Towards a unified methodology of study design and statistical analysis for causal inference in implementation science

It has been reported that it takes 17 years to turn 14 percent of original research to the benefit of patient care. Implementation science aims to change this by identifying causes of the failure to widely adapt evidence-based interventions, and develop and evaluate cost-effective remedies for this. Interestingly, for us in biostatistics, rather than having health outcomes as primary endpoints in implementation studies, what’s known as ‘process outcomes’, that is, outcomes measuring the feasibility, acceptability, adoption, penetration, fidelity, sustainability and costs can be the primary focus of the research. New methodologic questions arise as a result. Questions concerning the validity of causal inference in the face of imperfect or cluster randomization, or none at all, and with multi-component interventions where there is interest in the impact of components of the intervention package as well as the overall effect of the package itself; the need, or lack thereof, for individual-level data; and the speed and cost required for evaluation; must be addressed. Stepped wedge, two-phase and our new learn as you go design are relevant, as is mediation analysis and the analysis of individual, disseminated and total effects in the presence of spillover, which, in this context, is a desirable property of interventions. This talk will provide an overview of some of these issues, and review the work of Yale’s Center on Methods for Implementation and Prevention Science on a few of them.