Association. Dr Psaty is also a consultant to the FDA Drug Safety and Risk Management Advisory Committee and a member of the Institute of Medicine's Committee on the Ethical and Scientific Issues in Studying the Safety of Approved Drugs. With about 500 articles and commentaries in the medical literature, he publishes regularly, serves on the editorial board of several journals, and is a contributing writer at *JAMA*.

Rita F. Redberg, MD, MSc, FACC, FAHA

Editor

Archives of Internal Medicine

Professor of Medicine

Director, Women's Cardiovascular Services

University of California, San Francisco

Rita F. Redberg has been a cardiologist and Professor of Medicine at the University of California, San Francisco since 1990. She is currently the Chief Editor of *Archives of Internal Medicine* and has spearheaded the journal's new focus on health care reform and "less is more", which highlights areas of health care with no known benefit and definite risks. Dr. Redberg's research interests are in the area of health policy and technology assessment. She served on the Medicare Evidence, Development and Coverage Advisory Commission from 2003-2006. She currently is a member of the California Technology Assessment Forum, the Medical Policy Technology and Advisory Committee, and the Food and Drug Administration Cardiovascular Devices Expert Panel and is a consultant to the Center for Medical Technology Policy. She has recently completed with UCSF colleagues an extensive review of the FDA Cardiovascular Device pre-market approval (PMA) process. Dr. Redberg worked in the office of Senator Hatch and with the Senate Judiciary Committee on FDA related matters during her tenure as a Robert Wood Johnson Health Policy Fellow, 2003-2006. Dr. Redberg chaired the AHA/ACC Writing Group on Primary Prevention Performance Measures and is a member of the American College of Cardiology's (ACC) Clinical Quality Committee and serves on the Quality in Technology Work Group. She does comparative effectiveness research, and serves on the American College of Cardiology's Comparative Effectiveness Work Group, represents the ACC on the Institute of Clinical and Economic Review Advisory Board and serves on other ACC Committees, including several on appropriate use of cardiac imaging.. Dr Redberg graduated from Cornell University and the University of Pennsylvania Medical School and has a Masters of Science and Health Policy and Administration from the London School of Economics.

John Santa, MD, MPH

Director

Consumer Reports Health Ratings Center

Consumer Reports Health

John Santa is the Director of the Consumer Reports Health Ratings Center. The Ratings Center focuses on explicit approaches evaluating and comparing health services, products and practitioners. Dr Santa was the administrator of the Office of Oregon Health Policy and Research from 2000 to 2003. He helped organize and implement an evidence-based approach to prescription drug purchasing that eventually came to be known as the Drug Effectiveness Review Project. He has worked in leadership positions for hospitals, physician groups and health insurers. Dr. Santa has taught in multiple environments including medical school, residency training and graduate courses in Public Health. Dr. Santa received his bachelor's degree from Stanford University in 1972, his MD from Tufts University in 1976 and MPH from Portland State University in 2005. He has practiced primary care internal medicine in several settings, most recently at the Portland, Oregon VA.

Sebastian Schneeweiss, MD, ScD

Associate Professor of Medicine and Epidemiology
Harvard Medical School
Vice Chief, Division of Pharmacoepidemiology
Department of Medicine
Brigham and Women's Hospital

Sebastian Schneeweiss is Associate Professor of Medicine and Epidemiology at Harvard Medical School and Vice Chief of the Division of Pharmacoepidemiology and Pharmacoeconomics at the Brigham and Women's Hospital. He is Principal Investigator of the DEClDE Research Center on Comparative Effectiveness Research and the DEClDE Methods Center both funded by AHRQ and PI of the Harvard-Brigham Drug Safety Research Center funded by FDA. His research focuses on the comparative effectiveness and safety of biopharmaceuticals and analytic methods to improve the validity of epidemiologic studies using complex healthcare databases. Dr. Schneeweiss is Past President of the International Society for Pharmacoepidemiology and is Fellow of the American College of Epidemiology, the American College of Clinical Pharmacology, and the International Society for Pharmacoepidemiology. He is voting consultant on the FDA Drug Safety and Risk Management Advisory Committee and member of multiple scientific advisory boards.

Brian Strom, MD, MPH

George S. Pepper Professor of Public Health and Preventive Medicine
Professor of Medicine
Professor of Pharmacology
Chair, Department of Biostatistics and Epidemiology
Director, Center for Clinical Epidemiology and Biostatistics
Director and Chair, Graduate Group in Epidemiology and Biostatistics
Associate Vice President for Strategic Integration
University of Pennsylvania

Dr. Strom earned a B.S. in Molecular Biophysics and Biochemistry from Yale University in 1971, and then an M.D. degree from the Johns Hopkins University School of Medicine in 1975. From 1975-1978 he was an intern and resident in Internal Medicine and from 1978-1980 he was an NIH fellow in Clinical Pharmacology at the University of California, San Francisco. He simultaneously earned an M.P.H. Degree in Epidemiology at the University of California, Berkeley. He has been on the faculty of the University of Pennsylvania School Of Medicine since 1980. The Center for Clinical Epidemiology and Biostatistics that he has created at Penn includes over 550 faculty, research and support staff, and trainees. CCEB research currently receives over \$49 million/year in extramural support. More than 500 clinicians have been trained or are in training through the CCEB's Master of Science in Clinical Epidemiology degree program. All but approximately 50 have appointments in academic or other research institutions. In this process, Dr. Strom has become a leader in the rigorous formal training of clinical researchers.

Although Dr. Strom's interests span many areas of clinical epidemiology, his major research interest is in the field of pharmacoepidemiology, i.e., the application of epidemiologic methods to the study of drug use and effects. He is editor of the field's major text (now going into its fifth edition), and is now Editor-in-Chief for *Pharmacoepidemiology and Drug Safety*, the official journal of the International Society for Pharmacoepidemiology. In addition to writing more than 525 papers, he has been principal investigator for more than 240 grants, including over \$73 million in direct costs alone. Dr. Strom has also made substantial contributions to many additional extramurally-funded grants. Recent grants include an NCI Program Project Grant on Molecular Susceptibility to Hormone-Induced Cancers, awards from the Agency for Health Care Research and Quality for a Center for Research and Education on Therapeutics (CERTs), a Center of Excellence for Patient Safety Research and Practice, and a center within the Developing Evidence to Inform Decisions About Effectiveness (DEClDE) Network. He has been invited to more than 375 talks outside his local area, including being the keynote speaker for numerous international meetings. Dr. Strom has been a consultant to NIH, FDA, CDC, USP, AAMC, JCAHO, foreign governments, most major pharmaceutical manufacturers, and many law firms.

Dr. Strom was a member of the Board of Regents of the American College of Physicians, the Board of Directors of the American Society for Clinical Pharmacology and Therapeutics, the Board of Directors for the American College of Epidemiology, and the Board of Directors for the Association for Patient-Oriented Research. He was previously President of the International Society for Pharmacoepidemiology and the Association for Clinical Research Training. Dr. Strom was on the Drug Utilization Review Committee and the Gerontology Committee of the United States Pharmacopoeia. He served on the Drug Safety and Risk Management Advisory Committee for the US Food and Drug Administration. Dr. Strom was Chair of the Institute of Medicine's Committee to Assess the Safety and Efficacy of the Anthrax Vaccine, Chair of the Institute of Medicine Committee on Smallpox Vaccine Program Implementation, and was a member of the Institute of Medicine's Committee to Review the CDC Anthrax Vaccine Safety and Efficacy Research Program. He recently chaired the Institute of Medicine Committee to Review NIOSH's Traumatic Injury Program and is now a member of the Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice Guidelines.

Dr. Strom is a member of the American Epidemiology Society, and is one of a handful of clinical epidemiologists ever elected to the American Society of Clinical Investigation and American Association of Physicians. He has also been an elected member of the Institute of Medicine of the National Academy of Sciences since 2001. Dr. Strom received the 2003 Rawls-Palmer Progress in Medicine Award from the American Society for Clinical Pharmacology & Therapeutics, the Naomi M. Kanof Clinical Investigator Award of the Society for Investigative Dermatology, the George S. Pepper Professorship of Public Health and Preventive Medicine, and in 2006 he received the Sustained Scientific Excellence Award from the International Society for Pharmacoepidemiology. In addition, Dr. Strom was named the 2008 recipient of the John Phillips Memorial Award for Outstanding Work in Clinical Medicine. This award is from the American College of Physicians (ACP) and is considered to be one of the highest awards in Internal Medicine. Penn awards that Dr. Strom has received include the Class of 1992 Class Teaching Award and the Samuel Martin Health Evaluation Sciences Research Award. Dr. Strom received the 2004 Christian R. and Mary F. Lindback Award, the University's most prestigious teaching award, in recognition of the contribution he has made in his career to clinical research teaching.

Sean Tunis, MD, MSc

Director

Center for Medical Technology Policy

Sean Tunis, MD, MSc, is the Founder and Director of the Center for Medical Technology Policy in Baltimore, Maryland. CMTP's main objective is to improve the quality and relevance of clinical research by providing a neutral forum for collaboration among experts, stakeholders and decision makers. Dr. Tunis was a member of the Institute of Medicine Committee on Initial National Priorities for Comparative Effectiveness Research. He advises a wide range of domestic and international public and private health care organizations on issues of comparative effectiveness, evidence based medicine, clinical research, reimbursement and health technology policy.

Through September of 2005, Dr. Tunis was the Director of the Office of Clinical Standards and Quality and Chief Medical Officer at the Centers for Medicare and Medicaid Services (CMS). In this role, he had lead responsibility for clinical policy and quality for the Medicare and Medicaid programs, which provide health coverage to over 100 million US citizens. Dr. Tunis supervised the development of national coverage policies, quality standards for Medicare and Medicaid providers; quality measurement and public reporting initiatives, and the Quality Improvement Organization program. As Chief Medical Officer, Dr. Tunis served as the senior advisor to the CMS Administrator on clinical and scientific policy. He also co-chaired the CMS Council on Technology and Innovation

Dr. Tunis joined CMS in 2000 as the Director of the Coverage and Analysis Group. Before joining CMS, Dr. Tunis was a senior research scientist with the Technology Assessment Group, where his focus was on the design and implementation of prospective comparative effectiveness trials and clinical registries. Dr. Tunis also served as the Director of the Health Program at the Congressional Office of Technology Assessment and as a health policy advisor to the U.S. Senate Committee on Labor and Human Resources, where he participated in policy development regarding pharmaceutical and device regulation.

He received a B.S. degree in Biology and History of Science from the Cornell University School of Agriculture, and a medical degree and masters in Health Services Research from the Stanford University School of Medicine. Dr. Tunis did his residency training at UCLA and the University of Maryland in Emergency Medicine and Internal Medicine. He is board certified in Internal Medicine and holds adjunct faculty appointments at Johns Hopkins, Stanford and the University of California San Francisco Schools of Medicine.

Frances M. Visco, JD

President
National Breast Cancer Coalition

Fran Visco is the first president of the National Breast Cancer Coalition and Fund, a member of its board of directors and executive committee. Ms. Visco is an honors graduate of St. Joseph's University and Villanova Law School, where she was an editor of *The Villanova Law Review* and a chair of the Women's Law Caucus.

In 1993 President Clinton appointed Ms. Visco to the three-member President's Cancer Panel. She was the first consumer to chair the Integration Panel of the Department of Defense Peer-Reviewed Breast Cancer Research Program, and has been appointed to several Institute of Medicine (IOM) panels.

William S. Weintraub, MD, FACC

Cardiology Section Chief
Director, Christian Care Center for Outcomes Research
Christian Care Health System

Dr. Weintraub received his MD degree from Johns Hopkins in 1975. After training at Boston University, Mt Sinai and the University of Pennsylvania, he was appointed to the Penn faculty in 1980. He was recruited to Emory University in 1986 to direct efforts in outcomes research in cardiovascular medicine, overseeing the Emory cardiovascular databank. He founded the Emory Center for Outcomes Research (ECOR) in the mid-1990's, publishing over 200 papers while on the faculty at Emory. He was initially appointed as Associate Professor, being promoted to Professor of Medicine in 1994. He was also appointed to joint positions as Professor Epidemiology and Professor of Health Policy and Management. Dr. Weintraub retired from Emory University as Professor of Medicine Emeritus and Professor of Public Health Emeritus in 2005. He was appointed as the John H. Ammon Chair and Cardiology Section Head at Christiana Care Health System in 2005. He has also been appointed as Professor of Medicine at Jefferson University and Professor of Health Sciences (adjunct) at the University of Delaware. Dr. Weintraub also leads the Christiana Care Center for Outcomes Research (CCOR) and is on the research committee of the Delaware Health Sciences Alliance. Dr. Weintraub has also been an active lecturer and teacher. He founded and directs the Christiana cardiovascular fellowship training program, the first internal medicine fellowship in Delaware.

While at Emory, Dr. Weintraub was appointed the first chairman of the National Cardiovascular Data Registry of the American College of Cardiology, having first been appointed to the database committee of the ACC in 1992. Dr. Weintraub remains on the ACC NCDR management board. Dr. Weintraub has also served on the American Heart Association Database Executive Steering Committee. He is on the executive committee of a 6000 patient registry for Atrial Fibrillation (RECORD) developed by Sanofi-Aventis. He is on the board of the Cardiovascular Outcomes Research Consortium which has developed three registries in heart failure and ischemic heart disease. These registries have involved extensive multi-institution collaboration and coordination.

In addition to working on registries, Dr. Weintraub has been worked on clinical trials since the 1980's, being a principal on EAST, LRT, RESTORE, TACTICS-TIMI 18, SoS, EPHEBUS, CURE, CREDO and COURAGE. Activities in all of these trials have involved multicenter collaborations. The activities on both registries and clinical trials have afforded Dr. Weintraub extensive experience both leading multi-institutional research activities and participating in the leadership group.

Dr. Weintraub has specialized knowledge and skill in health status assessment and health care economics. He has been involved in the economic analysis for each of the trials noted above, and in the quality of life analysis for TACTICS-TIMI 18, SoS, EPHEBUS and COURAGE. Dr. Weintraub was one of the first in cardiovascular medicine to develop an economic analysis alongside a clinical trial. He is currently the PI of the NHLBI funded ASCERT trial, evaluating the comparative effectiveness and cost-effectiveness of revascularization strategies.

Dr. Weintraub has also been involved in informatics for over 25 years since his development of the cardiovascular database at Presbyterian-University of Pennsylvania Medical Center, and remains on the Informatics Committee of the American College of Cardiology. Dr. Weintraub oversees the extensive informatics development in cardiovascular medicine at Christiana, working with information services at Christiana. Information services and the Christiana outcomes center work in a deeply collaborative relationship to bring cutting edge technology as well as access to data from complex databases to bear on outcomes projects.

Dr. Weintraub has been heavily involved in committee activity for the American Heart Association and the American College of Cardiology. In addition to the database committees noted above, he has been on the steering committee for the American Heart Association Council on Quality of Care and Outcomes Research. He has been on the program committees for the American Heart Association Scientific Sessions, the American College of Cardiology, and the American Heart Association Forum on Quality of Care and Outcomes Research. He has been on the Research Committee of the American Heart Association, the American College of Cardiology Informatics Committee and the American College of Cardiology Data Standards Committee. Dr. Weintraub has also served on the Board of Trustees of the American College of Cardiology.

Andrew R. Willan, PhD

Senior Scientist

Child Health Evaluative Sciences, SickKids Research Institute

Professor of Biostatistics

Dalla Lana School of Public Health

University of Toronto

Dr. Willan is an academic biostatistician and clinical trial methodologist, and currently holds the positions of Senior Scientist and Scientific Director of Quantitative Methods at SickKids Research Institute, Professor of Biostatistics in the Dalla Lana School of Public Health at the University of Toronto, and Professor Emeritus in the Department of Clinical Epidemiology and Biostatistics at McMaster University. His contributions to statistical methodology include publications in the areas of cost-effectiveness analysis, value of information methods, management trials, crossover trials, non-nested regression analysis and bivariate response models. Dr. Willan has been particularly instrumental in developing the field of statistical analysis of cost-effectiveness data with twenty peer-review articles and a book, co-authored with Professor Andy Briggs, in the Wiley Statistics in Practice series, entitled *Statistical Analysis of Cost-effectiveness Data*. More recently Dr. Willan's research interest has focussed on using value of information methods for the optimal design and analysis of clinical studies, with eight peer-reviewed articles and a forthcoming book, co-authored with Professor Simon Eckermann and Maggie Hong Chen, in the Wiley Statistics in Practice Series, entitled *Value of Information Methods in Evidence-based Medicine: Jointly Optimizing Health Care and Research*. Dr. Willan's collaborative research has been primarily in clinical trials in obstetrics and paediatrics with numerous high profile trials published in *NEJM* and *The Lancet*. Previously positions held included the Head of Biometry of the Clinical Trials Program at the National Cancer Institute of Canada and the Head of Clinical Trials and Epidemiology for the Cancer Program at Sunnybrook Medical Centre in Toronto.

Timothy J. Wilt, MD, MPH

Professor of Medicine

University of Minnesota School of Medicine

Core Investigator

Minneapolis VA Medical Center for Chronic Disease Outcomes Research

Timothy Wilt, MD, MPH, is a Professor of Medicine at the University of Minnesota, Staff Physician in the Section of General Medicine at the Minneapolis VA Medical Center and a health services researcher. His research involves conducting clinical trials, systematic reviews and meta-analysis to evaluate the effects of health care interventions on outcomes in adults with chronic diseases. Dr. Wilt focuses on the detection, prevention and treatment of common conditions (especially urologic diseases) frequently managed by primary care providers. He is the co-director of the Agency for Health Research and Quality Minnesota Evidence-based Practice Center, Director of the VA-HSR&D funded Minneapolis VA Evidence Synthesis Program and a core investigator in the Minneapolis VA Center for Chronic Disease Outcomes Research (a VA National Health Services Research Center of Excellence). Dr. Wilt is the Chairman of the VA/NCI/AHRQ funded CSP #407: Prostate cancer Intervention Versus Observation Trial (PIVOT) comparing radical prostatectomy to watchful waiting in men with clinically localized prostate cancer. Dr. Wilt serves as the Coordinating and Founding Editor for the Cochrane Review Group in Prostate Diseases and Urological Malignancies. He is a member of the United States Preventive Services Task Force and the VA Preventive Services Advisory Committee. Dr. Wilt, has worked collaboratively with professional societies including the American Urological Association, American Thoracic Society, American College of Physicians, the American Society of Clinical Oncology (ASCO), the National Kidney Foundation and the Department of Veterans Affairs in preparing evidence-based reviews and clinical practice guidelines derived from these reviews.

John B. Wong, MD

Chief

Division of Clinical Decision Making

Tufts Medical Center

John B. Wong, MD, Professor of Medicine and general internist, is the Chief of the Division of Clinical Decision Making, Informatics and Telemedicine at Tufts Medical Center and the Tufts University School of Medicine. Dr Wong received his MD from the University of Chicago and had postgraduate training in internal medicine at Tufts including an NLM medical informatics fellowship in Clinical Decision Making. He is a Past President of the Society for Medical Decision Making and the statistical editor in decision and cost-effectiveness analysis for the *Annals of Internal Medicine*. He has been a member of AHCPR PORTs in ischemic heart disease and diabetes mellitus, guideline committees for American Association for the Study of Liver Disease, European League Against Rheumatism, American College of Chest Physicians, and the AMA/AASLD/AHA/ACC Physician Consortium for Performance Improvement Work Groups on Hepatitis C, Coronary Artery Disease, Hypertension and Heart Failure. His research focuses on the application of decision analysis to medical issues to help patients, physicians, and policymakers choose among alternative tests, treatments or policies, thereby promoting rational evidence-based efficient and effective patient-centered care that reflects individualized risk assessment and patient preferences.

Scott L. Zeger, PhD

Vice Provost for Research

Professor of Biostatistics

Johns Hopkins University Bloomberg School of Public Health

Scott L. Zeger has been Professor of Biostatistics at the Johns Hopkins Bloomberg School of Public Health since 1991 and the University's Vice Provost for Research since 2007. He served as interim provost in 2009 and chair of biostatistics from 1996 to 2007.

Dr. Zeger conducts statistical research on regression analysis for correlated responses as occur in surveys, time series, longitudinal or genetics studies. He has made substantive contributions to our

understanding of the effects on health of smoking and air pollution, progression of HIV, cognitive loss after cardiac surgery, normative aging and other topics.

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 has served as expert witness to the U.S. Department of Justice and several states in their civil suits against the tobacco industry and as a member of the Board of Scientific Advisors for the Merck Research Laboratory.

Professor Zeger is author or co-author of 3 books and more than 170 scientific articles and book chapters. *Science Watch* identified Dr. Zeger as one the top 25 most cited mathematical scientists of in the 1990s. He served for 12 years as founding co-editor of the Oxford University Press journal *Biostatistics* and a member of the Springer-Verlag editorial board for statistics. He was awarded the 2008 Wilks Award from the American Statistical Association for contributions to statistical science, 2007 Bradford Hill Medal from the Royal Statistical Society for outstanding contributions to medical statistics, and the 2007 Marvin Zelen Award from Harvard University for leadership in the field of biostatistics. In 2006, 2002 and 1988, the Johns Hopkins Bloomberg School Student Assembly awarded Dr. Zeger with the Golden Apple for excellence in teaching.

Anthony Zietman, MBBS, MD

Professor of Radiation Oncology
Massachusetts General Hospital
Harvard Medical School

Dr. Zietman received his undergraduate training at Oxford University in the UK and then went to medical school at the Middlesex Hospital, London University graduating in 1983. After residencies in internal medicine and clinical oncology he moved to the Massachusetts General Hospital in Boston, USA for a fellowship in radiation biology. Since joining the staff at the MGH he has authored over 100 original articles and reviews on many aspects of GU cancer. His particular research interests are in the specific roles of active surveillance, brachytherapy, hormone therapy, and proton beam therapy in the treatment of prostate cancer. He also has a long-standing interest in the organ-sparing management of bladder cancer. He is currently the Jenot and William Shipley Professor of Radiation Oncology at Harvard Medical School and President of the American Society for Therapeutic Radiology and Oncology (ASTRO). He is a trustee of the American Board of Radiology.