

PRESIDENTIAL INVITED SPEAKER



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MEDICAL PRODUCT, HEALTHCARE DELIVERY, AND ROAD SAFETY POLICIES: SEEMINGLY UNRELATED REGULATORY QUESTIONS

The evaluations of medical product effectiveness and safety, the quality of hospital care, and the safety of U.S. roadways involve the use of large, complex observational data to make policy decisions. Careful design and analysis of such data are critical given the large populations impacted. While increasing access to data of increased size and type permit, in theory, richer evaluations, study design should assume a more prominent role. This talk will describe three different policy problems: the impact of the hospital readmission reduction program, the effectiveness of seemingly similar drug eluting coronary stents, and the safety of U.S. motor carriers. Statistical issues common across these problems, including clustered data, multiple treatments, multiple outcomes, high-dimensional data, and lack of randomization, are highlighted and solutions discussed.

BIOGRAPHY

Sharon-Lise Normand is the S. James Adelstein Professor of Health Care Policy (biostatistics) in the Department of Health Care Policy at Harvard Medical School and in the Department of Biostatistics at the Harvard Chan School of Public Health. Dr. Normand earned her BSc (1984) and MSc (1985) degrees in statistics from the University of Western Ontario and her PhD (1990) in biostatistics from the University of Toronto. Dr. Normand's research focuses on the development of statistical methods for health services and regulatory policy research, primarily using Bayesian and causal inference approaches, including assessment of quality of health care, provider profiling, diffusion of medical technologies, and regulatory science. She has developed a long line of research on methods for the analysis of patterns of treatment and quality of care for patients with cardiovascular disease and with mental disorders in particular.

Dr. Normand has developed analytical approaches for comparing hospitals and physicians using outcomes and process-based measures. Since 2002, she served as director of Mass-DAC, the data-coordinating center responsible for collecting, analyzing, and reporting on the quality of care for adults discharged following a cardiac procedure from all non-federal hospitals in Massachusetts. She is serves as the director of the Medical Device Epidemiology Network (MDEpiNet) Methodology Center, a public-private partnership aimed at medical device evaluation. MDEpiNet partners with the FDA's Center for Device and Radiological Health and the Science and Infrastructure Center at Weill Cornell Medical School. Her focus is on the development of statistical approaches to active medical device surveillance, valid inferences from distributed networks, and the improvement of causal inference in the presence of high dimensional data.

On the mental health side, Dr. Normand is leading an NIMH-funded study to estimate the value of publicly funded mental health care for patients with serious mental illness. She is also undertaking an observational study to estimate causal dose "outcomes" curves in the context of understanding weight gain associated with cumulative antipsychotic drug exposure among subjects with schizophrenia for numerous different antipsychotics.

Dr. Normand was elected fellow of the American Statistical Association, fellow of the American Association for the Advancement of Science, fellow of the American College of Cardiology, and Associate Member of the Society of Thoracic Surgeons. She served as the 2010 President of the Eastern North American Region of the International Biometrics Society; was inaugural co-chair of the PCORI Methodology Committee; co-chairs a Committee on National Statistics/National Academy of Sciences panel reviewing the Safety Measurement System of the Compliance, Safety, Accountability program run by the Federal Motor Carrier Safety Administration; and served on several National Academy of Sciences Committees, including the Committee of Applied and Theoretical Statistics (CATS) focusing on the intersections of statistics and computer science for big data. Dr. Normand received ASA's Health Policy Statistics Section Long Term Excellence Award, the Outstanding Lifetime Achievement Award from the American Heart Association, the L. Adrienne Cupples Award for Excellence in Teaching, Research, and Service in Biostatistics from Boston University, and the Mosteller Statistician of the Year from the Boston Chapter of the ASA.