Objectives. The ultimate goal of translational research is to move new discoveries in laboratories to treatments received by patients in communities. Despite the enormous efforts and resources devoted to basic science and clinical research, this translation is limited by the uptake of new treatments in community practice settings. This is the impetus for the recent interests in implementation studies that aim to adopt and integrate evidence-based healthcare interventions into community practice settings, akin to engineering work to improve an existing industrial system.

Methods. The adoption of a novel procedure in a community practice setting is usually a local decision guided by local knowledge unique to the specific setting. The conventional statistical framework that aims to produce generalizable knowledge is inappropriate for local investigations that aim to produce local knowledge to inform local implementation decisions. As an alternative, we propose an analytic framework based on effectiveness and cost-effectiveness for the design of these local investigations, taking into account the finite patient horizon in a community practice setting, and the prior knowledge available from local experts.

Results. When prior knowledge does not indicate a clear preference between the new and the standard procedures, a local investigation should be conducted in order to guide the choice. The proposed approach often leads to substantially smaller sample sizes than the conventional approach. General guidance and specific formulae on sample size determination are provided.

Conclusions. The statistical framework proposed herein is useful for the design of local investigations that aim to produce local knowledge.
SPEAKER BIO

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Dr. Duan received a B.S. in mathematics from National Taiwan University, an M.A. in mathematical statistics from Columbia University, and a Ph.D. in statistics from Stanford University. He is an accomplished practicing biostatistician with research interests in health services research, prevention research, sample design and experimental design, model robustness, transformation models, multilevel modeling, nonparametric and semi-parametric regression methods, and environmental exposure assessment.

Dr. Duan is an elected fellow of the American Statistical Association and the Institute of Mathematical Statistics; he is a member of the editorial board for Statistica Sinica and Health Services & Outcomes Research Methodology, and a former associate editor for the Journal of the American Statistical Association. He served on a number of national and international panels, such as the Institute of Medicine’s Committee on Organ Procurement and Transplantation Policy and Committee on Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research, the National Research Council’s Committee on Carbon Monoxide Episodes in Meteorological and Topological Problems Areas, and the National Institute of Mental Health’s Behavioral Sciences Workgroup.

Dr. Naihua Duan’s primary research interest is in the application of biostatistics to various areas of psychiatric research, such as mental health services research, HIV prevention, clinical trials, etc.